WHO is constructing a tool to help build capacity to develop material transfer agreements (MTAs) governing biological materials and information (such as epidemiological data or genetic sequence data) connected to severe emerging diseases with potential to generate a public health emergency, and for which no, or insufficient, preventive and curative solutions exist. It is part of broader efforts to empower outbreak-affected countries, through knowledge transfer and tools, to manage appropriate ownership of samples while ensuring that the full public health potential of valuable biological material is realized.

The tool will be accessible to different types of user, including those in health ministries, laboratories or other relevant facilities, as well as those generating samples in the field. It will help users with different levels of experience, from those with little previous exposure to MTAs, through to experts looking for concrete examples of text. The tool will help both those sending and receiving samples. It will cover the movement samples and associated data for a wide range of purposes, from diagnosis, through to countermeasure research and development.

The need to take into account different users, sample types and contexts means that — while there have been calls for templates — such an approach would be challenging. As a result, the tool will be:

- **Interactive** - Enabling the user to tailor the information accessed to their particular context through the use of web-based tools rather than a static text.
- **Results-oriented** - Focusing on overarching principles, mapping possible approaches for accomplishing these aims rather than advocating for any specific models.
- **Multi-layered** - Allowing the user to access the required level of detail.
- **Flexible** - Including content for MTAs in many different contexts, for different purposes, by different types of user.
- **Comprehensive** - The tool will need to capture the full scope of views on key issues connected with MTAs and approaches for addressing them.

The tool will have three parts: Part I will address introductory material, such as why an MTA might be needed, the aim of the tool, when an MTA might be necessary, what might be included in an MTA, as well as a number of cross-cutting issues. Part II will explore possible content areas, describing the issues covered, why it might need to be included, possible consequences of not addressing it, as well as any connections to other content areas. Part III will then provide concrete examples of text, drawn from actual MTAs, addressing each content area.

The need for such a tool was agreed at an Informal Consultation held by the World Health Organization in collaboration with the Institut Pasteur in December 2016. The desire for such a tool originates from a shared objective of advancing public health, in particular building capacity and sharing public health benefits where the need is greatest. Building capacity for MTAs can contribute to improving preparation for future emergencies.

Participants desired a tool that was user friendly, tailored to the needs of both Member

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States (in particular lower- and middle-income countries) and other potential users, and focused on cases where WHO is not directly involved in sample transfer. The development process needed to be transparent and inclusive. As a result, WHO has released a compilation text for public consultation.

This is part of an iterative development process: the first phase was to identify challenging issues and possible approaches for addressing them (December 2016 consultation). In the second phase a more comprehensive text was compiled that examined in turn all the different components of an MTA (this text). The third phase releases the text for public comment. A fourth phase revises the text in light of the responses. A fifth phase converts the static text into an interactive, digital tool. A sixth phase tests and further refines the tool with possible end users.

WHO has compiled this text from materials identified for, during and after its consultation. It represents views and approaches provided by others and does not necessarily represent WHO positions on any of the issues covered. Its content is based upon contributions to date - it is not intended to be exhaustive. More views will need to be added. The current public comment process dramatically expands the community involved in developing this tool.

The purpose of the public consultation is to ensure that all relevant views and approaches are captured in the tool. It should also expand the number and range of specific examples. Comments are requested for:

- Identifying concepts or approaches not currently captured in the text;
- Providing additional exemplar text from existing MTAs, especially where they capture approaches not present in the current text;
- Highlighting additional sources of information on MTA-relevant topics to which users might be directed, with a particular focus on public health emergencies; and
- Proposing improvements to the current text that would make it more accessible or useful for its intended purpose.

Comments should be made electronically by close of business on Friday 16 June. They should be sent to: Farah AL-SHORBAJI at alshorbajif <at> who.int
PART I: Introductory material

What is an MTA?

A Material Transfer Agreements (MTA) is a contract governing the transfer of research materials between two organizations. It defines the rights of the provider and the recipient with respect to the materials and any derivatives. MTAs can help to ensure a common understanding as to what is being shared, for what purpose, and how it can be used. MTAs regularly govern the transfer of biological materials, such as samples but can also cover associated data, such as clinical information.


Why use an MTA?

A prompt response to a public health emergency can depend upon the ability to move relevant samples and data from one place to another. The movement of such samples and data must be as simple and transparent as possible, whilst protecting the interests of the owners of the samples. Increasing awareness of the potential value of certain samples or data has increased the demand for these protections.

MTAs play an important role in enabling transfers and subsequent use by the recipient, whilst protecting the interests of the transferee. For a summary of why these agreements are important and a discussion of some of the challenges in using them see: Science Commons: Material Transfer Agreement Project. http://www.mitpressjournals.org/doi/pdf/10.1162/ITGG.2007.2.3.137

Ultimately a decision must be made about whether the objective for the MTA process is to make it smooth, fast and efficient; or to ensure that it is maximally beneficial to those who most need it. While objectives for an MTA will differ widely, the best outcome will take both goals into account and create a balance that responds to different needs and communities.

Recent public health emergencies of international concern (PHEICs) with Ebola virus disease in West Africa and zika virus in Latin America have demonstrated the many difficulties of negotiating MTAs in an emergency context, and showed a clear need for agreed fundamental principles and scalable, sustainable approaches for MTA negotiation.

When might an MTA be necessary?

There are a number of scenarios where an MTA might help clarify conditions associated with the movement or use of samples and data. These might include:

- Export or international movement of samples and associated data;
- Domestic movement of samples or associated data to a separate legal entity (or in some cases perhaps even for different parts of the same legal entity);
- Determining the eventual use or further distribution of samples (or data derived from them) shared for one purpose but with the potential for additional uses;
- Uses or purposes where there are specific rules or regulations, or when a third party, such as a government agency such as a Ministry of Health, is (or needs to be) involved;
● Where the material being moved has a potentially important intrinsic value (either the material itself or the possibility of using it in other processes or for product development); and

● As part of larger overarching agreements, such as research protocols or bilateral agreements.

MTAs can be very simple documents, or more complex legal agreements. The level of detail may be determined by the potential commercial value of the material being transferred and the intended uses to which it will be put. A discussion of how these agreements might match the details of the transfer see: Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories, and Litigation https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315468/pdf/pbio.1002060.pdf

Cross-cutting issues

Overarching Principles

Past discussions have highlighted a number of overarching principles that could usefully be codified in an MTA including:

● **Speed** - in a public health emergency rapid action can be critical, making it important that as soon as possible samples are shared with a suitable reference laboratory and the results made available to those that need to know;

● **Sustainability** - the samples generated by a public health emergency can be important for understanding more about the disease and in developing tools to combat it. These important resources will need to be maintained and managed over the longer term. It will be important to think of how this can be realistically accomplished at the same time as addressing immediate public health needs;

● **Capacity building** - public health emergencies pose a collective threat. There remains much to be done to build the core capacities needed to address them effectively. This is an ongoing process requiring continual consideration. Successful capacity building may reduce the need to transport samples in the future;

● **Maximal preservation** - avoiding destruction of potentially useful samples or data. These are important biological resources. In some cases, they may be irreplaceable;

● **Trust** - it is important that the MTA process establishes a level of trust among the participants where they feel their needs are recognised in the text. This is important also to prevent populations from fearing or misunderstanding research and pushing back, and to prevent stigmatisation of communities. Issues around stigma, violence cannot be ignored.

● **Good faith** - prompt responses necessitated by public health emergencies are often not conducive to detailed negotiations, or focus on considerations beyond immediate needs. Addressing longer term arrangements for the samples may need to happen after the original transfer has been completed. Both parties will need to continue to work towards the broader public good, including through the commensurate sharing of any benefits accrued from sharing samples and associated data;

● **Good practices** - it is important that, despite the emergency setting, transfers of samples and associated data follow the highest possible standards, for example taking into account bioethics issues and procedures and practices for safe and secure storage, handling and shipping of materials; and
• **Consistency with applicable national and international laws** - For example, drafting an MTA will likely have to take into account a legal environment composed of both national and international laws. Applicable national laws may be contract laws, rules regarding conflicts of laws, national security laws or biosafety laws. Applicable international laws could be instruments such as the International Health Regulations (2005), in particular its Articles 6 and 46, or the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.

**Authorised individuals**

It is also important to consider who is signing an agreement. It is important that the individual is empowered to make all the binding commitments the agreement contains. Whilst the Ministry of Health may often play a leading role in developing and agreeing MTAs, many other government departments could be involved in their implementation. For example, an Environment Ministry might have the delegated authority to control the export of biological resources, which can include disease samples, or the Border Control and Customs agencies may have specific roles to play in allowing samples to leave the country. It is vital that those ultimately agreeing to MTAs (and the provisions they contain) are ultimately empowered to do so. Equally, the value of greater inter-agency cooperation and coordination should be noted.

**Contents of samples**

The likely contents of samples must also be considered. Many samples generated during a public health emergency are unlikely to be isolated pathogens. As a result, relevant samples and data will often include elements associated with the host or patient. In the longer run, such material might be of greater value than the pathogen as it could provide insights into the host’s reaction, offering important markers for diagnostics, vaccines or therapeutics.

**Value of samples**

Not all samples are equally valuable - a human sample alone is useful, but a sample linked to clinical data, or part of a series of samples over time, or which is linked with epidemiological data, can be more valuable. The MTA process should ensure that the greater the cost to the donor, the more benefit they receive. Samples can also be used in different ways. There is a need to differentiate between different types of outputs which could be generated from the movement of materials or data. These include: papers or other academic output; testing or quality assurance (QA) for a product already under development; or use in an unforeseen product, perhaps some time after the material was transferred or in subsequent technical developments. It might not be possible to know the value of a sample at the outset. This may warrant including provisions to negotiate further use should a sample prove particularly valuable.

**Potential for commercial development**

While in emergencies it is admirable to want to share information and samples, if commercial entities are involved it is unclear how willing they might be to do so. MTAs for use in emergencies may benefit from a non-commercial model, where any subsequent commercial use would require additional negotiation, possibly after the emergency is over. However, some institutions may be restricted by pre-existing commitments to funders or commercial partners on these issues. Non-commercial secondary use may be more broadly acceptable but it will still necessitate consideration of equitable benefit sharing and compliance with rules over the use of human tissues.
Provenance of samples

The increasing importance of knowing and demonstrating the chain-of-custody or provenance of material used for commercial development is also important. A well-documented process for the acquisition of material makes commercial sense by demonstrating due diligence and insulating those developing products from later claims contesting ownership.

Third-parties

In some cases it may be desirable to include a suitable third party in MTAs to act as a neutral party to ensure negotiation in good faith and an unbiased implementation.

For an exploration of several of these cross-cutting issues, see: Material Transfer Agreements: A University Perspective. 
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC523866/

What might be included in an MTA?

Whilst an MTA will need to be context specific, they share common sections, including:

1. Overarching principles
2. Parties
3. Materials and purpose of transfer
4. Definitions
5. Ownership and custodianship
6. Use
7. Further use, storage and destruction
8. Publication
9. Benefits Sharing
10. Intellectual property
11. Traceability
12. Dissemination of data and results
13. Relevant laws and applications
14. Monitoring, evaluation, and reporting
15. Nature of relationship, warranties, liabilities, notices, settlement of disputes, governing law, and consistency
16. Headings, amendments, waivers, and further assurances
17. Duration and Surviving Provisions
18. Signatory

For a discussion of common characteristics of MTAs used by non-profit and for-profit parties, see: Material transfer agreements: open science vs. proprietary claims. 
http://www.nature.com/nbt/journal/v23/n4/full/nbt0405-489.html
PART II: Content of an MTA

1. Overarching principles

It may be useful to start the MTA with a short section acknowledging the overarching principles governing the transfer. This can help to frame the agreement and provide context for the specific terms covered in later sections. These overarching principles can also act as a reference during the negotiation process. They can also be useful should it be necessary to return to the MTA at a later date, for example to reach an agreement on further uses for the transferred samples.

Principles that might be addressed in the opening section of an MTA for samples associated with a public health emergency might include:

- **Speed** - in a public health emergency rapid action can be critical, making it important that as soon as possible samples are shared with a suitable reference laboratory and the results made available to those that need to know;

- **Sustainability** - the samples generated by a public health emergency can be important for understanding more about the disease and in developing tools to combat it. These important resources will need to be maintained and managed over the longer term. It will be important to think of how this can be realistically accomplished at the same time as addressing immediate public health needs;

- **Capacity building** - public health emergencies pose a collective threat, there remains much to be done to build the core capacities needed to address them effectively. This is an ongoing process requiring continual consideration. Successful capacity building may reduce the need to transport samples in the future;

- **Maximal preservation** - avoiding destruction of potentially useful samples or data. These are important biological resources. In some cases, they may be irreplaceable;

- **Trust** - It is important that the MTA process establishes a level of trust among the participants where they feel their needs are recognised in the text. This is important also to prevent populations from fearing or misunderstanding research and pushing back; and to prevent stigmatisation of communities. Issues around stigma, violence cannot be ignored.

- **Good faith** - prompt responses necessitated by public health emergencies are often not conducive to detailed negotiations, or focus on considerations beyond immediate needs. Addressing longer term arrangements for the samples may need to happen after the original transfer has been completed. Both parties will need to continue to work towards the broader public good, including through the commensurate sharing of any benefits accrued from sharing samples and associated data;

- **Good practices** - it is important that, despite the emergency setting, transfers of samples and associated data follow the highest possible standards, for example taking into account bioethics issues and procedures and practices for safe and secure storage, handling and shipping of materials; and

- **Consistency with applicable national and international laws.**

2. Parties

The parties to an MTA can vary, ranging from individual laboratories in countries to their Ministries of Health (MOH). Regardless of the purpose of the MTA (e.g. single purpose –
diagnostic versus multiple – diagnostic and further research), it is essential to determine between which parties the MTA must be signed and to avoid a multiplication of MTAs between various parties, for example a first MTA between the MOH and a lab and another MTA, possibly contradictory or at least introducing confusion, between the same lab and the emergency responder/medical care provider which took the sample. Language could be inserted into an MTA obliging signatories to ensure that other MTAs or agreements signed on the Material should have terms compatible (or at least compatible with MTA terms between Ministry of Health and Laboratory).

It is important that the start of the MTA states clearly who is signing it, on whose behalf, and whom it binds and provide rights to, including third party beneficiary providers. In the case of MTAs signed in the context of outbreaks, emergency treatment, when emergency responders/medical care providers on the ground are those providing the material but are not the signatories of the MTA because such MTA is between the MOH and the recipient lab, MTAs could usefully include the medical care provider as a third-party beneficiary and include a provision stating that results must be provided to that medical care provider directly and systematically.

In most cases, the sampling is not done by the labs, but by caregivers, phlebotomists, contact tracers, researchers, surveillance teams, etc. Sample collection is done for the purpose of performing specific tests related to patient management (caregivers), screening (surveillance teams) or answering the research question of the study protocol (researchers).

An MTA will need to clarify what should be done with the remains of the samples or data: destruction, preservation, other use, exportation, etc.

In case the labs directly do the sampling for research, the MTA should be only between labs and MOH with the support of a research protocol approved by an Ethics Research Committee (ERC).

It may also be important later in the MTA to detail specific roles and responsibilities, e.g. nominating technical representatives authorised on behalf of the parties to release relevant materials or information.

3. Purpose

It is important that the purpose of the MTA and the purpose of the use of the samples is detailed clearly in the text. This effectively provides the boundaries on what can and cannot be done with the samples. It might be accomplished in a general overarching manner (e.g. the purpose of the transfer is for diagnostic purposes), in which case a separate section near the start of the agreement might suffice. It could also be dealt with in the section for definitions. It might be replaced or supplemented by more detailed descriptions of specific tests, reagents, and activities permitted for use in the relevant section later in the MTA and detailed in a Materials Transfer Document to accompany the samples.

Wherever it is addressed, it is important that the purpose accurately captures the needs of the transfer. This will probably be context specific. For example, the purpose of an MTA to move samples into a biobank for longer term storage is different from a transfer for diagnostic purposes, which is also different from moving samples for use in developing vaccines or therapeutics.

It may also be necessary to refer back to the purpose of the MTA in other areas of the text e.g. when dealing with period of use or for detailing provisions for additional uses.

It is also very important to clearly define the “Material” and it is imperative to define and organise the data accompanying the Material that is transferred – especially since it is likely to identify the subject / patient whose material is transferred. Also needed to be framed is
the specific matter of reliquats. This definition is important for several reasons: First, it can help expanding or narrowing the scope of activities allowed under the MTA and exclude certain activities (e.g. cloning or combining the virus with something else). Second, especially if ownership is addressed and in case the possible later transfer of the sample to a biobank is considered, a broad definition of the “material” will catch a lot of “things” (substances, subset of the sample) that could have been done with the sample by the laboratory in the diagnostic phase.

4. Definitions
The meaning of a number of specific terms will usually need to be laid out in detail to ensure common understandings amongst the parties. Core concepts that might need to be addressed in this manner can include:

- Access or access rights
- Anonymous
- Background technology
- Biospecimen / specimen
- Commercial purpose
- Confidential Information
- Data (clinical & associated)
- Funded development
- Incidental findings*
- Information or Background Information (including the information held by either party prior to the agreement and supplied under it)
- Intellectual property rights
- Invention
- Materials, including derivatives, samples and progeny
- Modifications
- Non-profit / non-profit organization
- Personal/Patient identifiers*
- Progeny
- Provider
- Permitted purpose/ intended use of transferred materials and associated data
- Recipient
- Remains of samples / unused material*
- Repository / biobank
- Research Use (as opposed to commercial development)*
- Results
- Subsequent/third party use (or onward use)*
- Unmodified derivatives

5. Ownership of samples / materials and custodianship

Recent consultations on MTAs for use in public health emergencies heard that different stakeholders held incompatible views as to who owned samples, or whether ownership, rather than guardianship, was the most appropriate framing of this issue. It has been suggested that the MTA tool should not be too specific on issues of ownership – where necessary, the tool should reflect the divergence of opinion on this issue, bearing in mind different contexts, legal regimes and scenarios.

One approach that can help address these concerns is to address the acquisition of rights or title by the recipient over the materials or associated data transferred. Some MTAs explicitly state that the recipient gains no such rights.

There are important ownership questions around the results from the intended use. Some MTAs explicitly state that any results produced are owned by those that generate them (i.e. the recipient). In other cases, this issue is not addressed, posing possible confusion as to what can be done with the results generated. Would a laboratory receiving samples primarily for diagnostic purposes be able to aggregate and anonymise the data generated and use it in part?

* Past consultations heard this term may need defining but no examples have been identified to date.
of a publication? Such papers have been traditional outputs from recipient laboratories following their involvement in addressing a public health emergency. They are seen by some as a *quid pro quo* for their involvement. Careful definition of ‘results’ and ‘purpose’ might be necessary to explicitly capture permission and in what way the contribution of those supplying the sample should be reflected. This may also be connected to a publication section in an MTA.

There are also important considerations as to the ownership of any derivatives or data generated through the intended use. For example, some might argue that an isolated culture is sufficiently different from the original sample to have a different ownership. Equally, the resources produced during the intended purpose may be intangible, for example, genetic sequence data. Who would own this data?

Past discussions have also highlighted that in order to ensure that the interests of individual providers of material, and where relevant, donor communities, are given due weight in efforts to prepare relevant MTAs, it may be useful to consider:

- How to avoid causing direct or indirect harm to such individuals or groups?
- How to include these community interests in any agreement?
- How to engage these communities, in particular on any agreed further use of the material?
- How to obtain relevant consents?
- What to do when consent cannot be sought? (e.g. death or unavailability of the donor or their representatives)
- How to protect privacy & confidentiality?
- How to foster participation of researchers from affected countries? (capacity building)
- How to deal with incidental findings?

6. Use

The MTA should detail somewhere (whether in the body of the agreement or in attached statements of work) as exactly as possible the uses to which the materials and information can be put. If possible it might also explicitly state what uses of the material and information provided are not permitted or require further consent, possibly under a subsequent MTA. It will be important to define the types of intended investigations or activities to be conducted with the samples. Past consultations heard of a grey area between surveillance and clinical trials. When samples are being used to enhance surveillance, it will be important to carefully define exactly what activities the outbreak investigations will include.

These details might be contained in a section on the purpose of the MTA. It might be addressed in the section on definitions. Alternatively, it might require a section or statement of work of its own, depending on the complexity of the intended use.

Questions as to the necessity of shipping samples out of the country should be addressed. This might necessitate linking the use of materials and information to specific locations or facilities. Further movement of materials or information might need to be considered.

Inclusion of express prohibitions as to the use of the Material may be considered as well. For example, warnings that the Material cannot be used in humans and/or animals.

This section might also address who has access to the materials or data transferred or the results produced. For example, some MTAs limit access to only those that require it for the intended use. They might also determine how and when results and data produced can be
shared with third parties. This will need to take into account the importance of data sharing in public health emergencies.

Somewhere in the MTA, possibly in this section, it will be necessary to address issues of confidentiality. How should the background information, or any other confidential information provided for the intended purpose or otherwise associated with the MTA, be handled? How should patient confidentiality be addressed?

7. Further use, transport out of country, storage and destruction

After the conclusion of the intended use, what is to happen to remaining materials, information or their derivatives? Some MTAs included an expectation for further use - that the materials and data transferred, and the results produced, are used within a specific timeframe towards an intended public good (such as expanding our knowledge of the disease). In open access models, the recipient is empowered to freely share the remaining materials and derivatives produced.

Other MTAs specifically limit to what other uses the samples or associated data might be put. Not addressing this issue in an MTA (depending on how the purpose of the transfer is captured) may lead to a lack of clarity on this issue. MTAs used in other settings often require the transferred materials and associated data to be destroyed or returned to the supplier after the intended use. This may not be desirable in the context of a public health emergency where the samples may be irreplaceable. Some MTAs specify that the recipient partner is to store the remaining materials pending a decision on further use, sometimes specifying details of what can or cannot be done during storage.

Past consultations on MTAs for use in public health emergencies heard of a need to find the right balance between conservation of samples and blocking any use of them. It has been suggested that the challenges of agreeing the optimal use of valuable samples, for example through a common research agenda, could potentially prevent important research from being undertaken.

Issues to be considered when drafting a section on further use include:

- Is there an expectation that data or results generated will enable further relevant work? If so, under what conditions might a third party undertake such work?
- How should the samples be preserved, for how long, and at whose cost?
- Who gets to decide the future of material or information?
- Should a percentage of samples be specifically set aside for future use?
- What should happen to residual samples (unused material), especially in terms of availability for third parties, permitted uses, or existing research agenda(s)?
- In which context(s) and under which condition(s) is it acceptable to keep remains of samples for potential further use?
- In which circumstances is it unacceptable not to keep remains of samples for potential transfer to a biobank or for further research for the higher public good?
- How will any planned further use be vetted against rules and ethical oversight requirements in the supplier’s country?
• What should happen with derivatives, such as virus isolates?
• What happens if a relevant biobank(s) is created?
• When, how and with what notification or agreements should remaining or unused material be destroyed.
• What role is there for community engagement or input from the individuals or communities from which the samples were drawn?

Answering these questions may not be necessary in the MTA itself, instead a placeholder may be inserted clarifying how they might be dealt with in the future. For example, simple clauses might be included that require the recipient to reach agreement with the supplier before any further use is pursued, or residual samples transferred or destroyed. This could significantly simplify the MTA required for the initial transfer. It might minimise the administrative burden during a public health emergency.

A future use clause might limit use for the intended purposes, perhaps by determining the scope of access, but set out how a recipient might obtain permission for additional uses. This could include determining the details of the request, for example that it must be made in writing, it could determine to whom such requests must be addressed, or how to handle requests for future use by third parties.

Some MTAs also clarify that the supplier has the right to supply remaining materials, or similar samples to others. This helps clarify that the transfer does not form an exclusive arrangement.

It may also be possible here to differentiate between future uses - including those determined to be for research purposes, and those considered to be for commercial development or exploitation. This may have a notable impact on other sections of the MTA that deal with benefit sharing and intellectual property by allowing broad principles to be agreed in an initial MTA and more detailed discussions over the future value of the materials being determined at a later date, potentially after the public health emergency is concluded or specific future uses determined.

8. Publication

Issues around publication of results are relevant to MTAs. For example, is there a requirement or expectation that the results of permitted activities are made publicly available? What review provisions need to be in place? What timeframes are reasonable?

Some MTAs differentiate between academic and commercial partners - where the results produced may be fed into very different processes and yield different benefits (see the section on benefit sharing).

In the context of data sharing in a public health emergency, it might also be necessary to consider how the results generated by permitted activities can be best shared with those that have a need to know, whether that be, inter alia, researchers, medical personnel, public health officials, policy makers, affected communities. These results could be important for updating standards or procedures, or even affect practical measures to control the outbreak. In the context of a public health emergency, it may be desirable, and is increasingly normal, for such
results to be shared with these communities prior to publication. This issue is connected with the Dissemination of Data and Results.

**9. Sharing of Benefits Arising out of the Utilization of the Material**

A number of relevant benefit sharing principles were identified during past consultations on MTAs, including:

- **Equity** – What is fair and equitable in a public health emergency? What benefits can be expected in the shorter term? Or the longer term? Consideration of securing priority status to access to countermeasures developed from the sharing of samples is important.

- **Reciprocity** - Access to material on the basis of the MTA and the sharing of benefits arising from the utilization of the material should occur on an equal footing.

- **Public health interests** - Access to benefits should be negotiated in good faith with the consideration of global public health priorities at the core.

- **Third party access to benefits** - Consideration of whether to pass on benefit sharing obligations to third party recipients and successive transfer recipients should be considered and negotiated as appropriate.

- **Compliance with Nagoya** – Many Member States now have legally binding obligations derived from this instrument. The MTA needs to be constructed so as to facilitate compliance with these obligations. Clarity as to the appropriate focal point for meeting these obligations during a public health emergency and any special provisions that might be in place (such as retroactive notification of transfers and negotiation of attendant benefit sharing) may be desirable.

Different types of benefit might be derived from the sharing of samples and there are different mechanisms that might facilitate the sharing of these benefits (TABLE 1).

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Benefit Sharing Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge</td>
<td>Reasonable acknowledgement of the supplier of samples in publications derived from the use of the materials. Training sessions and transfer of know-how during and post outbreak.</td>
</tr>
<tr>
<td>Results</td>
<td>Sharing with the supplier of samples any data, results and findings from research conducted with the samples.</td>
</tr>
<tr>
<td>Products or Medical Countermeasures</td>
<td>Preferential access of the supplier of the samples to any product or medical countermeasure derived from the use of the materials for public health purposes.</td>
</tr>
<tr>
<td>Commercialisation</td>
<td>Management of all intellectual property derived from the use of the materials on terms which take into consideration global public health imperatives.</td>
</tr>
</tbody>
</table>
Reagents and Services | Access on preferential terms for public health purposes for the supplier of samples to reagents or services derived from the use of the materials.

| Development | Direct involvement in setting research agendas, or in the prioritization of research objectives. Broader support for the supplier of samples to take advantage of developments in public health and strengthened capacity to build an effective economic sector.

**TABLE 1:** Different benefits derived from sharing samples during a public health emergency and mechanisms that might facilitate the sharing of these benefits.

Discussions of issues around ‘access on preferential terms’ have occurred repeatedly in the context of MTAs and there is no universal understanding as to its meaning. Access, for example, is connected to affordability, research input, research outputs, and product development. Access might mean lower prices for countermeasures developed using a sample. It can also be connected with fewer intellectual property barriers to generate more innovation, and greater product possibilities. Access issues are therefore intertwined with the intellectual property issues.

10. **Intellectual property**

This section of an MTA might need to deal with two different types of intellectual property (IP).

First, on rare occasions the materials or data being transferred might include existing intellectual property. This might necessitate agreeing in advance access rights to materials already covered by IP.

Second, there are broader questions as to how any benefits generated from the transfer or subsequent uses might be captured in IP. Using IP as a benefit sharing tool can be complicated. Resolving issues around IP is often expensive and time consuming. The capacity or regulatory regime necessary for taking and enforcing IP may not exist in all countries. In general, the minimal possible IP should be used to accomplish any necessary protections. It is also important that any IP provisions within an MTA should be as simple and user-friendly as possible.

IP is not only relevant for enabling commercial development, or as part of benefit sharing agreements. For example, defensive patenting can help keep developments in the public domain.

There are a number of different approaches to protecting IP which might be used in different circumstances, including:

- Open access;
- Co-ownership of IP;
- A third-party beneficiary;
- Patent-pooling;
- Cross-licensing;
- The supplier retains the IP; and
- The recipient takes the IP.

There are a number of practical issues that might need to be addressed if IP is being protected. How is this to be handled if the IP is the output of collaborations between multiple parties? It
might also be necessary to consider who can grant licenses or sub-licenses, or if and how licenses might be transferred. It might be necessary to identify who is entitled to seek IP protections and in what jurisdictions.

Identifying the most appropriate approach will likely be context specific. What is to be done with the transferred samples and associated data could help determine which approach might be most suitable. To this end, issue-spotting analysis, identification and analysis of relevant IP issues, can be useful. It will be important to tailor measures to local legal frameworks. As a result, both parties are likely to need to consult experts in IP if it is to be addressed in an MTA.

It is important to consider the cost implications of different IP models, including determining who would bear these costs, and what the likely impact on the cost of permitted or future use might be. It is also necessary to consider what resources might already exist to enable IP to be taken (e.g. are there robust functional IP regimes in place covering the actions of both the supplier and the recipient? Can both parties access the necessary legal experts?).

Given that determining IP provisions can be time consuming and costly, there have been calls for them to be set aside in the context of public health emergencies. Past consultations have heard examples where no IP is conferred unless requested, in which case the burden is on the recipient to make clear their ambitions for the IP.

Regardless what approach to IP is determined to be most appropriate, an MTA should take into account public health needs. In general, even in models where IP provisions have been put in place, there is an expectation that publication and data sharing should be open.

Whatever model is adopted, the terms must also be enforceable – other clauses in the MTA, such as those determining arrangements for dispute resolution, may be important.

IP provisions need to be flexible enough to address both specific IP generated from the use of samples and data, as well as background IP (for example, procedures, methodologies, and secondary products).

It may be useful to include provisions triggering a re-negotiation of IP, for example, should the use of the samples and associated data result in unforeseen commercial opportunities.

Finally, there may be risks associated with failing to address IP provisions. In some cases, an absence of IP provisions in an MTA may enable others to seek those rights, although it might be possible to address this through strategic publication - placing key knowledge or resources in the public domain.

Open access

Should it be agreed that the parties will not seek IP protection, it will be essential to include specific language to that effect in the IP section of the agreement.

Not mentioning IP in an MTA is not the same as indicating that none should be taken i.e. failing to include a provision on IP may enable the recipient to claim any and all resulting IP. Issues around IP for third parties might also usefully be considered.

Such an approach is cheap, simple and places a minimal burden on parties to the MTA. It still requires the inclusion of proactive obligations on publication and knowledge and data sharing.

Including a clause prohibiting the taking of IP may be suitable when transfers are particularly time sensitive (negating the need to analyse and negotiate more complicated IP provisions) or
where the capacity or regulatory framework to take and enforce IP might be missing in one or
more party. It is useful for providing an open source platform destined for use for the public
good.

A relevant case study of such an approach is the WHO Pandemic Influenza Preparedness
Framework, in particular Annex 1, Article 6.

Co-ownership of IP

All parties to an MTA could agree on an equitable co-ownership mechanism for the
management of future IP which takes into consideration public health imperatives. Such an
agreement can be relatively straightforward to draft and to reach agreement on as the
negotiations are effectively bilateral. This agreement can also help to ensure equity through co-
ownership.

On the other hand, such a model is comparatively difficult to manage and implement. It can
quickly become complicated due to differences in national approaches to IP. As a result, any
such mechanism would need to be preceded by careful analysis of the different national legal
and regulatory regimes. These agreements often also complicate decision making as a
dedicated structure acceptable under both regulatory frameworks can be necessary.

A co-ownership model for IP may be suitable where both parties have strong traditions of IP and
no other model can be agreed upon.

Patent-pooling

In some cases, it might be desirable to pool patents in pursuit of a specific purpose. Public
health patent pools do exist.

Private sector buy-in is required for patent-pooling to be effective, as it ensures that the pool has
sufficient coverage to actually allow the necessary work to be undertaken.

A patent-pooling model for IP may be suitable where there are existing collective efforts towards
a specific goal closely related to the transfer of materials.

A useful case study of a patent-pooling approach might be Hepatitis B Vaccine and the
Medicines Patent Pool.

Cross-licensing

There are also examples where the necessary IP to accomplish a specific task can have
different owners. This model enables reciprocal arrangements between those holding the
relevant IP to enable collaborative projects which leverage multiple sources.

A cross-licensing model for IP may be suitable where both need access to each other’s IP in
areas associated with the transfer of materials.

A third-party beneficiary

A variation on other approaches might be to involve an additional beneficiary - embedding a
neutral third-party into the development, implementation, and enforcement of an MTA. These
third-parties could include other organizations with public health objectives, such as the World
Health Organization or MSF. Granting an automatic license to such bodies can be particularly
important in the pursuit of broader public health imperatives.
There may be challenges in identifying a suitable third-party as it is important they have no direct interest in the transfer, are mandated to work towards a public good, and have a suitable financial status (for example, operating on a non-profit basis).

Adding an extra party to an agreement complicates it logistically and may increase the time it takes to find consensus. It can, however, be useful for ensuring equity. A useful case-study were the MTAs involving WHO during the EVD PHEIC in West Africa.

Supplier retains the IP

The supplier can retain all rights to future IP but commits to exploit these rights in a manner which is consistent with global public health considerations, for example by granting to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect of affordable royalties, taking into account development levels in the country of end use of the products.

It is also possible that a third party, such as the WHO, might support the supplier in protecting its IP if such a capacity does not exist.

Such an approach is comparatively simple as all the IP resides in one place. It intrinsically favours the supplier. This provides a firm foundation for streamlined decision making and simplifies efforts to make use of the IP in the future (potentially encouraging commercial development). However, that means that all the power also resides with a single entity, providing a potential disincentive for collaboration. It can also mean that all the costs associated with the IP fall on the supplier as well as the burden of identifying potential users of the IP and negotiating the terms of use.

The supplier retaining the IP may be suitable where the supplier has a well-developed IP legislative and regulatory framework and the resources to register, manage and leverage the IP generated.

A useful case study of this approach is the recent decision by GSK not to seek licenses for products in low and middle income countries.

Recipient takes the IP

If detailed, or if there are no other provisions included in an MTA, the recipient may be free to reserve all rights to IP derived from using the samples or associated data. The MTA represents one opportunity to place conditions upon the recipient (such as that any IP taken must take into account public health imperatives).

It might also be necessary to reflect ownership issues, restrictions or conditional terms derived from earlier documents, such as informed consent provisions, MTAs associated with the provisions of material to the supplier, or pre-standing agreements between the parties.

It is important to distinguish between ownership of the samples (which, dependent upon other clauses within the MTA, might not be transferred with the samples or data) from any derivatives or IP generated from them.

This approach is comparatively simple, as all the IP resides in one place. It intrinsically favours the recipient. As this means all the associated costs also reside with the recipient, it may be necessary where the supplier lacks the necessary resources or regulatory capacity. However, that means that the supplier will need to surrender some degree of control over further use. It
will likely require the negotiation of a comprehensive licensing agreement to ensure some
degree of benefit sharing. As a result, it will also be closely connected to the details of the
governing law, for example for enforcement and dispute resolution.

The recipient retaining the IP may be suitable where it is important to incentivize collaboration
by recipients.

For more information on IP elements of MTAs, see: Specific Issues with Material Transfer
Agreements

11. Traceability

It is important to maintain traceability of the samples during transfer and to document the terms
and conditions of the transfer and any key responsibilities. To ensure traceability of the
materials and associated data transferred, it is often the responsibility of both the sending and
receiving parties to maintain an audit trail. This should ensure that the material can be retrieved
at any time. The details of how this should be undertaken can be included in this part of an
MTA.

Approaches to traceability can be as simple as detailing when and where the materials and
associated data were put, when they were transferred, and to whom. They might be more
comprehensive, for example, the WHO Influenza Virus Traceability Mechanism which tracks
relevant samples transfers around the world.

12. Dissemination of data and results

In addition to publication of findings (Section 8), there are a number of issues connected to
results that need to be reflected in an MTA. For example, with whom will the results be shared
and to what aim? Who will have access to the raw data, rather than published findings? What
are the provisions for pre-publication data sharing for public health purposes? What restrictions
need to be placed on the disclosure of relevant information? How can quality control of results
and data be accomplished and what role is there for peer review?

There are at least two common models currently used for data and results. In most public health
settings, and increasingly prevalent for data and results produced using public funds, there is an
expectation that they will ultimately be made openly available. In other settings, especially as
part of commercial development, data and results produced can be seen as proprietary, and in
some cases access is via license. In some cases, third parties such as WHO might be granted
special access to proprietary information for health work for the public good.

It may also be desirable to include provisions that describe how data and results will be shared
amongst parties to the MTA. For example, should the recipient of samples share any data and
results with the supplier prior to publication? Should all data and results be shared, or only that
to be published? Should these results be shared with third parties, such as WHO, for public
health purposes? Is a license required to do that? What provisions are in place to ensure the
data and results are shared with the sample donors or affected communities?

There may also be issues connected to dissemination of information relating to the existence of
the agreement itself. For example, when and how is it permissible to name the partners to the

agreement? When and under what conditions are press releases to be produced, and by whom?

13. Relevant laws, regulations and good practice

Providers and recipients should ensure consistency with any applicable national and international laws and many MTAs might include provisions detailing relevant commitments.

Relevant international rules can be legally binding, such as relevant provisions of the International Health Regulations (2005), in particular their Articles 6 and 46, or the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. They might include international normative documents, such as the WHO Laboratory Biosafety Manual, the UN Recommendations of the Transport of Dangerous Goods, or those for the protection of human and animal subjects, such as those enshrined in the Helsinki Declaration.

When considering relevant laws and regulations, it might be important to cover such issues as: ethical use or oversight, laboratory biosafety, laboratory biosecurity, or good practices for handling, storage or shipping samples or associated information, or the data or results generated. It could also cover issues connected to human rights and patient confidentiality issues.

The MTA might usefully identify individuals or bodies responsible for compliance in relevant areas.

14. Monitoring, evaluation, and reporting

It is common to include provisions governing reports on the use of material provided under the MTA, including the provision of information covering results, updates on how much material has been used, and how much remains.

Some MTAs specify how and when reports should be made. This can include both regular update reports and a more in-depth final report after the intended purpose has been completed.

In other cases, depending upon the intended purpose of the transfer, more detailed oversight of the planned work might be desirable. This section could also detail agreements for monitoring or evaluating the work undertaken. This would be unusual for transfers for diagnostic purposes.

15. Nature of relationship, warranties, liabilities, insurance, settlement of disputes, governing law and consistency

It will be important that the MTA addresses such issues as the nature of the relationship between the parties as this can have profound implications on responsibility. Some agreements might establish formal relationships between the supplier and recipient. It is more common for MTAs to specify that the transfer does not amount to a more formal relationship.

Issues around warranties are also important. It might be necessary to include terms detailing expectations around the materials and data being provided. They are often supplied ‘as is’ with no guarantees as to the contents or viability.

The same is true for any liabilities stemming from the provision of materials or data and any permitted uses. Some MTAs specify that each party is individually responsible for the manner in
which they carry out relevant activities. It is also sometimes necessary to consider indemnifying  
parties against possible claims or costs arising from the intended purpose. Note that alternative  
language for limitation of liability may be offered by some institutions because of their affiliation  
with foreign governments.

It is particularly important to consider under the laws of which jurisdiction the MTA will operate  
in, and in whose court system potential disputes must be settled. To this end, it might be  
prudent to consider how any disputes relevant to the MTA might be settled. In some cases,  
specific sources of arbitration might be identified.

Provisions can be added to address what should happen should one of the parties breach the  
agreement. This could lead to transfers being halted or work stopped.

It is important to clarify what is to happen in case of inconsistency between the text of the MTA  
and the protocol (or for that matter any other document) in cases where there may be  
differences between the stated purpose, study protocols, and documentation. Establishing from  
the outset which has primacy can prevent complications later.

16. Headings, amendments, waivers, and further assurances

There are a number of other common legal elements to be found in agreements such as MTAs.  
These might include:

- **Status of the headings in the MTA** - commonly there to help navigate the document, rather  
  than as part of the interpretation of its terms;

- **Provisions for the amendment of the MTA** - usually only possible by common consent, in  
  writing and duly signed and witnessed;

- **Terms covering waivers of rights** - sometimes used to indicate that any flexibility shown by  
  one party in how another party is implementing the MTA does not formally waive any rights  
  under the agreement; and

- **Further assurances** - which might include statements of the intent to carry out activities in  
good faith of achieving the intent, as well as the letter, of the agreement, or for addressing  
the transfer of rights and obligations to third parties.

17. Duration and Surviving Provisions

It is important to set appropriate start and end dates for the MTA and any permitted uses. Once  
again this might be tied to the purpose of the MTA. It is possible that the end of the agreement  
might be marked by an activity, rather than a date - for example, the completion of the intended  
purpose, or the provision of a final report.

It is essential to provide which rights and obligations will survive the termination of the MTA,  
including for example confidentiality clauses, publications or release of data into the public  
domain, as well as licenses or agreements for further use.

It is also important to consider the events that could cause an early termination of the  
agreement, for example, the merger of the recipient laboratory with another laboratory, if the  
laboratory is found unable to meet regulatory requirements, or the laboratory simply ceases its  
operations.
18. Signatory

This is where the nominated and authorised individuals sign the agreement on behalf of their relative institutions or organizations.
PART III: Examples of text from existing MTAs

2. Parties

Example text

This Materials Transfer Agreement is made as of the Effective Date.............................. and will cover all shipments of zika Virus until [the declaration of the end of the PHEIC by the World Health Organization]

BETWEEN:

[Name of Ministry of Health, having an address at ___________ (hereinafter the “MOH” or “Provider”)

AND:

[Name of Recipient Laboratory, having an address at ___________ ] (hereinafter the “Lab short name” or “Recipient”) (Collectively “Parties”)

Example text

This Materials Transfer Agreement is made as of the Effective Date.............................. and will cover all shipments of … until …

BETWEEN:

[Name of Ministry of Health, having an address at ___________ (hereinafter the “MOH” or “Provider”) or [Name of Medical Care giver - ________]

AND:

[Name of Recipient Laboratory, having an address at ___________ ] (hereinafter the “Lab short name” or “Recipient”) (Collectively “Parties”)

Example text

Technical Representatives: The following individuals are authorized by the Provider and the Recipient, respectively to provide or receive the Materials and Information on their behalf, unless another individual is subsequently designated in writing by either Provider or Recipient:

For the Provider:

For the Recipient:

Example text

This Agreement is made by and between:

a) <Name of providing University and address >(“the Donor Institution”)

and

b) <Name of Recipient Scientist’s Institution and address> (“the Recipient Institution”)
This Agreement is made by and between:

a) (“the Donor Institution”) and b) (“the Recipient Institution”)

The PROVIDER is making the MATERIAL available as a service to the research community. The RECIPIENT may use the MATERIAL for any lawful purpose, including COMMERCIAL PURPOSES, in accordance with the following terms and conditions.

This Agreement is made the…………..day of ……….  between
………………….. whose registered office is situated at …………………………. (hereinafter
called "Recipient")
and
………………………….., having its principal offices …………………………. (hereinafter
"Provider")
in the frame of [network].

In this Agreement:

The Provider is the laboratory sending Materials, as herein defined,
(name and address of the provider or providing institution, designation of the
laboratory (i.e. whether NIC/WHO CC/H5RL/ERL/other authorized laboratory),
name of authorized official, contact information for authorized official)
(hereinafter referred to as “the Provider”)

and

The Recipient is the laboratory receiving Materials, as herein defined,
(name and address of the recipient or recipient institution, designation of the
laboratory (i.e. whether NIC/WHO CC/H5RL/ERL/other authorized laboratory),
name of authorized official, contact information for authorized official)
(hereinafter referred to as “the Recipient”)

Provider and Recipient are hereafter collectively referred to as “Parties”

3. Purpose

WHEREAS this Materials Transfer Agreement sets out the understanding of the Parties with respect to the provision of Materials by the Provider to the Recipient, who wishes to use the Materials for the Purpose, subject to the terms and conditions of this Materials Transfer Agreement, and its MTD.

NOW THEREFORE, in consideration of the foregoing, the mutual covenants and obligations contained in this Materials Transfer Agreement and its MTD, and other good and valuable consideration, the Parties will adhere to the following conditions:
Example text

Supply and License: Provider will deliver to Recipient the Materials and Information. Subject to the terms and conditions of this Materials Transfer Agreement and its MTD, Provider hereby grants Recipient the right to use the Materials and Information for the Purpose, during the Period of Use unless terminated earlier or unless extended by written mutual agreement of the Parties. It is explicitly understood that any other use by the Recipient of the Materials and Information shall be subject to Provider’s advance agreement in writing.

Example text

Supply and License: Provider will deliver to Recipient the Materials and Information. Subject to the terms and conditions of this Materials Transfer Agreement and its MTD, Provider hereby grants Recipient the right to use the Materials and Information for the Purpose, during the Period of Use unless terminated earlier or unless extended by written mutual agreement of the Parties. It is explicitly understood that any other use by the Recipient of the Materials and Information shall be subject to Provider’s advance agreement in writing and will be subject to applicable authorisations in country of origin of Material (notably ethical clearance), including with respect to research or any other use that are not regulated as medical research in the country of the Recipient or that do not require prior authorization under the legislation of the country of the Recipient.

Example text

This Agreement records the terms under which the Donor Institution will make available <details of Material> (the "Material"). The term “Material” includes all unmodified progeny generated from the material supplied and that part of all derivatives and the derivative’s progeny which contains any of the material supplied or its progeny. The Recipient Institution will hold the Material in trust on the terms of this Agreement and solely for the purpose of [intended purpose] (“the Research Project”) within the research group of [Recipient Scientist] (“the Recipient Scientist”).

Example text

This Agreement records the terms under which the Provider Institution will make available to the Recipient Institution the Material identified in [Appendix] (the “Material”). The term “Material” means material, other than human gametes or embryos, which consists of, or includes human cells and which is considered “Relevant Material” for the purposes of [relevant legislation] together with related data. The Recipient Institution will hold the Material on the terms of this Agreement and solely for the purpose of [intended purpose] (“the Study”) and as described in [Appendix], within the research group of [Recipient Scientist] (“the Recipient Scientist”). The Recipient Institution hereby agrees to comply and procure that the Recipient Scientist and all personnel who work with the Material comply with the following terms and conditions:

Example text

This [agreement] and the attached Implementing Letter (the “Implementing Letter” and, together with the Agreement) is entered into between the PROVIDER and the RECIPIENT (or the “Parties”, as further identified in the [Implementing Letter] and governs the exchange and use of the certain materials specified in this Agreement between the Parties. The provisions of this [agreement] shall be given precedence in interpretation in the event of any conflict between this [agreement] and the Implementing Letter.
Provider agrees to transfer to Recipient’s Investigator the following Research Material: [ ].

Recipient acknowledges that this agreement is entered into in order to encourage scientific collaboration and exchange of data and material in the field of rare diseases.

NOW IT IS HEREBY AGREED AS FOLLOWS:

Pursuant to Recipient’s request that certain research material be made available for research and/or testing purposes, Provider agrees to provide to Recipient this biological material under the following terms and conditions:

[biological materials] as defined in [agreement section] of the Framework (hereinafter “Materials”) transferred from the Provider to the Recipient are subject to the provisions of this Agreement.

The Provider or recipient will consider support to the strengthening of the laboratory and surveillance capacity of the networks of developing countries.

When it is necessary to transfer samples for storage or other uses from one organization to another within the country and abroad, the provider organization holding the samples on behalf of sample sources shall negotiate an appropriate contract with the recipient organization. This contract shall be in the form of a Materials Transfer Agreement (MTA). In order to justify transfer of human materials abroad, researchers, sponsors and collaborators should demonstrate that in-country capacity to perform certain types of investigations/testing does not exist or is inadequate. Samples may be transferred for quality assurance and laboratory reference purposes. Researchers, sponsors and collaborators are encouraged to build, develop or strengthen local capacity for any investigative testing to fulfil the objectives of the proposed research. All exchanges and transfers (including importation and exportation) of materials for research purposes shall require clearance from [regulator], except for exchange of human materials between organizations within the country. [Regulator] shall maintain a depositary of all MTAs. Applications for permission to exchange or transfer human materials for research purposes shall be made to [regulator]. The application must be accompanied by a MTA.

[Institution] shall send to the Recipient’s Principal Investigator the Materials in a manner consistent with the optimum stability and safe delivery of the Materials.

[Institution] shall provide the Recipient with any protocols that [Institution] may have concerning the handling, storage and safety of the Materials.
4. Definitions

Access

"Access right" means rights to use results or background under the terms and conditions laid down in this Agreement. Unless agreed otherwise, access rights do not include the right to sublicense. However, any legal entity that enjoys access rights in order to complete the action or for research use may authorize another legal entity to exercise those rights on its behalf, provided that the following conditions are fulfilled: (a) the legal entity that enjoys access rights is liable for the acts of the other legal entity as if those acts had been performed by this former legal entity; (b) access rights granted to the other legal entity do not include the right to sublicense.

Anonymous

Stripped of identifying information and of codes that could be used to link data or samples back to a specific individual. Although anonymous materials do not by definition contain linking codes, they need not necessarily be de-identified (as defined below). Note that materials containing certain demographic information may not be considered anonymous, depending on the size of the population from which the materials or data are derived.

Background technology

"Background Technology" means any and all products, services, processes, technologies, materials, software, data and other innovations that are created by you or a third party prior to or outside of this Project and that are to be used as part of the Project.

Biospecimen / specimen

A Biospecimen is a quantity of tissue, blood, urine, or other human-derived material.

Commercial purposes

"COMMERCIAL PURPOSES" means the sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization.

COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. However, industrially
sponsored academic research shall not be considered a use of the MATERIAL or
MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of
this definition are met.

Confidential Information

Example text

General Obligations to maintain Confidentiality - During implementation of the action and for
[Number of] years after the period set out in this agreement, the parties must keep confidential
any data, documents or other material (in any form) that is identified as confidential at the time it
is disclosed (“confidential information”).

Example text

Confidential Information - All technology and know-how disclosed by one party (the “Disclosing
Party”) to another party (the “Receiving Party”) hereunder (“Confidential Information”) shall be
used solely and exclusively by Receiving Party in a manner consistent with the licenses granted
hereunder and the purposes of this Agreement as stated in the preamble and recitals hereto;
maintained in confidence by the Receiving Party; and shall not be disclosed to any non-party or
used for any purpose except to exercise its rights and perform its obligations under this
Agreement without the prior written consent of the Disclosing Party, except to the extent that the
Receiving Party can demonstrate by competent written evidence that such information: (a) is
known by the Receiving Party without obligations of confidentiality at the time of its receipt and,
not through a prior disclosure by the Disclosing Party, as documented by the Receiving Party’s
business records; (b) is in the public domain other than as a result of any breach of this
Agreement by the Receiving Party; (c) is subsequently disclosed to the Receiving Party on a
non-confidential basis by a third party who may lawfully do so; or (d) is independently
discovered or developed by the Receiving Party without the use of Confidential Information
provided by the Disclosing Party.

Example text

Master Confidential Disclosure Agreement - Confidential Information means, (i) all information
provided at any [agreement-associated] Meeting with respect to any aspect of a Project,
regardless of whether or not such information is identified or marked as confidential and
regardless of whether or not a written record is subsequently provided if the information was
provided orally and (ii) all recorded information, including data marked “Confidential” or bearing
a similar legend.

Data

Example text

Data means recorded information used or generated in the performance of [project].

This agreement defines the following categories of data:

(i) Standardized Data: all data resulting from an assay after it has been defined as a
Standardized Assay, which is performed by persons or organizations certified to
perform;
(ii) Non-Standardized Data: all data not resulting from Standardized Assays other than Comparative Data;

(iii) Comparative Data: all Data resulting from comparative evaluation of Non-Standardized Data or Standardized Data produced by a [Member].

(iv) Comparative Standardized Data: all Data resulting from comparative evaluation of Standardized Data produced by a [Member]; accordingly Comparative Standardized Data is a subset of the Comparative Data.

Funded development

Example text

“Funded Development” means any and all products, services, processes, technologies, materials, software, data and other innovations (including modifications, improvements and further developments to Background Technology) to be created by [grantee] or a third party under this Project.

Example text

Examples of Funded Developments include, but are not limited to, the following:

- Products: compounds, formulations, diagnostics, therapeutics, prophylactics, and devices
- Services: treatments, delivery systems, communications, and infrastructure developments
- Processes: methods, formulae, and algorithms
- Technologies: platforms, mechanisms, and tools
- Materials: drawings, analysis, curriculum, guidelines, and policy recommendations
- Software: code, development kits, and applications
- Data: [raw or compiled]
- Other Innovations

Information or Background Information

Example text

“Information” means the anonymized information relating to the Materials as supplied by the [Supplier] to Recipient.

Example text

“Background”: any information, techniques, Know-how, software and materials (regardless of the form or medium in which they are disclosed or stored) that are provided by one party to another for use in the Project (whether before or after the date of this Agreement), except any Result.

* In the specific context of this agreement, materials meant something other than the tangible biological goods being transferred.
“Background” means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that: (a) is held by the beneficiaries before they acceded to the Agreement, and (b) is needed to implement the action or exploit the results."

**Intellectual Property Rights**

Intellectual Property Rights (IPRs): all present and future intellectual property rights including but not limited to patents, trade and service marks, design rights, copyright, database rights, trade secrets and know-how, in all cases whether registered or not or registerable, and including all registrations and applications for registrations of any of these and rights to apply for the same as well as any renewals, extensions, continuations, combinations or divisions thereof, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these anywhere in the world.

**Invention**

“Invention” means any software or new discovery, improvement or invention, including any Modification, made by the Recipient through the use of the Materials and/or the Confidential Information.

**Materials**

“Materials” means all types of tangible chemical, biological and/or physical materials. (§1 Definition) Materials are transferred for the performance of the Action from “Providing Beneficiary” to “Recipient Beneficiary.”

The term “Material” means material, other than human gametes or embryos, which consists of, or includes human cells and which is considered “Relevant Material” for the purposes of the [relevant legislation] together with related data.

“ORIGINAL MATERIAL” means the material transferred subject to this Agreement. A description of the material being transferred will be specified in an implementing letter.

“MATERIAL” includes ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL does not include MODIFICATIONS or other substances created by the RECIPIENT through the use of the MATERIAL, which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES.
Human materials are substances including, but not limited to, blood, urine, stool, saliva, hair, nail clippings, skin, and any other associated bio-products obtained from human research participants or patients or healthy persons.

The materials being transferred/exchanged must be fully described, including a description of derivative products, if any. Quantities must be specified and appropriately packaged.

**Modifications**

“MODIFICATIONS” means substances created by the Recipient that contain or incorporate the MATERIAL.

**Non-profit organizations**

NONPROFIT ORGANIZATION(S): A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.

**Permitted purpose**

Permitted Purpose: to conduct the [Research Project] in the manner and timeframe set out in [Annex], subject to the provisions of this MTA.

**Progeny**

“PROGENY” means unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism.

**Provider**

“PROVIDER” means the organization providing the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter.

“PROVIDER SCIENTIST” The name and address of this party will be specified in an implementing letter.
Recipient

Example text

“RECIPIENT” means the organization receiving the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter.

“RECIPIENT SCIENTIST” The name and address of this party will be specified in an implementing letter.

Example text

Recipients are all entities that receive materials from the provider, such as influenza vaccine, diagnostic and pharmaceutical manufacturers, as well as biotechnology firms, research institutions and academic institutions. Each recipient shall select options based on its nature and capacities.

Repository

Example text

Repository is the physical entity where the Research Materials will be stored and distributed following the Recipient’s approved processes and procedures.

Results

Example text

“Results” means the results of the work performed by the Recipient, including but not limited to virus isolates, genetic sequences, data and information, analyses and conclusions.

Example text

“Result”: All information, Know-how, results, inventions, software and other Intellectual Property identified or first reduced to practice or writing in the course of the Project.

Unmodified derivatives

Example text

“UNMODIFIED DERIVATIVES” means substances created by the RECIPIENT that constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by PROVIDER, or monoclonal antibodies secreted by a hybridoma cell.

5. Ownership of samples / materials and custodianship

Example text

Supply of Material and Data Set(s) - The Supplier may from time to time provide to the Recipient Material and Data Set(s) and other Confidential Information pursuant to the terms and conditions of this Agreement.
All rights to the Materials and Information shall exclusively be and remain vested in the supplier. The supplier hereby grants the Recipient the right to use such Materials and Information for the Purpose (it being explicitly understood and agreed that any other use shall be subject to the supplier’s advance agreement in writing). Recipient will not claim any rights in respect of such Materials and Information, other than as explicitly provided herein.

The Recipient acknowledges and agrees that the ownership of Materials and Data Set(s), in particular of Human Biological Material, may be specifically regulated in the Host Country; such regulations may differ from those applicable in the country of the Recipient. Without limitation to the provisions of the preceding sentence, the parties agree that the Recipient does not obtain any right, title, or interest in any of the Materials and Data Set(s) furnished by the Supplier.

Each Beneficiary shall remain the exclusive owner of its Background. Participation in the Action shall not affect such ownership rights in its Background, without prejudice to any rights and obligations under this Consortium Agreement and the Grant Agreement.

Each beneficiary remains free to license, transfer or otherwise dispose of its ownership rights in Background, subject to any rights and obligations under this Agreement and the consortium agreement.

Where a beneficiary transfers ownership of Background, it must pass on its obligations specified under this Agreement and the consortium agreement, regarding that Background, to the transferee, including the obligation to pass those obligations on to any subsequent transferee.

A beneficiary may, without the consent of the other beneficiaries but provided that the other beneficiaries are informed without undue delay and that the transferee agrees in writing to be bound by this Agreement and the consortium agreement, transfer its Background to any of the following: (a) its affiliated entity, (b) any purchaser of all or a substantial amount of its relevant asset, and (c) any successor entity resulting from the merger with or consolidation of such a beneficiary.

Results are owned by the beneficiary that generates them. Each beneficiary remains the exclusive owner of its Sideground but a different allocation of ownership may be agreed upon in the consortium agreement.

Unless otherwise specified herein, each Beneficiary remains the exclusive owner of its [Results]. Beneficiaries are not required to grant any Access Rights to [Results]. Two or more beneficiaries own results jointly if: (a) they have jointly generated them and (b) it is not possible to (i) establish the respective contribution of each beneficiary, or (ii) separate them for the purpose of applying for, obtaining or maintaining their protection.

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership, to ensure compliance with their obligations under this Agreement.
Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licenses to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given: (a) at least 45 days advance notice and (b) fair and reasonable compensation.

Option 1: Beneficiaries may agree here that ownership of certain Results, once said Results have been generated, shall be transferred from the initial owner to another Beneficiary.

Option 2: Beneficiaries may agree here that where Results have been generated by one Beneficiary as a result of a cash contribution from another Beneficiary, these Results would be transferred to that second Beneficiary.

Unless otherwise agreed in the joint ownership agreement in the case of joint ownership of Results, each Co-Owner is granted a non-exclusive, world-wide, fully paid up, royalty-free, perpetual, irrevocable licence to use the jointly owned Results for Research Use, including the right to grant non-exclusive sub-licences to its Affiliated Entities and to Third Parties without the need to inform the other Co-Owners. Each Co-Owner and its Affiliated Entities shall have a license to use for Direct Exploitation the jointly owned Results, including the right to grant non-exclusive licences subject to the following conditions [different terms can be inserted].

Each Beneficiary remains free to transfer its ownership rights in Results.

Where a Beneficiary transfers ownership of Results, it must pass on its obligations specified under the Grant Agreement and the Consortium Agreement to the transferee.

Unless agreed otherwise (in writing) for specifically-identified Third Parties or unless impossible under applicable laws on mergers and acquisitions, a Beneficiary that intends to transfer ownership of Results must give at least forty-five (45) Days’ notice to the other Beneficiaries that still have (or still may request) Access Rights to the Results. This notification must include sufficient information on the new owner to enable any Beneficiary concerned to assess the effects on its Access Rights.

Unless agreed otherwise (in writing), any other Beneficiary may object within thirty (30) Days of receiving the notification if it can show that the transfer would adversely affect its Access Rights. In this case, the transfer may not take place until an agreement has been reached between the Beneficiaries concerned.

Notwithstanding the above, a Beneficiary may, without the consent of the other Beneficiaries but provided that the other Beneficiaries are informed [within sixty (60) Days] from the date of transfer and that the transferee agrees in writing to be bound by the Grant Agreement and the Consortium Agreement, transfer its Results to any of the following: a) its Affiliated Entity, b) any purchaser of all or a substantial amount of its relevant assets, and c) any successor entity resulting from the merger with or consolidation of such a Beneficiary.

Provided that any Access Right to the Results can be exercised (requested and granted) and that any additional obligations under the Grant Agreement or the Consortium Agreement are complied with by the Beneficiary who owns Results, each Beneficiary may license its own Results to any legal entity as it deems fit.

Example text

The foundation’s approach has been to not take ownership in technologies created with its funds, although it’s possible that the foundation may take limited residual (march-in) rights if
during the due diligence process it determines that such rights are necessary to ensure the achievement of the strategic objectives toward Global Access; provided, however, if such rights are sought, they will be expressly described in either the body of the grant agreement or the project’s underlying collaborative documentation.

Example text

The RECIPIENT agrees to provide appropriate acknowledgement of the source of the MATERIAL as requested by the PROVIDER. Any request for attribution will be specified in the Implementing Letter.

Example text

1. The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.

2. The RECIPIENT retains ownership of: (a) MODIFICATIONS (except that, the PROVIDER retains ownership rights to the MATERIAL included therein), and (b) those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES). If either 2 (a) or 2 (b) results from the collaborative efforts of the PROVIDER and the RECIPIENT, joint ownership may be negotiated.

Example text

This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient’s Investigator therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes.

Example text

Within sixty (60) days from the date of this Agreement above, Provider shall provide Recipient with samples of the Biological Material, in good condition along with associated information and data developed by Provider as appropriate. The samples shall be sent to the attention of: ………………. or his designee, at Recipient’s site; ………………… (address of the site for delivery). All custodianship of the Biological Material will pass to Recipient from the point of delivery of the sample to the Recipient’ site. Recipient will then be responsible for its use, storage and disposal for the term of the Agreement. Recipient agrees not to take or send the Biological Material to any other location or to a third party without advance written approval of Provider.

Example text

Sample sources own the samples. Samples sources may withdraw their samples if the samples are linked. Samples shall be held in trust on behalf of the sample sources by a duly registered and recognized organization in [country]. The organization entrusted with custodianship of the samples shall have the authority to decide use, transfer, storage and future use of the samples taking into consideration rights and welfare of the research participants.
6. Use

Example text

Unless with the prior written approval of Provider (whose approval may be withheld at its sole discretion) or unless expressly permitted by the terms of a separate written agreement entered into between the Parties, Recipient agrees that the Material and Information will not be used for any purpose other than the Purpose and will be used only by Recipient at Recipient’s organization.

Example text

Recipient’s Personnel: Recipient will limit provision and disclosure of Material and Information to those directors, officers, employees and consultants of Recipient who need to know or need to use the Material or Information in order to assist Recipient in carrying out the Purpose. The Recipient will ensure that Recipient’s directors, officers, employees, and consultants as aforesaid shall be bound by similar obligations of confidentiality and restrictions on use as contained in this Agreement.

Example text

The Material may only be used by those under the Recipient Scientist’s direct supervision in the Recipient Institution’s laboratories under suitable containment conditions, and in compliance with all applicable statutes and regulations. The material may not be used in human subjects or for clinical or diagnostic purposes.

Example text

The Recipient Institution will not use the Material for administration to human subjects or human application as that term is defined in the [relevant legislation] (or equivalent as each may be replaced or amended from time to time), or for clinical or diagnostic purposes.

Example text

The Recipient Institution may use the Material for the purposes of the Study and as described in [Appendix], from the date of receipt of the Material. The Recipient Institution will comply fully with all applicable environmental, health and safety laws, the [relevant legislation] and other Applicable Laws with respect to its use (including, but not limited to, disposal or return).

Example text

The RECIPIENT shall use, store, and dispose of the MATERIAL and any MODIFICATIONS in accordance with good laboratory practice and shall ensure compliance with all applicable laws, rules, and regulations, including laws, rules, and regulations governing export control and safety.

Example text

The Recipient Institution will not transfer the Material to any other body, or permit its use within the Recipient Institution other than by the Recipient Scientist's research group, without (in each case) prior written consent from the Donor Institution. The Material may not be used by the Recipient Scientist in research which is subject to the provision of any rights to a commercial third party without prior written consent.

Example text

The RECIPIENT and the RECIPIENT SCIENTIST agree that the MATERIAL:
a) is to be used solely for teaching and academic research purposes;
b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER;
c) is to be used only at the RECIPIENT organization and only in the RECIPIENT SCIENTIST’s laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision; and
d) will not be transferred to anyone else within the RECIPIENT organization without the prior written consent of the PROVIDER.

Example text
This research material may not be used in human subjects. The Research Material will only be used for research purposes by Recipient’s Investigator in his/her laboratory, for the research project described below, under suitable containment conditions. This Research Material will not be used for commercial purposes such as screening, production or sale, for which a commercialization license may be required. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

This Research Material will be used by Recipient’s Investigator solely in connection with the following research project (“Research Project”) described with specificity as follows (use an attachment page if necessary):

Example text
Recipient hereby accepts, upon the terms and conditions herein specified, the custodianship of the Biological Material to enable Recipient to use the Biological Material for the sole purpose of conducting experimental research to the exclusion of any commercial use of the Biological Material. The experimental research conducted by Recipient with the Biological Material, hereinafter the “Research”, is described in [clause].

Example text
The recipient should fully describe the intended use of the materials. The recipient should also specify whether the materials would be used for research purposes only or for commercial applications or both.

Example text
The Recipient shall ensure that the Materials are:

- used only for the purposes of the Investigation and not for administration to human subjects;
- handled and stored in accordance with any reasonable protocols provided to the Recipient pursuant to [Clause];
- not made available to anyone other than personnel of the Recipient engaged in carrying out the Investigation.

Restrictions on access to information or background information

Example text
During the action, the beneficiary enjoys access right to the background of the other beneficiaries, solely for the purpose and to the extent necessary for undertaking and completing the action. Such access must be granted on a royalty-free basis.
During and after completion of the action, beneficiaries and their affiliated entities enjoy (unless prevented or restricted from doing so by obligations to others which exist at the date of accession to this Agreement) access rights to the background of the other beneficiaries, only to the extent reasonably required for the purpose of the research use of results.

Restrictions on access to results

Example text
Access Rights for Implementation: During the Action, the Beneficiaries enjoy Access Rights to the Results of the other Beneficiaries, solely for the purpose and to the extent necessary for undertaking and completing the Action. Such Access Rights are granted under Royalty-Free Condition.

Confidentiality

Example text
Recipient shall take all reasonable measures to keep the Materials and Information confidential and shall only use such Materials and Information for the Purpose. Disclosure shall be made only to those persons who have a need to know such Confidential Information for the aforesaid Purpose (as described herein), and who are bound by similar obligations of confidentiality and restrictions on use as contained herein.

Notwithstanding any of the foregoing, there shall be no obligations of confidentiality or restrictions on use if and to the extent the Recipient can demonstrate through competent evidence that:

1. the Materials or Information are publicly available, or become publicly available otherwise than by action of the Recipient; or
2. the Materials or Information were already known to the Recipient (as evidenced by its written records) prior to its receipt hereunder; or
3. the Materials or Information were received, without an obligation of confidentiality, from a third Party not in breach of an obligation of confidentiality, or
4. the Recipient is required to disclose the Materials or Information in order to comply with applicable laws or regulations or with an order of a competent court or public authority, provided that the Recipient will in such event promptly notify the Provider in writing of such obligation and shall provide adequate opportunity to the Provider to object to, or restrict, such disclosure or request confidential treatment thereof.

The obligations of confidentiality and restrictions on use set forth herein shall survive the expiration or termination of this Agreement.

Example text
The Recipient shall hold and maintain in confidence all Confidential Information. In this connection, the Recipient shall: (i) take all reasonable measures to keep such Confidential Information confidential, including taking such action as may be appropriate to prevent the unauthorized access, use or disclosure of the Confidential Information; (ii) use the Confidential Information solely for carrying out the Project and only to the extent that is reasonably necessary to achieve the Project objectives and not for any other purpose. (Any other use or
transfer to any Third Party (other than Representatives pursuant to [Section] below) of the Material and Data Set(s) or the other Confidential Information by the Recipient requires the prior and written approval of the Supplier and, as required by applicable laws, the competent authorities in the Host Country.; and (iii) only disclose the Confidential Information to those persons who have a need to know or are authorized to receive the Confidential Information under the terms of this Agreement, and who are bound by similar obligations of confidentiality and restrictions on use as contained herein.

In addition, the Recipient acknowledges and agrees that the use or transfer of Material and Data Set(s) or the other Confidential Information may require the prior authorization of competent authorities in the Host Country, including with respect to Project that are not regulated as medical research in the country of the Recipient or that do not require prior authorization under the legislation of the country of the Recipient. Supplier shall use reasonable efforts to obtain any required authorizations as needed for the Project prior to sending Material and Data Set(s) or other Confidential Information to Recipient or Recipient’s designated subcontractor for the Project. Without limitation to the provisions of the preceding sentences, the Recipient agrees not to use or store the Material and Data Sets at any facility outside of the control of the Recipient unless authorized by Supplier.

The Recipient shall only authorize access to the Confidential Information to its Representatives whose knowledge is necessary to enable the Recipient to carry out the Project, and shall guarantee that such use by its Representatives shall be consistent with the assurances and obligations set forth in this Agreement. Prior to disclosing any Confidential Information to any of its Representatives, the Recipient shall obtain their written agreement and undertaking to maintain and preserve the confidentiality of the Confidential Information and to comply with each of the terms and provisions of the Agreement.

Unless different period is stipulated by the Supplier, the obligations of this [Article] shall continue for a period of ten years after the expiration or termination of this Agreement.

The Recipient shall promptly report in writing to the Supplier any use or disclosure of the Confidential Information not provided for by this Agreement of which it becomes aware. The Supplier in its sole discretion may require the Recipient to: (a) promptly investigate and respond to the Supplier’s concerns regarding any alleged disclosure; (b) promptly resolve any problems identified by the investigation; (c) submit a corrective action plan with steps designed to prevent any future unauthorized disclosures; and/or (d) require that all Material, Data Set(s) and other Confidential Information (including any document created by or on behalf of Recipient and containing Confidential Information) be immediately returned or destroyed.

Confidentiality Obligation - Without prejudice to any obligations of confidentiality in the Funding Conditions, none of the parties will either during the Project Period or for [Number of] years after the end of the Project Period, disclose to any third party nor use for any purpose, except carrying out the Project, any other party's Confidential Information.

Request for Disclosure under Freedom of Information Act - If any party that is subject to the [Freedom of Information Act] receives a request under that Act to disclose any information that, under this Agreement, is the Confidential Information of another party, it will notify that other party and will consult with it promptly and before making any disclosure under that Act. That other party will respond to party that received the request within [Number of] Business Days after receiving the notice, providing information to assist the party that received the request to
determine whether or not an exemption to the Freedom of Information Act applies to the information requested under that Act.

Exceptions to Confidentiality Obligations - None of the parties will be in breach of any obligation to keep any Background or other information confidential or not to disclose it to any other party to the extent that it:

(i) is known to the party making the disclosure before its receipt in connection with the Project, and not already subject to any obligation of confidentiality to another party;

(ii) is or becomes publicly known without any breach of this Agreement or any other undertaking to keep it confidential;

(iii) has been obtained by the party making the disclosure from a third party in circumstances where the party making the disclosure has no reason to believe that there has been a breach of an obligation of confidentiality;

(iv) has been independently developed by the party making the disclosure; or

(v) is disclosed pursuant to the requirement of any law or regulation (provided, in the case of a disclosure under the [Freedom of Information Act], none of the exceptions to that Act applies to the information disclosed) or the order of any Court of competent jurisdiction, and the party required to make that disclosure has informed the party whose information it is, within a reasonable time after being required to make the disclosure, of the requirement to make the disclosure and the information required to be disclosed; or

(vi) is approved for release in writing by an authorized representative of the party whose information it is.

None of the parties will be in breach of any obligation to keep any Background that is not Confidential Information or other information, confidential or not to disclose them to any third party by:

(i) Publishing it if it has followed the procedure in the clause on Academic Publication and has received no Confidentiality Notice within the period stated in that clause; or

(ii) disclosing it to the Funding Body in accordance with the Funding Conditions.

None of the parties will be in breach of any obligation to keep another party’s Background, or other information, confidential or not to disclose them to any third party, by making them available to [any Group Company or any person working for or on its behalf or on behalf of a Group Company], who needs to know the same in order to exercise the rights granted provided they are not used except as expressly permitted by this Agreement and the recipient undertakes to keep that Background or that information confidential.

Example text

Confidentiality of Licensee Information - If required by a License Agreement, each Party will, to the extent permitted by law, keep confidential the terms of such License Agreement and any business information received from the Licensee (e.g., revenues, business development reports, milestones accomplished, sub-licensee information and sublicense agreements), except that a Party may report revenue it receives in accordance with its reporting requirements to sponsors and may include such revenue in aggregate licensing revenue reported by such Party.
Example text

General Obligations to maintain Confidentiality - During implementation of the action and for [Number of] years after the period set out in this agreement, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (“confidential information”).

If a [recipient] requests, [donor] may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they: (a) need to know to implement the Agreement and (b) are bound by an obligation of confidentiality.

The [recipient] may disclose confidential information to its staff, other [member] institutions and bodies or third parties, if: (a) this is necessary to implement the Agreement or safeguard the [recipient’s] financial interests and (b) the recipients of the information are bound by an obligation of confidentiality.

Unless otherwise agreed between the Parties, they may use Confidential Information only to implement this [agreement]. No Confidential Information of the Disclosing Beneficiary may be used by the Receiving Beneficiary for any purpose other than the performance of the Receiving Beneficiary’s obligations or the exercise of the Receiving Beneficiary’s rights under this Consortium Agreement.

The Beneficiaries may disclose Confidential Information to their personnel, other individuals under the supervision and control of the Receiving Beneficiary, Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-Contractors involved in the Action only if they: (i) need to know the Confidential Information to implement this Consortium Agreement or the Action, and (ii) are bound by obligations of confidentiality at least equivalent to those set forth herein. Any disclosure of Confidential Information by the Receiving Beneficiary to other Third Parties requires the prior written consent of the Disclosing Beneficiary. The Receiving Beneficiary must use all reasonable endeavors to ensure that persons and/or entities receiving Confidential Information from it do not disclose such Confidential Information. The Receiving Beneficiary shall be responsible to the Disclosing Beneficiary for any disclosure by any such personnel, Affiliated Entities, Linked Third Parties, Associated Partners, Sub-Contractors and Third Parties, which violates the terms of this Consortium Agreement.

The Receiving Beneficiary shall return to the Disclosing Beneficiary all documents or other materials containing any of the Disclosing Beneficiary’s Confidential Information, which are in its possession, power or control or in the possession, power or control of its personnel, other individuals under the supervision and control of the Receiving Beneficiary, Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-Contractors involved in the Action who have received such Confidential Information from the Receiving Beneficiary pursuant to this Clause, whenever requested to do so by the Disclosing Beneficiary, and where such Confidential Information is not required by the Receiving Beneficiary for the use or exercise of (i) Access Rights for completing the Action or (ii) other rights or licenses under this Consortium Agreement.
Agreement. The return or destruction of Confidential Information will not affect the Receiving Beneficiary’s obligation to observe the confidentiality and non-use restrictions in respect of the Disclosing Beneficiary’s Confidential Information set out in this Consortium Agreement. The Beneficiary shall be entitled to keep one (1) copy of the Confidential Information in a secure place for the purpose of evidence. The provisions of this Clause shall not apply to copies of electronically exchanged Confidential Information made as a matter of routine information technology backup and to Confidential Information or copies thereof which must be stored by the Receiving Beneficiary according to provisions of mandatory law.

Example text
Confidential Information - All technology and know-how disclosed by one party (the “Disclosing Party”) to another party (the “Receiving Party”) hereunder (“Confidential Information”) shall be used solely and exclusively by Receiving Party in a manner consistent with the licenses granted hereunder and the purposes of this Agreement as stated in the preamble and recitals hereto; maintained in confidence by the Receiving Party; and shall not be disclosed to any non-party or used for any purpose except to exercise its rights and perform its obligations under this Agreement without the prior written consent of the Disclosing Party, except to the extent that the Receiving Party can demonstrate by competent written evidence that such information: (a) is known by the Receiving Party without obligations of confidentiality at the time of its receipt and, not through a prior disclosure by the Disclosing Party, as documented by the Receiving Party’s business records; (b) is in the public domain other than as a result of any breach of this Agreement by the Receiving Party; (c) is subsequently disclosed to the Receiving Party on a non-confidential basis by a third party who may lawfully do so; or (d) is independently discovered or developed by the Receiving Party without the use of Confidential Information provided by the Disclosing Party.

Example text
Master Confidential Disclosure Agreement - Confidential Information means, (i) all information provided at any [agreement-associated] Meeting with respect to any aspect of a Project, regardless of whether or not such information is identified or marked as confidential and regardless of whether or not a written record is subsequently provided if the information was provided orally and (ii) all recorded information, including data marked “Confidential” or bearing a similar legend.

Confidential Information (as defined in the Master CDA), including but not limited to Data, that is shared between [those named in the agreement] will be held in confidence according to the terms of a [Master CDA].

Confidentiality Obligations - Each [Member], as a Receiving Party, agrees that it will:

(a) Use the Confidential Information received from a Disclosing Party solely for the Purpose (defined as “carrying out their own activities within the corresponding [Projects]”),

(b) Treat the Confidential Information with reasonable care to avoid disclosure of the Confidential Information to any third party, person, firm or corporation other than as expressly stated herein, and

(c) Except to the extent prohibited or, where applicable, to the extent authorized by law, be liable for use of the Disclosing Party's Confidential Information outside the scope of
the Purpose as well as for any unauthorized disclosure directly resulting from their failure to exercise such reasonable care.

Disclosure to Employees and Affiliates - Each Receiving Party shall be entitled to disclose the Disclosing Party’s Confidential Information to its employees and the employees of its Affiliates (as defined below) as well as its agents and consultants who are bound by confidentiality and restricted use obligations no less strict than those set out herein. However, each Receiving Party shall only disclose the Disclosing Party’s Confidential Information to those of its employees, agents, consultants and Affiliates who shall reasonably need to know such Confidential Information in order to evaluate such Confidential Information for the Purpose and/or to make decisions or render advice in connection with the Purpose and who shall be informed of the existence of this Master CDA and shall agree in writing or via employment policy to be bound by the terms hereof or be otherwise bound by law not to disclose such Confidential Information. Each Receiving Party shall be responsible for ensuring that its employees, agents and consultants of its Affiliates, and its consultants who receive Confidential Information comply with the terms of this Master CDA.

Exceptions - Notwithstanding anything to the contrary in this Master CDA, the Receiving Party shall have no obligation with respect to the Confidential Information received from a Disclosing Party to the extent such information is:

(a) Already known by the Receiving Party at the time of disclosure as can be demonstrated by competent proof;

(b) Publicly known, or subsequently becomes publicly known, without the wrongful act or breach of this Master CDA by the Receiving Party;

(c) Rightfully received by the Receiving Party from a third party having the lawful right to make such a disclosure, where said disclosure is rightfully made without an express obligation of confidence;

(d) Approved for release or disclosure by written authorization of the Disclosing Party;

(e) Independently developed by the employees or agents of the Receiving Party without the use or knowledge of the Confidential Information provided by the Disclosing Party as can be demonstrated by competent proof; or

(f) Required to be disclosed pursuant to any competent judicial or government request, requirement or order, provided that the Receiving Party so disclosing takes reasonable steps to provide the Disclosing Party with sufficient prior notice in order to allow the Disclosing Party to contest such request, requirement or order and provided that such Confidential Information is disclosed only subject to reasonably available restrictions on further disclosure and use, and otherwise remains subject to the obligations of confidentiality and restricted use set forth in this Master CDA.

Example text

General Obligations to maintain Confidentiality - The confidentiality obligations no longer apply if: (a) the disclosing party agrees to release the other party; (b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality; (c) the recipient proves that the information was developed without the use of confidential information; (d) the information becomes
generally and publicly available, without breaching any confidentiality obligation, or (e) the
disclosure of the information is required by law.

The confidentiality obligations under this Clause does not apply if: (a) the Disclosing Beneficiary
agrees in writing that it no longer considers the Confidential Information as protected by the
terms of this Clause (b) the Confidential Information was already known by the Receiving
Beneficiary or any of its Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-
Contractors or is given to such parties by a Third Party without obligation of confidentiality to the
extent such Third Party was not bound by any obligation of confidentiality with respect to such
Confidential Information; (c) the Receiving Beneficiary proves that the information was
developed independently by the Receiving Beneficiary or its Affiliated Entity, Linked Third
Parties, Associated Partners and/or Sub-Contractors without the use of Confidential Information;
(d) at the time of disclosure, the Confidential Information is or after such disclosure becomes
generally and publicly available, without breaching any confidentiality obligation by the
Receiving Beneficiary; (e) Disclosure of Confidential Information shall be permitted if the
Receiving Beneficiary is required to do so by or in connection with any laws, regulations or legal
processing, or court of competent jurisdiction, provided that such disclosure is subject to all
applicable governmental, regulatory or judicial protection available and immediate written notice
of such requirement is given to the Disclosing Beneficiary with a view to agreeing the timing and
the content of such disclosure. The same shall apply in case a disclosure of Confidential
Information to a patent office or equivalent supervisory required for the purposes of obtaining
patent protection, provided, that the Beneficiary opting for patent or similar protection must give
prior written notice to the Disclosing Beneficiary with a view to agreeing the timing and the
content of such disclosure.

Prior to the transfer of the Biological Material to Recipient, Provider will ensure that the samples
are either coded or anonymised, so that under no circumstances will Recipient be supplied with
the identity of the patient, or any basic clinical information, that in Provider’s opinion could
identify the patient.

To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3)
years from the date of its disclosure, any of Provider’s written information about this Research
Material that is stamped “CONFIDENTIAL,” except for information that was previously known to
Recipient or that is or becomes publicly available or which is disclosed to Recipient without a
confidentiality obligation. Any oral disclosures from Provider to Recipient shall be identified as
being CONFIDENTIAL by notice delivered to Recipient within ten (10) days after the
date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of
the Research Project, but if Provider has given CONFIDENTIAL information to Recipient such
public disclosure may be made only after Provider has had thirty (30) days to review the
proposed disclosure to determine if it includes any CONFIDENTIAL information, except when a
shortened time period under court order or the Freedom of Information Act pertains.

Each of Recipient and Provider undertakes to retain in confidence and not disclose to any third
party any confidential information and samples received from the other party. Such information
may, however, be disclosed insofar as such disclosure is necessary to allow a party, or its
employees to defend against litigation, to file and prosecute patent applications, or to comply
with governmental regulations. Such obligation of confidentiality shall be waived as to
information and samples which (i) is in the public domain; (ii) comes into the public domain through no fault of the receiving party; (iii) was known prior to its disclosure by the receiving party, as evidenced by written records; or (iv) is disclosed to the receiving party by a third party having a lawful right to make such disclosure. Such obligations of confidentiality shall continue for five (5) years from the completion or termination of the Research.

Example text

4.1 The Recipient shall keep confidential any confidential information relating to the Materials that is disclosed to it by Sanger pursuant to this Agreement. The Recipient shall only use such information for the purposes of the Investigation and shall not disclose it to any person other than personnel of the Recipient engaged in carrying out the Investigation.

Clause 4.1 shall not apply to any information that:

- is published by and/or is contained in any publication which Sanger has published or becomes public knowledge other than through breach of this Agreement; or
- is independently developed by the Recipient or acquired from a third Party, to the extent that it is acquired with the right to disclose it; or
- was lawfully in the possession of the Recipient prior to the date of this Agreement; or
- is required to be disclosed by law or any court of competent jurisdiction, any tax or regulatory authority or any binding judgement, order or requirement of any other competent authority, provided that the Recipient shall inform Sanger where possible prior to any such disclosure.

7. Further use, transport out of country, storage and destruction

Expectation for further use

Example text

Each beneficiary must — up to four years after the period set out in [agreement] — take measures aiming to ensure “exploitation” of its results (either directly or indirectly, in particular through transfer or licensing) by: (a) using them in further research activities (outside the action); (b) developing, creating or marketing a product or process; (c) creating and providing a service, or (d) using them in standardization activities.

Example text

The RECIPIENT may distribute the MATERIAL and substances created by the RECIPIENT through use of the MATERIAL, including PROGENY, UNMODIFIED DERIVATIVES, and MODIFICATIONS, without requesting consent from the PROVIDER. RECIPIENT agrees to notify the PROVIDER of any distributions of the MATERIAL to third parties as requested by the PROVIDER. Any request for notification will be specified in the Implementing Letter.

Example text

The RECIPIENT and/or the RECIPIENT SCIENTIST shall have the right, without restriction, to distribute substances created by the RECIPIENT through the use of the ORIGINAL MATERIAL only if those substances are not PROGENY, UNMODIFIED DERIVATIVES, or MODIFICATIONS.
Under a separate implementing letter to this Agreement (or an agreement at least as protective of the PROVIDER's rights), the RECIPIENT may distribute MODIFICATIONS to NONPROFIT ORGANIZATION(S) for research and teaching purposes only.

Example text
The Provider agrees to the onward transfer and use of the Materials, to all members of the [network], on the same terms and conditions as those provided in Standard Material Transfer Agreement within the [network].

The Provider consents to the onward transfer and use of the Materials to entities outside the [network] on the condition that the prospective recipient has concluded a Standard Material Transfer Agreement outside the [network].

The Provider shall inform the [designated point] of shipments of Materials to entities inside/outside the [network] by recording in the [database].

Example text
The recipient shall only further transfer the [biological materials] if the prospective recipient has concluded an SMTA with the [network].

Any such further transfer shall be reported to the [designated point].

The [authorised individual] may, under exceptional circumstances, allow the [biological materials] to be transferred to a prospective recipient while requesting this aforementioned recipient to enter into an [agreement], and report to the “Advisory Group” accordingly.

The recipient may exchange [biological materials] with any other holder of an [agreement] concluded with the [network].

Example text
The provider organization should clearly state whether the recipient organization is allowed to own any derivatives of the material developed over time. The provider organization may allow the recipient organization to retain the derivatives without any stipulations.

The MTA must state who owns any new products discovered through the use of the material. If nothing is stated about this in the MTA, the provider organization automatically assumes ownership.

Restrictions on future use

Example text
Upon expiration or earlier termination of the Period of Use, Recipient will cease all use of the Material and Information, and will destroy any remaining Material.

Example text
The Recipient Institution agrees to obtain the written consent of the Provider Institution if there is any material change to the proposed use of the Material in the Study as described in [Appendix].
Example text

The Materials shall be used solely for performance of the Action in accordance with this Consortium Agreement. The Recipient Beneficiary needs to have all the required authorizations under all applicable laws and regulations to perform the Allocated Work using the Materials. The Materials shall be used in full compliance with all applicable laws and regulations. The Materials shall not be analysed or modified except as necessary for the purpose of the Action.

The Materials shall not be transferred or made available to any individual other than those under the supervision and control of the Recipient Beneficiary, its Affiliated Entities, Associated Partners and/or Sub-Contractors. Upon completion of the Action, or the expiry or termination of this Consortium Agreement, any unused Materials will be either returned to the Providing Beneficiary, which made them available, or disposed of/destroyed in accordance with all applicable laws and regulations and provide Providing Beneficiary with a written confirmation of such disposal or destruction.

All Materials are transferred with no warranties, express or implied, of merchantability or fitness for a particular purpose or otherwise. In particular, no Providing Beneficiary represents or warrants that the use of the Materials will not infringe or violate any patent or proprietary rights of Third Parties.

To exercise access right, this must first be requested in writing.

Example text

Authorized Use and Access of Material and Data Set(s) and Other Confidential Information -

The Recipient shall hold and maintain in confidence all Confidential Information. In this connection, the Recipient shall: (i) take all reasonable measures to keep such Confidential Information confidential, including taking such action as may be appropriate to prevent the unauthorized access, use or disclosure of the Confidential Information; (ii) use the Confidential Information solely for carrying out the Project and only to the extent that is reasonably necessary to achieve the Project objectives and not for any other purpose. (Any other use or transfer to any Third Party (other than Representatives pursuant to Section 3.3 below) of the Material and Data Set(s) or the other Confidential Information by the Recipient requires the prior and written approval of the Supplier and, as required by applicable laws, the competent authorities in the Host Country.); and (iii) only disclose the Confidential Information to those persons who have a need to know or are authorized to receive the Confidential Information under the terms of this Agreement, and who are bound by similar obligations of confidentiality and restrictions on use as contained herein.

Example text

If there are specific restrictions for the recipient organization, they should be [guidance] described. Specific restrictions may, for example, include: to be used for one purpose and not the other; to be used in a specific site or country only or to be used strictly under the laws of a specific country. It should, however, be noted that any research project to be conducted in future using stored samples of human origin will be subject to review and approval by a Research Ethics Committee in the provider's country.
Continued access for research use

Access Rights for purpose of Research Use of Results: During and after completion of the Action, Beneficiaries and their Affiliated Entities enjoy Access Rights to the Background of the other Beneficiaries, only to the extent reasonably required for the purpose of the Research Use of Results. The parties can indicate the choice of Royalty-Free condition or Fair and Reasonable Conditions other than Royalty Free condition.

Continued access for commercial development

Access Rights for Direct Exploitation: Beneficiaries are not required to grant Access Rights for Direct Exploitation to their Background and may use, exploit, sublicense or otherwise commercialize their Background as they see fit, subject to the Access Rights granted for implementation as set forth in [Clause] and for Research Use as set forth in [Clauses]. In the event that Direct Exploitation of Results by a Beneficiary requires Background of another Beneficiary necessary to use such Results the Access Rights to such Background may be negotiated between the Beneficiary owning such Background and the Beneficiaries involved.

Nothing in this Agreement grants the Recipient Institution any rights over the Material (other than as specifically granted by this Agreement) or under any patents, nor any right to use, or permit the use of, any products or processes containing, using, or directly derived from the Material for profit making or commercial purposes (“Commercial Use”). If the Recipient Institution wishes to make Commercial Use of the Material or a product directly derived from the Material it agrees to negotiate in good faith with the Donor Institution or its representative for the grant of an appropriate licence or the conclusion of a revenue sharing agreement, if justified. The Donor Institution will have no obligation to grant a licence.

Without written consent from the PROVIDER, the RECIPIENT and/or the RECIPIENT SCIENTIST may NOT provide MODIFICATIONS for COMMERCIAL PURPOSES. It is recognized by the RECIPIENT that such COMMERCIAL PURPOSES may require a commercial license from the PROVIDER and the PROVIDER has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the MODIFICATIONS. Nothing in this paragraph, however, shall prevent the RECIPIENT from granting commercial licenses under the RECIPIENT’s intellectual property rights claiming such MODIFICATIONS, or methods of their manufacture or their use.

The MTA should include directions for handling commercializable products, including sharing of any royalties. The parties may wish to include a clause, which allows them to negotiate a separate MTA should the need for commercialization arise.
Request in Writing

Unless otherwise specified in this Agreement, in order for a Beneficiary to exercise its Access Rights, these must first be requested in writing. Access Rights to Background for implementation, Access Rights to Results for implementation, and Access Right for Research Use are hereby requested in writing by the Beneficiaries by way of signature of the Consortium Agreement, and are hereby granted by the respective Beneficiary, by means of signature of the Consortium Agreement.

Scope of Access Rights

All Access Rights pursuant to the Consortium Agreement shall be granted on a nonexclusive basis and are worldwide, perpetual and irrevocable. Such Access Rights shall not include the right to sub-license such Access Rights. However, a Beneficiary who enjoys Access Rights may authorize another legal entity, for instance an Affiliated Entity, to exercise those rights on the Beneficiary’s behalf, provided that the following conditions are fulfilled: (a) the Beneficiary that enjoys Access Rights is liable for the acts of the other legal entity as if those acts had been performed by the Beneficiary; and (b) Access Rights granted to the other legal entity do not include the right to sub-license.

The Research Use Access Right (As an option): The Research Use Access Right includes that any Beneficiary, or its Affiliated Entities, licensees and designees, may refer to any Results or Background necessary to use such Results of another Beneficiary, in regulatory documentation relating to any product owned by such Beneficiary, or its Affiliated Entities, licensees and designees. Such regulatory documentation may include the marketing authorization application, patient information leaflet, summary of product characteristics and equivalent documentation anywhere in the world. Prior to the submission of such Results or Background in such regulatory documentation, the submitting Beneficiary shall provide notice of its intent to make such submission to enable the owning Beneficiary to file for Intellectual Property protection covering such Results or Background (related to such Results). In such case the submission may be delayed for [a reasonable period of time] necessary to obtain such a protection.

Access by Third Parties

After completion of the Action, Third Parties have the right to request Access Rights to the Results for Research Use. Such conditions may not be more favourable than the conditions applied between Beneficiaries (and their Affiliated Entities) for Research Use, pursuant to [Agreement].

Nothing included in this Agreement, including any intellectual property protection being undertaken by the Recipient Institution on any new use made with the Material, shall prevent the Donor Institution from being able to distribute the Material to other commercial or non-commercial entities.
Nothing included in this Agreement shall prevent the Provider Institution from being able to distribute the Material to other entities as described in [Appendix]. If, as per the details included in [Appendix], the Material is to be transferred to another institution for the purposes of the Study, the responsibility for compliance with the terms of this Agreement rests with the Recipient Institution.

The RECIPIENT and the RECIPIENT SCIENTIST agree to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST’s direct supervision. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the MATERIAL available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at NONPROFIT ORGANIZATION(S)) who wish to replicate the RECIPIENT SCIENTIST’s research; provided that such other scientists reimburse the PROVIDER for any costs relating to the preparation and distribution of the MATERIAL.

Recipient agrees not to take or send the Biological Material to any other location or to a third party without advance written approval of Provider.

Authorized users of the materials should be mentioned. The users cited must agree to abide by the terms and conditions of the MTA. Transfer to third parties not mentioned in the MTA is prohibited without written consent of the provider organization or their assignees.

Storage

A separate informed consent form shall be used for samples, which are collected with the intention of being stored and used in future studies. The consent form, which is separate from the one used for enrolment of research participants into the study, shall include the following components: purpose of sample storage, quantities of samples to be stored, place where samples will be stored, measures to protect confidentiality, policies that will govern use of the samples in future research, potential risks and benefits of storing samples for future research and any other information deemed necessary by the researcher or Research Ethics Committee. After explaining the need to store the samples, the research participant shall be given the option to choose whether his/her sample should or should not be stored for future studies. A [national] scientist shall be included as co-investigator in all future studies using the human materials collected from [country]. A research participant shall not be penalized for his/her refusal to store the samples. Research participants reserve the right to withdraw their samples from storage if the samples are linked. Any future research study on such samples is subject to review by a Research Ethics Committee. Where identifiable samples have been collected, for example, as
part of routine surveillance, emergency procedures, laboratory quality control, notifiable
diseases, routine counselling and testing, etc., without the prior intention of conducting research
on the samples, samples sources shall be traced to provide consent for use of the samples in
research.

8. Publication

Example text
Each party may use the Results to update relevant recommendations and develop any
guidelines, including publication thereof, and may further publish the Results, provided that a
Party wishing to submit a manuscript for publication is to transmit to the other Parties for their
review any material intended to be published at least fifteen (15) working days (seven (7) days
for abstracts) before a proposed publication is submitted to any editor, publisher, referee or
meeting organizer. In the absence of an objection by the other Parties within that 15 day period
(or 7 days as the case may be) concerning prejudice to their proprietary rights, the publication
may proceed.

Example text
Any employee or student of any Academic Party (whether or not involved in the Project) may,
provided that Academic Party has not received a Confidentiality Notice, Publish any Background
(unless it is the Confidential Information of another party) or any of the Results.

Each of the Academic Parties will submit to any other party that owns the Intellectual Property in
any of the Results or that has contributed any Background to the Project, in writing, details of
those Results, and of that Background that any employee or student of that Academic Party
intends to Publish, at least [30][60] days before the date of the proposed submission for
Publication. Any other party may, by giving written notice to the party that has submitted those
details (“a Confidentiality Notice”): require that party to delay the proposed Publication for a
maximum of [number of] month[s] after receipt of the Confidentiality Notice if, in its reasonable
opinion, that delay is necessary in order to seek patent or similar protection for any of its
Background or any the Results that are to be Published; or prevent the Publication of any of its
Background that is Confidential Information. The Confidentiality Notice must be given within
[number of] days after receipt of details of the proposed Publication. If a Confidentiality Notice
is not received within that period, the proposed Publication may proceed, provided that, whether
or not a Confidentiality Notice has been given, any other party’s Background that is Confidential
Information may not be published.

Example text
Unless it goes against their legitimate interests, each beneficiary must — as soon as possible —
“disseminate” its results by disclosing them to the public by appropriate means (other than those
resulting from protecting or exploiting the results), including in scientific publications (in any
medium).

Each beneficiary must ensure open access (free of charge, online access for any user) to all
peer-reviewed scientific publications relating to its results.

Example text
The Recipient Scientist will acknowledge the source of the Material in any publication reporting
on its use. If the Recipient Scientist wishes to include in a publication any information which has
been provided by the Donor Institution with the Material and which was clearly marked as
“confidential” at the point of disclosure ("Confidential Information"), the Recipient Scientist will request permission from the Donor Institution, providing a copy of the text before publication takes place.

Example text
The Recipient Scientist will acknowledge the source of the Material in any publication reporting on its use. If the Recipient Scientist wishes to include in a publication any information which has been provided by the Provider Institution with the Material and which was clearly marked as "confidential" and "proprietary" at the point of disclosure ("Confidential Information"), the Recipient Scientist must obtain written permission from the Provider Institution, providing a copy of the text to allow a reasonable period for review before publication takes place, such permission not to be unreasonably withheld or delayed. If so requested by the Provider Institution, the Recipient Institution shall provide the Provider Institution with a confidential copy of the findings of the Study.

Example text
This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications.

Example text
In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider’s contribution of this Research Material unless requested otherwise.

Example text
Recipient shall share the results of the Research obtained through use of the Biological Material with Provider. In particular, Recipient undertakes to send a copy of any such publication based on use of the Biological Material (or derivative), promptly after it is published, to Provider, and to [network] at the following e-mail address [email].

In accordance with scientific customs, the contributions of those who have made Biological Material available or of the [network] Scientists if appropriate, will be reflected expressly in all written or oral public disclosures concerning the Research using the Biological Material, by acknowledgment or co-authorship, as appropriate. The origin of the Biological Material must be included in such disclosures, as follows: “We thank [bank X] for providing the samples. [bank X] is a partner of the [Network] established in [year] thanks to [funding],[website address].”

Example text
The Recipient shall appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza virus with pandemic potential or reagents, using existing scientific guidelines.

Example text
If applicable, the Recipient shall appropriately acknowledge in presentations and publications, the contributions of [network] laboratories providing the materials identified in [Article], using existing scientific guidelines.
The provider organization may require the recipient organization to publish or not to publish the data obtained from the material under specified conditions.

If the provider organization allows any publication, it may be agreed that the provider organization is acknowledged as the provider of the material.

**Review provisions**

Any publication as referred to above will duly acknowledge the other Parties in accordance with generally accepted authorship practices. In addition to review of the content of publications as referred to above, each Party will have the right to review the acknowledgement and request reasonable changes to the use of its name, or request that its name be deleted altogether.

**9. Benefit sharing**

Such access rights for research use must be granted on a non-exclusive basis under fair and reasonable conditions (i.e. appropriate conditions, including financial terms or royalty-free, taking into account the actual or potential value of the background to which access is requested and other characteristics of the research use envisaged).

The Parties shall make appropriate arrangements to promote that any product which may result from collaborative research and development work undertaken as a result of this Memorandum of Understanding, shall be made widely available to the public on reasonable terms, including in particular to the public sector of developing countries on preferential terms. Any possible additional benefits, including royalties, shall be granted to each Party with due account being taken of the relative value of each Party’s financial, intellectual and other contributions to the product (provided that priority shall always be given to the objective of the Parties set forth in the first sentence of this paragraph).

The Recipient shall actively seek the participation of scientists to the fullest extent possible from originating laboratories and other authorized laboratories, especially those from developing countries, in scientific projects associated with research on clinical specimens and/or influenza virus from their countries and actively engage them in preparation of manuscripts for presentation and publication.

The recipient agrees to comply with the commitments selected below, in accordance with the terms set out in the Annex to this agreement.
A. For manufacturers of vaccines and/or antivirals, the recipient shall commit to
at least two of the following options:

A1. Donate at least 10% of real time pandemic vaccine production to WHO.

A2. Reserve at least 10% of real time pandemic vaccine production at affordable prices
to WHO.

A3. Donate at least X treatment courses of needed antiviral medicine for the pandemic
to WHO.

A4. Reserve at least X treatment courses of needed antiviral medicine for the pandemic
at affordable prices.

A5. Grant to manufacturers in developing countries licenses on mutually agreed terms
that should be fair and reasonable including in respect of affordable royalties, taking into
account development levels in the country of end use of the products, on technology,
know-how, products and processes for which it holds IPR for the production of (i)
influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics.

A6. Grant royalty-free licenses to manufacturers in developing countries or grant to
WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the
production of pandemic influenza vaccines, adjuvants, antivirals products and
diagnostics needed in a pandemic.

WHO may sublicense these licenses to manufacturers in developing countries on appropriate
terms and conditions and in accordance with sound public health principles.

Where Option 5 or 6 is selected, the Recipient shall regularly provide to WHO information on
granted licenses and the status of implementation of the licensing agreement. WHO shall
provide such information to the Advisory Group.

B. Manufacturers of products relevant to pandemic influenza preparedness and
response, that are not manufacturing vaccines or antivirals, shall commit to one of the following

B1. Donate to WHO at least X2 diagnostic kits needed for pandemics.

B2. Reserve for WHO at least X2 diagnostic kits needed for pandemics, at affordable
prices.

B3. Support, in coordination with WHO, the strengthening of influenza specific laboratory
and surveillance capacity in developing countries.

B4. Support, in coordination with WHO, transfer of technology, know-how and/or
processes for pandemic influenza preparedness and response in developing countries.

C. The recipient shall, in addition to the commitments selected under A or B above, consider
contributing to the measures listed below, as appropriate:

- Donations of vaccines;
- Donations of pre-pandemic vaccines;
- Donations of antivirals;
- Donations of medical devices;
- Donations of diagnostic kits;
- Affordable pricing;
- Transfer of technology and processes;
- Granting of sublicenses to WHO;
- Laboratory and surveillance capacity building.

Example text

The MTA should state clearly what technologies would be transferred to the provider organization or country. Other collateral benefits to the provider organization such as building infrastructure, training and provision of certain services may be included.

10. Intellectual Property

Access to Information or Background Information

Example text

Each party grants each of the other parties a royalty-free, non-exclusive license to use its Background for the purpose of carrying out the Project, but for no other purpose. None of the parties may grant any sub-license to use any other party's Background except: (1) that any party may allow its Group Companies, and any person working for it or any Group Company, or on its behalf or that of any Group Company, to use any party’s Background for the purpose of carrying out the Project, but for no other purpose; or (2) if the owner of the Background grants further license.

Except as otherwise expressly permitted under this agreement, none of the parties will have the right to use another party's Background or Results (whether to exploit its own or any other Results or for any other purpose) unless it negotiates and obtains a further license that allows it to do so. The owner of the Intellectual Property in any Background or Result may refuse to grant that further license, and if it agrees to grant that further license, the terms of that further license may include a royalty or other payment in return for that further license.

Example text

Beneficiaries are not required to grant access rights for direct exploitation to their own background and may use, exploit, sublicense or otherwise commercialize their background as they see fit, subject to access rights for research use.

Example text

This Agreement does not affect the ownership of any Intellectual Property in any Background or in any other technology, design, work, invention, software, data, technique, know-how, or materials that are not Results. The Intellectual Property in them will remain the property of the party that contributes them to the Project (or its licensors). No license to use any Intellectual Property is granted or implied by this Agreement except the rights explicitly granted in this Agreement.

Example text

The Provider under [agreement] may have used technology protected by IPRs for the generation and/or modification of the Materials. Any recipient of such Materials acknowledges that such IPRs shall be respected.
Access to results

Example text

Except as otherwise expressly permitted under this agreement, none of the parties will have the right to use another party's Background or Results (whether to exploit its own or any other Results or for any other purpose) unless it negotiates and obtains a further license that allows it to do so. The owner of the Intellectual Property in any Background or Result may refuse to grant that further license, and if it agrees to grant that further license, the terms of that further license may include a royalty or other payment in return for that further license.

Example text

Where direct exploitation by a beneficiary or third party requires results owned by another beneficiary, the access rights may be negotiated between the parties involved.

After the completion of the action, third parties shall have the right to request and receive access rights to the results of the beneficiaries for research use.

Such access rights must be granted on a non-exclusive basis under conditions considered appropriate by the owner of the results and the third party concerned. Those conditions may not be more favorable than the conditions applied to beneficiaries and affiliated entities for research use.

The beneficiaries must give access to their results — on a royalty-free basis — to the [donors]. Such access rights are limited to non-commercial and non-competitive use. This does not change the right to use any material, document or information received from the beneficiaries for communication and publicizing activities.

Each beneficiary may transfer ownership of its results. It must however ensure that its obligations under this agreement also apply to the new owner and this new owner has the obligation to pass them on in any subsequent transfer.

A beneficiary that intends to transfer ownership of results must give at least 45 days advance notice to other beneficiaries that still have (or still may request) access rights to the result. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

Notwithstanding the above, a beneficiary may, without the consent of the other beneficiaries but provided that the other beneficiaries are informed without undue delay and that the transferee agrees in writing to be bound by this agreement and the consortium agreement, transfer its results to any of the following: (i) its affiliated entity; (ii) any purchaser of all or a substantial amount of its relevant assets; (iii) any successor entity resulting from the merger with or consolidation of such a beneficiary.
No Party to this MTA shall seek to obtain any intellectual property rights to the Results and each Party agrees to release such results in the public domain through publications and by making such results otherwise available to interested Parties. The Parties shall require that any subsequent recipients of the Results shall similarly not seek to obtain any intellectual property rights to the Results and similarly release such results in the public domain.

The Recipient agrees that it shall not seek Intellectual Property rights of any kind, or any other protection in respect of the Materials and Data Set(s), other Confidential Information or any Results, without the Supplier's prior written consent.

Neither the Provider nor the Recipient should seek to obtain any intellectual property rights (IPRs) on the Materials.

The Provider and the Recipient acknowledge that any IPRs on the Materials obtained before the date of adoption of the [founding document] will not be affected by [agreement].

Co-ownership of IP

Authority to File Patents - The Lead Institution has the responsibility and authority to take all reasonable actions necessary and appropriate to seek patent protection for the Patent Rights in accordance with the terms of this Agreement. The Lead Institution may not delegate this authority to a Licensee, unless stated otherwise in Exhibit A or unless such delegation is approved by the Other Institution(s) for a particular Licensee. Although the Lead Institution will have the ultimate decision authority in these matters, the Lead Institution will use reasonable efforts to keep the Other Institution(s) reasonably informed as to all material patent prosecution actions and decisions, and the Lead Institution will give due consideration to any recommendations made by the Other Institution(s) concerning the patent prosecution. Lead Institution will provide, or direct outside patent counsel to provide, Other Institution(s) with all serial numbers and filing dates, together with copies of all applications in the Patent Rights and patents that issue from the Patent Rights, including copies of all office actions, responses and all other communications from the U.S. Patent and Trademark Office and the patent offices in any other jurisdictions.

Foreign Patent Prosecution - In instances where there is no commitment from a Licensee to reimburse Patent Expenses, Lead Institution will consult with the Other Institution(s) regarding foreign filings reasonably in advance of the filing deadline. If an Other Institution(s) is not willing to pay its Share of Patent Expenses for any such foreign filing, it will so notify the Lead Institution in writing in accordance with [Section] and the consequences stated under [Section] will apply if the Lead Institution elects to proceed with foreign filings.

Consequences of Other Institution Withdrawing from Paying or Defaulting on Payment of Patent Expenses - If another Institution becomes a Withdrawing Party, then the other Party(ies) may elect to either terminate this Agreement by providing 30 days' prior written notice, or to pay the Withdrawing Party’s Share of Patent Expenses (the “Covered Expenses”). If the other Party(ies)
elect to pay the Covered Expenses, the “Consequences of Withdrawal” indicated in the
Transaction Terms will apply, subject to the following:

(a) If the Transaction Terms indicate a reduction in the Withdrawing Party’s Share of Net
Consideration, that reduction will only be applicable to Net Consideration reasonably
attributable to the Patent Rights for which the other Party(ies) are paying Covered
Expenses;

(b) If the Transaction Terms indicate a recovery of a multiple of the Covered Expenses,
the Party(ies) paying the Covered Expenses will be entitled to recover that amount from
the first of any License Consideration reasonably attributable to Patent Rights for which
the other Party(ies) are paying Covered Expenses;

(c) If the Transaction Terms indicate “Share only with Withdrawing Party’s Inventors,”
then the Withdrawing Party’s Share of Net Consideration for any Net Consideration
reasonably attributable to the Patent Rights for which the other Party(ies) are paying
Covered Expenses will be reduced to zero, but the paying Party will pay the Withdrawing
Party’s inventors a share of such Net Consideration in accordance with the paying
Party’s policy;

(d) If the Transaction Terms indicate “Meet and Confer,” then the Parties will confer and
negotiate in good faith a fair accommodation to the other Party(ies) for the additional
cost and risk, if any, assumed by paying the Covered Expenses; and

(e) Nothing in this [Section] will eliminate the right of a Withdrawing Party under
[Section] to reimbursement of Patent Expenses actually paid by the Withdrawing Party.

Abandonment of Patent Rights by Lead Institution - The Lead Institution will not abandon the
prosecution of any patent application (except in favor of a continuation, divisional or
continuation-in-part application) or the maintenance of any Patent Rights without notifying the
Other Institution(s) in writing at least 90 days in advance of any applicable deadline and allowing
the Other Institution(s) the opportunity to prosecute or maintain such Patent Rights at its sole
expense in the name of Other Institution(s) and Lead Institution. If the Other Institution(s) wishes
to continue prosecution of such Patent Rights, then the Parties will negotiate in good faith an
appropriate arrangement to enable the Other Institution(s) to continue prosecution and
commercialization of such Patent Rights, which may include the Parties entering into a new
agreement that gives an Other Institution the lead in patent prosecution and licensing with
appropriate adjustments in the economic arrangements between the Parties.

Patent Assignments - Lead Institution will record assignments of Patent Rights in the names of
the Lead Institution and the Other Institution(s) in the U.S. Patent and Trademark Office and
other government patent offices, as applicable, and will provide Other Institution(s) with a copy
of each recorded assignment.

Patent Expenses:

(a) The Patent Expenses invoiced to the Parties prior to the Effective Date are identified
as Past Patent Expenses in the Transaction Terms. Within 90 days of the Effective Date,
the other Party(ies) will pay its Share of Patent Expenses with respect to the Past Patent
Expenses to the Parties that incurred such expenses.

(b) The Lead Institution will be solely responsible for reviewing and approving all Patent
Expenses incurred after the Effective Date and for ensuring that all Patent Expenses are
paid in a timely manner. The Lead Institution will furnish to the Other Institution(s) copies
of all invoices for Patent Expenses on a regular basis. The Other Institution(s), within 90
days after receipt of the invoices, will reimburse to the Lead Institution its Share of
Patent Expenses, which have been paid by the Lead Institution and not reimbursed by a
Licensee. Notwithstanding the foregoing, Lead Institution will notify Other Institution(s)
prior to incurring any Extraordinary Patent Expenses. In the event such advance notice
is given, the Other Institution(s) may elect to pay its Share of Patent Expenses for such
Extraordinary Patent Expenses or decline to pay such share and have the
consequences stated in [Section] apply. In the event Extraordinary Patent Expenses
are incurred and advance notice was not given, Other Institution(s) will not be
responsible for reimbursing any portion of such Extraordinary Patent Expenses.

(c) Upon at least 90 days’ prior written notice from an Other Institution to the other
Party(ies), such Other Institution may decline to pay its Share of Patent Expenses
incurred after such notice period for either of the following as specified in such notice: (i)
all Patent Expenses outside the United States, or (ii) all Patent Expenses. If the other
Party(ies) pays such Patent Expenses, then the consequences stated in [Section] will
apply.

Reserved Rights - Each Party expressly reserves the right to use the Patent Rights and
associated inventions or technology for educational and research purposes, and to grant such
educational and research rights to other non-profit institutions. Each Party can also license
rights to the U.S. government as required by its obligations related to research funding.

A third-party beneficiary

Example text

Ownership of any intellectual property rights arising from collaborative activities under this
Memorandum of Understanding shall be agreed by the Parties on a case-by-case basis.
However, regardless of whether the Parties shall agree that ownership of the intellectual
property rights of a particular collaborative activity shall be vested in WHO and [insert name of
contractual partner] jointly, or WHO or [insert name of contractual partner] alone, or in any third
party, the Parties agree that the industrial or commercial exploitation of such rights shall be
designed to achieve the objectives set forth in paragraph 6.1 above, and shall be subject to and
exercised in accordance with an agreement to be negotiated in good faith between WHO and
[insert name of contractual partner ], or WHO, [insert name of contractual partner] and the third
party concerned, as the case may be.

Recipient takes the IP

Example text

Where the Purpose or Use involving the Material results in an Invention, discovery, know-how or
any finding that has the likelihood of adding to the general knowledge about the disease,
including without limitation the procedures for collection and storage of samples, diagnosis,
treatment, survival chance, quality of life, safety guidelines and other topics shall be shared
promptly and systematically with the Provider and the third parties beneficiaries to this MTA
without awaiting Publication.
The party that creates or generates any Result will own the Intellectual Property in that Result, and may take such steps as it may decide from time to time, at its expense and sole discretion, to register and maintain any protection for that Intellectual Property, including filing and prosecuting patent applications for any Result, and taking any action in respect of any alleged or actual infringement of that Intellectual Property. Where any third party such as a student or contractor is involved in the Project, the party engaging that contractor will ensure that the student and the contractor assign to it any Intellectual Property they may have in the Results in order to be able to give effect to the provisions of this clause.

Where any Result is created or generated by two or more parties jointly and it is impossible to distinguish each party's intellectual contribution to the creation of the Intellectual Property in that Result, the Intellectual Property in that Result will be owned by those parties in equal shares.

The owners may take such steps as they may decide from time to time, at their joint and equal expense, to register and maintain any protection for that Intellectual Property, including filing and prosecuting patent applications for any Result, and taking any action in respect of any alleged or actual infringement of that Intellectual Property. If one or more of the owners does not wish to take any such step or action, the other owner(s) may do so at their expense, and the party not wishing to take such steps or action will provide, at the expense of the party making the request, any assistance that is reasonably requested of it.

Any joint owner of any of the Intellectual Property in any Result may deal with and exploit that Intellectual Property as though it were the sole owner, without being required to account to any other joint owner for any share in the revenues generated by that dealing or exploitation, provided that no joint owner may grant any third party any rights that detract from any other joint owner’s right to deal with any jointly owned Intellectual Property.

License to Use Results for the Project - Each party grants each of the other parties a royalty free, non-exclusive license to use the Results for the purpose of carrying out the Project. Any party may allow its Group Companies, and any person working for it or any Group Company, or on its behalf or that of any Group Company, to use any of the Results for the purpose of carrying out the Project.

Negotiation for License to Use Results beyond the Project - Each party (the Potential Grantor) will, if another party (the Party Wishing to Exploit) gives it written notice (an Option Notice) at any time during the Project Period plus a further [XXX] months, negotiate the terms on which the Potential Grantor will grant rights to the Party Wishing to Exploit to exploit the Intellectual Property in some or all of its Results and its Background.

Following the Potential Grantor’s receipt of an Option Notice, the Potential Grantor and the Party Wishing to Exploit will negotiate in good faith, for a period of up to [number of days or months] after the date of receipt of the Option Notice (the Negotiation Period) the terms of an assignment or license. If the parties are unable to agree the terms of an assignment or license within the Negotiation Period, the rights of the Party wishing to Exploit -beyond the purpose or duration of the project will lapse.

The Potential Grantor will not, during the Negotiation Period, negotiate with any other party with a view to granting a license to use its Results or Background or assigning the Intellectual Property in its Results or Background nor, during the [number of] months following the end of the Negotiation Period, will the Potential Grantor grant a license of any of its Result or assign any of the Intellectual Property in its Results or Background to any party on any terms more favorable than those offered to the Party Wishing to Exploit pursuant to this clause.
Until the earlier of the end of the Negotiation Period and the date of the assignment or grant of a license pursuant to this clause, the Potential Grantor will consult with the Party Wishing to Exploit about making patent applications in respect of the Results. If, during the Negotiation Period, the Party Wishing to Exploit wishes the Potential Grantor to apply for any patent in relation to any of the Results, the Party Wishing to Exploit will reimburse to the Potential Grantor the reasonable costs and expenses incurred by the Potential Grantor since the date of this Agreement in relation to the filing and prosecution of that patent application, including (without limitation) patent agents’ fees, as a result of any request to apply for, or to maintain, any patent at the Party Wishing to Exploit’s request. If the Potential Grantor later licenses or assigns to another party any of the Results or the Background for which the Party Wishing to Exploit has paid any such costs and expenses, the Potential Grantor will reimburse those costs and expenses to the Party wishing to Exploit.

Example text

The RECIPIENT is free to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL but agrees to notify the PROVIDER upon filing a patent application claiming MODIFICATIONS or method(s) of manufacture or use(s) of the MATERIAL.

Example text

When Provider is the PHS (Public Health Services): Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s). Unless prohibited by law from doing so, recipient agrees to hold the United States Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of Recipient’s use for any purpose of the Research Material.

When Recipient is the PHS: The PHS shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. The PHS is not authorized to promise rights in advance for inventions developed under this Agreement. Provider acquires no intellectual property rights under this MTA, but may apply for license rights to any patentable invention that might result from this Research Project. It is the intention of PHS that Provider not be liable to PHS for any claims or damages arising from PHS’s use of the Research Material; however, no indemnification is provided or intended.

Example text

[Supplier] hereby grants to the Recipient a non-exclusive worldwide royalty-free research licence under its intellectual property rights to use the Materials for the purposes of the Investigation.

[Supplier] makes no warranty or representation that the Materials (whether when used for the Investigation or otherwise) do not and will not infringe the intellectual property of a third party. [Supplier] hereby excludes to the fullest extent permitted by law any liability arising (whether directly or indirectly) from any action, claim, proceedings, demands, losses (including but not limited to loss of profit), costs, awards damages and payments made by Recipient arising from a claim by a third party that the use of the Materials for the purposes of the Investigation or otherwise infringes the intellectual property of the third party.

Nothing in this Agreement shall operate to transfer to the Recipient any intellectual property rights of [Supplier] in the Materials.
All intellectual property rights (including, without limitation, design rights, copyrights, database rights, rights in confidential information and know-how and the right to apply for patents) and all results, data and discoveries arising out of the Investigation shall belong to the Recipient. Except as specifically provided in [Clauses], [Supplier] shall have no right or licence in respect of such intellectual property rights, results, data and/or discoveries.

In this Agreement, “Invention” shall mean a patentable invention developed by the Recipient in the course of the Investigation that relates directly and principally to the Materials itself.

If the Recipient files any application for a patent in respect of an Invention, it shall at [Supplier]'s request and expense, grant to [Supplier] a non-exclusive, worldwide, royalty-free licence to use for research purposes only any resultant patents solely in connection with the Materials (with the right to sub-license solely in connection with the distribution of the Materials to third parties by [Supplier] under a substantially similar agreement to this agreement).

Any publication of the results of the Investigation shall acknowledge [Supplier] as having made available the Materials.

Protective patenting

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if: (a) the results can reasonably be expected to be commercially or industrially exploited and (b) protecting them is possible, reasonable and justified (given the circumstances).

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, the Joint Undertaking may — under certain conditions — assume ownership to ensure their (continued) protection.

When deciding on the protection of Results, the Beneficiary must consider the legitimate interest of its own and other Beneficiaries. Means of protection may include, but are not limited to, patenting or maintaining the Results as confidential know-how.

Each Beneficiary shall enter into appropriate agreement(s) with its employees, agents or third parties to make sure the ownership to the Results is properly transferred to the Beneficiary.

The funder must be noted in any application for protection on the Results filed by the Beneficiary.

12. Dissemination of data and results

Sharing Information
(a) Each Party shall, on request, disclose to the other Parties, in the form of written documentation, on a confidential basis in accordance with the terms of [the agreement], all data and information already available to it, or developed by it during the course of this Collaboration Agreement, relating in any way to the Purpose.

(b) Each party should take the responsibility to ensure that results – even when preliminary – are adequately robust and have undergone quality control, prior to public disclosure.

(c) Each party has an obligation to publicly disclose quality controlled interim results according to a specific expedited timeline commitment for results sharing that should be made in protocols and analysis plans before trial commencement.

(d) Prior to the start of any clinical trial (i.e. prior to the first subject receiving the first experimental intervention) a clinical trial registry entry is to be made on a [registry]. Where the registry has a results summary section, public disclosure of interim and final results should occur using the results summary component of the registry.

(e) Final results are to be publicly disclosed, no later than 28 days after the primary study completion date, using the results summary section of the registry entry.

Example text

Data ownership and associated intellectual property rights shall be discussed and agreed upon by collaborating partners at the inception of a research project. Collaborating research partners shall negotiate data ownership and use in accordance with the host organization’s data use and ownership policies. Ownership of data shall be clearly stated in the research protocol or collaborative research agreements, which shall be reviewed by the Research Ethics Committee and registered with [regulator].

Collaborating research partners shall agree on appropriate data access and use rights before commencement of the study. Researchers shall have in place mechanisms for maintaining confidentiality of research participants and their communities.

A collaborating research partner shall not transfer data to a third party without the written consent of the other partner.

Local researchers shall have unrestricted access rights to data sets collected through a collaborative research project.

Researchers shall ensure that research records from which the data has been obtained are available at the research site for at least five years after completion of the research project. Electronic records are acceptable.

Researchers shall, as appropriate, make all reasonable efforts to share findings of research with the host organization, research participants, key stakeholders and communities in which research was done.

Researchers shall describe in the protocol plans for research results dissemination and ensure its execution.

Researchers shall be sensitive about the ethical implications of the research results, and take appropriate measures to protect research participants and their communities.
Open Access

Example text

“Global Access” requires that products, services, processes, technologies, materials, software, data or other innovations (collectively, “Funded Developments”) arising from projects funded by the Foundation be managed in a manner that ensures “Global Access.” Global Access requires that (a) the knowledge and information gained from the Project be promptly and broadly disseminated and (b) the Funded Developments be made available and accessible at an affordable price (i) to people most in need within developing countries or (ii) in support of the U.S. educational system and public libraries, as applicable to the funded project.

Example text

By law and policy, [network] non-exclusive licenses. Licenses to platform technologies, including in the field of diagnostics, will be available on a nonexclusive basis or in some cases under an exclusive license with very narrow product specific limitations. Consistent with applicable laws, regulations and policies, exclusive licenses will be considered for potential drug (small molecular entities and biologics) and vaccine components and will be limited to defined indications and territories. Nonexclusive licenses will be available for technologies to the extent defined indications and territories are not already licensed exclusively or subject to an exclusive license option under a [agreement].

Example text

Regarding the digital research data generated in the action (“data”), the beneficiaries must: (a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following: (i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible; (ii) other data, including associated metadata, as specified and within the deadlines laid down in the “data management plan” in Annex 1. (b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action’s main objective would be jeopardized by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.

Open Access to Research Data

Example text

Regarding the digital research data generated in the action (“data”), the beneficiaries must: (a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following: (i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible; (ii) other data, including associated metadata, as specified and within the deadlines laid down in the “data management plan” in [Annex]. (b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).
As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in [Annex], would be jeopardized by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.

Sharing amongst parties to the MTA

Example text
The Results shall be shared by Recipient with the supplier and each Party, the MOH, and WHO shall be free to use such Results for further research and development purposes, and to update their respective counselling messages and recommendations and to develop relevant guidelines, including the right of publication thereof.

Example text
The Results shall be shared by Recipient as soon as they are obtained, regardless of their status (preliminary, definitive or otherwise) in a timely, systematic manner with the supplier and each Party, the MOH, WHO, and the emergency responder medical care / treatment unit which is treating the patient (donor) from whom the specimen was taken for testing and each of Recipient, the MOH, and WHO shall be free to use such Results for treatment, further research and development purposes, and to update their respective counselling messages and recommendations and to develop relevant guidelines, including the right of publication thereof. The Recipient hereby grants MOH, WHO and third party beneficiary TBD a non-exclusive royalty-free, perpetual, irrevocable, worldwide license to use such Results/Data for any legally permitted purpose as determined by them and disclose such information to regulatory authorities and to other third parties. For purposes of this Agreement, “Data” is defined as any and all results, conclusions, observations, formulations, methodologies, algorithms, reports of testing, case reports forms and any other data arising from the studies, tests, essays or evaluations using the Material under this Agreement.

Licensing of results, including special licenses for the public good

Example text
Provided that any access rights to the results can be exercised and that any additional obligations under this Agreement or consortium agreement are complied with by the beneficiary who owns results, the latter may grant licenses to its results (or otherwise give the right to exploit them) to any legal entity.

Example text
Any and all data and information that are made or developed by the Parties under this Agreement or otherwise in connection with the Collaboration’s activities, shall be owned by the Party or Parties generating such data or information, provided that WHO is hereby vested with a worldwide, royalty-free, sub-licensable, irrevocable and perpetual, non-exclusive license in all such data and information made or developed covering all applications and uses for which the rights may be exercised, including but not limited to publication of the data and/or information.

Example text
The Manufacturer is willing to release the above mentioned information (hereinafter referred to as “the Information”) to WHO, for the purpose of enabling WHO to assess such Information and facilitate expert consensus on ethical protocols for the clinical testing and use of the Product for
the treatment or prevention [disease name] (hereinafter referred to as "the Purpose"), provided that WHO undertakes to release the Information only to persons who have a need to know for the Purpose and are bound by like obligations of confidentiality and non-use, as are contained in this Agreement.

WHO undertakes to regard the Information as the Manufacturer’s proprietary information and agrees to take all reasonable measures to ensure that the Information is not used or disclosed, in whole or in part, other than as provided in [paragraph], for a period of [number of] years from the date of disclosure to WHO (with exceptions).

The parties agree that if and to the extent that the public disclosure of any of the Information is required to enable clinical use of the Product, WHO shall seek the Manufacturer’s prior written consent for such disclosure, which consent shall not be unreasonably withheld.

Example text

Each Academic Party and each of its employees and students will have the irrevocable, royalty-free right to use the Results for the purposes of academic teaching and academic research [and clinical patient care][, including research projects sponsored by any third party]. The rights in this clause are subject to the rules on Academic Publication.

Example text

Except for the rights expressly granted herein, the RECIPIENT agrees that no other rights or licenses, whether express or implied, are granted to the RECIPIENT under any patent, patent application, or other proprietary right of the PROVIDER. As between the parties, each retains all right, title, and interest in works and inventions made by its personnel, and nothing herein shall be construed to transfer ownership of any invention, patent, patent application, or other proprietary right.

Example text

If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

Use of Names

Example text

Without limiting the Parties’ rights to describe this collaboration as necessary, neither Party will issue a press release referring to the parties’ collaboration under this MTA, and/or otherwise use the name and/or emblem of the other Party in any public statement, without the prior written consent of that other Party.

Example text

None of the parties will use another party’s name or the name of any of the Key Personnel provided by another party, or another party’s logo, in any press release or product advertising, or for any other promotional purpose, without first obtaining that other party’s written consent.
Except as provided for under [sections of agreement], no party shall use any other party’s name, logo or trademarks for any purpose including without limitation publicity or advertising, except with the prior written consent of the other party.

Neither Recipient nor Provider shall use the name of the other party or any contraction or derivative thereof or the name(s) of the other party’s faculty members, employees, contractors or students, as applicable, in any advertising, promotional, sales literature, or fund-raising documents without prior written consent from the other party.

Subject to [clause], the Recipient shall not use [Supplier’s] name in any publication, public announcement or other public disclosure without the consent of [Supplier].

Without limiting the Parties’ rights to describe this collaboration as necessary, neither Party will issue a press release referring to the parties’ collaboration under this MTA, and/or otherwise use the name and/or emblem of the other Party in any public statement, without the prior written consent of that other Party.

Each party may disclose to third parties or make public statements, by press release or otherwise, regarding the existence of this Agreement, the identity of the parties, the terms, conditions and subject matter of this Agreement, or otherwise in reference to this Agreement, provided such disclosures or statements are accurate and complete with respect to the subject.

13. Relevant laws, regulations & good practice

Recipient will use the Materials and Information for the Purpose only and in compliance with all applicable international, federal, provincial/state and local laws, rules, guidelines and regulations.

The Recipient acknowledges and agrees that the use or transfer of Material and Data Set(s) or the other Confidential Information may require the prior authorization of competent authorities in the Host Country, including with respect to Project that are not regulated as medical research in the country of the Recipient or that do not require prior authorization under the legislation of the country of the Recipient. Supplier shall use reasonable efforts to obtain any required authorizations as needed for the Project prior to sending Material and Data Set(s) or other Confidential Information to Recipient or Recipient’s designated subcontractor for the Project.

Each of the parties agree to comply with all applicable [location] anti-corruption, anti-bribery and local employment laws, as well as any other applicable legislation, laws and regulations in
connection with their performance under this Agreement, (including that relating to import and
export control, transportation of hazardous materials, anti-money laundering, and tax laws).
Either party’s failure to comply with any provision of this Clause is considered to be a breach of
this Agreement.

Example text
The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and
regulations, [regulations and guidelines] such as, for example, those relating to research
involving the use of animals or recombinant DNA.

Example text
Recipient shall use the Biological Material in compliance with all applicable laws and
government regulations. Under no conditions will the Material be used in human subjects.
The Biological Material has been collected and processed by Provider in compliance with all
applicable laws, rules, regulations and other requirements of any applicable governmental
authority, including without limitation those applicable to patient informed consent.

Example text
The Provider undertakes the following with respect to the Materials:

- To comply with its respective [network] terms of reference.
- To ensure that the Materials are handled in accordance with applicable WHO guidelines
  and national bio-safety standards.
- The Recipient undertakes the following with respect to the Materials:
  - To comply with its respective [network] terms of reference.
  - To ensure that the Materials are handled in accordance with applicable WHO guidelines
    and national bio-safety standards.

Biosafety and biosecurity

Example text
The Recipient further agrees that the Material: must not be treated as if the Material is free of
contamination, as biological materials have the potential for carrying viruses, latent viral
genomes and other infectious agents in an unapparent state; and must always be handled
carefully by trained persons who follow all safety guidelines and protocols when working with
the Material and under laboratory conditions which afford adequate biohazard containment.

Example text
The Recipient further agrees that the Material: must not be treated as if the Material is free of
contamination, as biological materials have the potential for carrying viruses, latent viral
genomes and other infectious agents in an unapparent state; cannot be used in humans; is
hazardous and designated as biosafety level ___ and must always be handled carefully by
trained persons who follow all safety guidelines and protocols when working with the Material
and under laboratory conditions which afford adequate biohazard containment. The Recipient
shall retain the Material, Information and Data produced by the Recipient in the performance of
the Scope of Work in a secure location and on a secure network system whose address shall be
provided to the Provider and which will meet the standards legally in force in the country where
the Material is kept or the standards reasonably expected among the industry to be followed for
the storage of such Material, whichever standards provide the highest level of safety and privacy.

Example text

The Recipient shall ensure that the [biological materials] are handled in accordance with applicable WHO guidelines and national bio-safety standards.

Shipping

Example text

Unless otherwise agreed, Provider shall be responsible for appropriately packing and shipping the Materials for shipping and transportation.

Example text

The Recipient Institution shall use a courier with suitable skill and experience to safely transport the Material in accordance with all Applicable Laws. The Recipient Institution will bear the cost of carriage and any necessary insurance. The Provider Institution makes no charge for the Material / the Material is provided subject to the reimbursement by the Recipient Institution to the Provider Institution for its costs of extracting from storage and preparing the Material as set out in [Appendix]. Risk in and responsibility for the Material shall pass to the Recipient Institution once it is loaded onto transport as organised by the Recipient Institution. If so requested by the Provider Institution the Recipient Institution shall provide it with written confirmation of the safe receipt of the Materials promptly after their delivery to the Recipient Institution’s laboratory.

Example text

The Recipient undertakes the following with respect to the Materials:

- To inform [organization] of shipments of Materials to entities inside/outside the [network] by recording in the [database].
- In the event of further transfers within the [network], to do so in accordance with [agreement].

Data and results

Example text

1. Research data must be generated using sound scientific techniques and processes;
2. Research data must be accurately recorded in accordance with good scientific practices by the people conducting the research;
3. Research data must be analyzed appropriately, without bias and in accordance with good scientific practices;
4. Research data and the Results must be stored securely and be easily retrievable;
5. Data trails must be kept to allow people to demonstrate easily and to reconstruct key decisions made during the conduct of the research, presentations made about the research and conclusions reached in respect of the research; and
6. Each party must have the right, on not less than 30 days written notice, to visit any other party to verify that it is complying with the above practices and procedures.

Human rights, including patient confidentiality

Example text

The Parties acknowledge the importance of the protection of human and animal subjects in any research, public health, or medical program. Both Parties’ countries have adopted laws and regulations on the protection of human and animal subjects involved in research. Each Party shall undertake all activities contemplated by this MTA in accordance with all applicable laws, regulations, and policies.

Example text

In order to ensure that medical confidentiality and privacy of patients are fully respected, Parties agree that Material and Data Set(s) and the other Confidential Information shall contain no Personal Data. The Supplier shall ensure that Material and Data Set(s) and the other Confidential Information contain no Personal Data prior to any disclosure or transmission of Material and Data Set (s) and other Confidential Information.

Example text

Personal Data and Human Samples Collection and Informed Consent: When Personal Data and/or Human Samples are introduced to the Action by or on behalf of a Beneficiary, such Beneficiary must ensure that: (1) the Personal Data and the Human Samples are Processed in accordance with all laws, rules, regulations and guidelines applicable to their collection, use, handling, disposal and further Processing, including without limitation – data protection legislations; (2) if applicable, the Personal Data and Human Samples are collected with voluntarily given informed consent of the Donors of the Personal Data and Human Samples covering the activities of the Action, including the collection, processing, storage, use and transfer including the addressees of the transfer of the Personal Data and Human Samples as provided for under the Action, such informed consent must be revocable any time with effect for the future; (3) the responsible ethics committee/Institutional Review Board (IRB) has given its approval to the collection, processing, storage, use and transfer of the Personal Data and Human Samples under the Action, and (4) if applicable, the Donors of the Personal Data and Human Samples have not withdrawn their informed consents.

Limited Scope of Personal Data and Human Samples That Can Be Used in the Action: Beneficiaries will not introduce to the Action Personal Data and Human Samples that are collected for reasons unrelated to the Action, with limited exceptions. Personal Data and Human Samples shall be accessed only for the purpose of the Project and the corresponding agreements, i.e. the Grant Agreement and the Consortium Agreement. Further Processing of such introduced Personal Data and Human Samples by the accessing Beneficiary for own purposes or for purposes of Third Parties is not permitted, unless expressly permitted in the informed consent.

Use of Personal Data and Human Samples in the Action: Beneficiaries are responsible for their Processing, storing, using and transferring of Personal Data and/or Human Samples in compliance with the applicable Data Protection Legislation and for purposes that are consistent with the consent obtained, if applicable.
Example text

The Recipient agrees that Materials (a) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects unless such use is expressly approved by the Provider in writing and the Recipient’s use shall be in accordance with the appertaining clinical protocol, informed consent and subject to any required Institutional Review Board and / or Ethics Committee approvals and / or other necessary approvals as applicable; (b) will not be used for Commercial Purposes; and (c) will only be used by individuals who are legally obligated, in the manner and to the extent required in the applicable Material Transfer Record Forms, to allocate their respective right in any and all Inventions (and any patent rights or other rights arising therefrom); and (d) will not be given or made available to [Members] or third parties unless approval to do so has been given on the respective Material Transfer Record Form by the Provider and in which case such transfer will also be under the conditions of this Master MTA, and subject to the approval of the originator of the materials.

Example text

Any person who collects identifiable human materials shall ensure that appropriate informed consent has been obtained from the sample sources, including consent for storage for possible uses in future. Collection of samples should follow acceptable standard procedures.

14. Monitoring, evaluation, and reporting

Example text

Notices: All reports and notices or other documents that a Party is required or may want to deliver to the other Party will be in writing and delivered by (i) personal delivery or a nationally recognized courier service and deemed to have been received at the time of delivery, or (ii) registered or certified. The Recipient will provide the supplier with a written progress report of the work performed hereunder on (monthly) a basis. In addition, within [number of] days of completion of the (work) (study), Recipient will provide supplier with a final report, describing in a detailed manner the work performed, the results obtained and the conclusions drawn therefrom.

15. Nature of relationship, warranties, liabilities, insurance, settlement of disputes, governing law and consistency

Nature of relationship

Example text

Independent Contractor: The relationship between the parties is that of independent contractors and nothing in this Materials Transfer Agreement will be construed as establishing an agency, partnership, joint venture, or employment relationship between the parties. No Party has the authority to act on behalf of the other Party, or to commit the other Party in any manner at all or cause the name of the other Party to be used in any way not specifically authorized by this Materials Transfer Agreement.
Warranties

Example text

Disclaimer of Warranties: Provider provides the Material and Information to Recipient “as is”.
Recipient agrees to assume the sole responsibility for their packing, transportation, handling, storage, use and disposal. Provider makes no representation, warranty or guarantee, whether expressed or implied, with respect to the Materials and Information, including but not limited to, any representation as to the durability, use, fitness for a particular purpose, or non-infringement on the proprietary rights of a third Party.

Example text

Warranties of Non-Infringement - Each of the parties warrants to each of the others that, to the best of its knowledge and belief (having made reasonable enquiry of those of its employees involved in the Project or likely to have relevant knowledge [and in the case of each Academic Party any student involved in the Project], but not having made any search of any public register) any advice or information given by it or any of its employees [or students] who work on the Project, and the content or use of any Results, Background or materials, works or information provided in connection with the Project, will not constitute or result in any infringement of third-party rights.

No Warranties - None of the parties makes any representation or gives any warranty to any of the others that any advice or information given by it or any of its employees [or students] who work on the Project, or the content or use of any Results, Background or materials, works or information provided in connection with the Project, will not constitute or result in any infringement of third-party rights.

Other Warranties - The express undertakings and warranties given by the parties in this Agreement are in lieu of all other warranties, conditions, terms, undertakings and obligations, whether express or implied by statute, common law, custom, trade usage, course of dealing or in any other way. All of these are excluded to the fullest extent permitted by law.

Example text

Disclaimers - Except as set forth in [section], no party extends any warranties of any kind, either express or implied, including but not limited to the warranties of merchantability or fitness for a particular purpose with respect to the patent rights. In addition, each of the parties expressly disclaims any warranty that the practice of the patent rights will not infringe any patent, copyright, trademark, or other rights of third parties. No party will make statements, representations, or warranties, or accept liabilities or responsibilities, with respect to or potentially involving the other party, that are inconsistent with this section.

Limitations - To the maximum extent permitted by law, in no event will any party be responsible for any incidental damages, consequential damages, exemplary damages of any kind, lost goodwill, lost profits, lost business and/or any indirect economic damages whatsoever regardless of whether such damages arise from claims based upon contract, negligence, tort (including strict liability or other legal theory), a breach of any warranty or term of this agreement, and regardless of whether a party was advised or had reason to know of the possibility of incurring such damages in advance.
In respect of any information or materials (including Results, Background, and Confidential Information) supplied by one Beneficiary to another hereunder or pursuant to the Grant Agreement, the supplying Beneficiary shall be under no obligation or liability other than as expressly stated herein and no warranty condition or representation of any kind is made, given or to be implied as to the sufficiency, accuracy or fitness for purpose of such information or materials, or the absence of any infringement of any (intellectual) proprietary rights of Third Parties or the other Beneficiaries. A recipient Beneficiary, by the use of such information and materials, shall be entirely responsible for any loss, damage or injury resulting from its use of such information and materials.

Each Beneficiary ("Indemnitor") shall indemnify each other Beneficiary and their employees, Affiliated Entities, Sub-Contractors, Linked Third Parties, and agents ("Indemnitee") and defend and hold each of them harmless, from and against loss, damage, liability, cost, expense, or injury (including reasonable attorneys’ fees and expenses) (individually a “Loss” and collectively, “Losses”) incurred by such Indemnitee resulting from any claim, complaint, proceeding or cause of action brought by a Third Party, including [Third Party Claims] alleging or arising from (i) the material breach of any representation, warranty or covenant made by the Indemnitor hereunder, (ii) gross negligence or willful misconduct on the part of the Indemnitor in performing its obligations under this Consortium Agreement, or, subject to [agreement] (iii) infringement of Third Party intellectual property rights by such Indemnitor, its employees, Sub-Contractors, Linked Third Parties, Affiliated Entities or its agents; provided in each case that (a) the foregoing obligation to indemnify shall not extend to claims for indirect or consequential loss or damage, including but not limited to loss of profit, revenue or contracts; and (b) the total limit of liability of any Indemnitor to the Indemnitee collectively in respect of any one claim or series of connected claims, shall not exceed the financial value (of the Grant or of the in-kind contribution, as the case may be, corresponding to that Indemnitor’s Action Share; and (c) an Indemnitor shall not be obligated to indemnify an Indemnitee for any Losses to the extent such Losses arise as a result of (i) the material breach of any representation, warranty or covenant made by the Indemnitee under this Consortium Agreement or (ii) any gross negligence or willful misconduct on the part of any Indemnitee.

Nothing in this Consortium Agreement may be construed to limit (i) the right of any party to bring an action for damages against any Third Party, including claims for indirect, special or consequential damages, based on any acts or omissions of such Third Party or (ii) the liability of a party for personal injury or death resulting from the negligence of such party or its employees, officers, directors, agents, or representatives (as applicable).

The Indemnitee shall immediately advise the Indemnitor of any such Loss or Third Party Claim in writing. The Indemnitor shall have the right to select defense counsel and to direct the defense or settlement of any claim which is the subject of this indemnity. The Indemnitee shall reasonably co-operate with the Indemnitor and its legal representatives in the investigation and defence of any such claim. The Indemnitee may obtain representation by separate legal counsel, at its own expense. The Indemnitee shall refrain from making any admission of liability or any attempt to settle the claim without the Indemnitor’s prior written consent.

Freedom to Operate - Without prejudice to any of the foregoing provisions of [this agreement], each Beneficiary acknowledges that it shall be solely responsible for ensuring that, to the best of its knowledge, its activities under the Consortium Agreement, in particular implementing the Action and making any Research Use of Results or undertaking the Direct Exploitation of...
Results whether such Results are owned by it or to which it has been granted Access Rights do not infringe or misappropriate Third Party Intellectual Property.

Example text

The Recipient Institution understands that the Material is experimental in nature, and may have hazardous properties. The Donor Institution makes no representations and gives no warranties either express or implied in relation to it: for example, no warranties are given about quality or fitness for a particular purpose; or that the use of the Material will not infringe any intellectual property or other rights of third parties. The Donor Institution will not be liable for any use made of the Material.

Example text

The Recipient Institution understands that the Material may have hazardous properties, contain infectious agents or pose other health and safety risks. Subject to [clause], the Provider Institution makes no representations and gives no warranties either express or implied in relation to it: for example (without limitation), no warranties are given about quality or fitness for a particular purpose, or freedom from infection. The Provider Institution will not be liable for any use made of the Material by the Recipient Institution. The Recipient Institution will use the Material in accordance with good laboratory practice standards, all due skill and care and with dignity, sensitivity and respect. The Recipient Institution will comply with all Applicable Laws, approvals, rules, codes of practice and regulations governing the transportation, storage, use and disposal of the Material. The Recipient Institution warrants that it will only use, or permit the use of the Material in work that has ethical approval, as stated in [Appendix].

The Provider Institution warrants that where required by Applicable Laws the Material has been obtained from humans with the appropriate consent as required by the [relevant legislation] and with ethical approval and the Provider Institution shall be liable for any claims arising due to the breach of this warranty. The Provider Institution hereby grants to the Recipient Institution a non-exclusive research licence to use the Material for the Study only. The Provider Institution further warrants that it has not provided any information (and does not intend to provide any information) which has led or may lead to the Recipient Institution being able to identify the person from whom the relevant material came.

Example text

Any MATERIAL delivered pursuant to the Agreement is understood to be experimental in nature and may have hazardous properties. The provider makes no representations and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the material will not infringe any patent, copyright, trademark, or other proprietary rights.

Example text

This Research Material is provided as a service to the research community. It is being supplied to recipient with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose.

Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.
Example text
Provider makes no representations and extends no warranties of any kind, either expressed or implied. Provider and its directors, officers, employees, or agents assume no liability and make no representations in connection with the Biological Material or the derivatives or the information or their use by Recipient or its investigators. Recipient will defend, indemnify and hold harmless Provider, its directors, officers, employees, and agents from any damages, claims, or other liabilities which may be alleged to result in connection with the Biological Material, derivatives or information. There are no expressed or implied warranties of merchantability or fitness for a particular purpose, or that the use of the Biological Material and related information will not infringe any patent, copyright, trademark or other rights.

Example text
The Provider makes no warranties as to the safety of the Materials, or as to the accuracy or correctness of any data provided with them. Likewise, the provider does not make any warranties as to the quality, viability, or purity (genetic or mechanical) of the Materials being furnished. The Provider and the Recipient assume full responsibility for complying with their respective national biosecurity and biosafety regulations and rules as to import, export or release of biological materials.

Example text
The MTA should explain that the provider is giving the material "as is" and does not promise that material will perform in any specific way. The MTA should have a clause which states that the MTA may be amended at any time by written mutual consent of the parties.

Example text
The failure of either party to enforce or to exercise any right under this Agreement does not constitute a waiver of that right and shall not affect that party's right later to enforce or to exercise it.

Example text
The Recipient accepts that the Materials are supplied on a "as is" basis, are experimental in nature and that [Supplier] makes no warranty or representation, express or implied, as to the properties, capabilities or safety of the Materials. Save in the case of death or personal injury resulting from [Supplier]'s negligence, [Supplier] hereby excludes to the fullest extent permitted by law all liability for any action, claim, proceedings, demands, losses (including but not limited to loss of profit), costs, awards damages and payments made by Recipient that may arise (whether directly or indirectly) in any way whatsoever from the supply of the Materials and their use by Recipient.

[Supplier] understands that any Invention which is licensed to it pursuant to [Clause] is licensed on an "as is" basis. The Recipient excludes all warranties, conditions or representations, express or implied, as to such Invention's safety, quality, suitability for any purpose or any other of its properties or capabilities.

No variation of or amendment to this Agreement shall bind either party unless made in writing and signed by a duly authorised representative of each party.
Liabilities

Example text

Liability: Each Party shall be solely responsible for the manner in which it carries out its activities under this MTA. Thus, a Party shall not be responsible for any loss, accident, damage or injury suffered or caused by the other Party, or the staff or sub-contractors of the other Party, in connection with, or as a result of, the activities under this MTA.

Example text

Indemnity - Each [Commercial] Party (the Indemnifying Party) will indemnify each of the other parties and their employees [and students] (the Indemnified Parties), and keep them fully and effectively indemnified, against each and every claim made against any of the Indemnified Parties as a result of that Indemnifying Party’s use of any of the Results or any materials, works or information received from an Indemnified Party pursuant to the terms of this Agreement, provided that the Indemnified Party must:

(i) promptly notify the Indemnifying Party of details of the claim;
(ii) not make any admission in relation to the claim;
(iii) allow the Indemnifying Party to have the conduct of the defense or settlement of the claim; and
(iv) give the Indemnifying Party all reasonable assistance (at the Indemnifying Party’s expense) in dealing with the claim.

The indemnity in this clause will not apply to the extent that the claim arises as a result of the Indemnified Party’s negligence, its deliberate breach of this Agreement, its breach of confidentiality obligation or its knowing infringement any third party’s Intellectual Property.

No Liability for Others’ Use - None of the parties accepts any liability or responsibility for any use which may be made by any other party of any Results, nor for any reliance which may be placed by that other party on any Results, nor for advice or information given in connection with any Results.

No liability for Indirect Damages - The liability of each party to all of the others for any breach of this Agreement, any negligence or arising in any other way out of the subject matter of this Agreement, the Project or the Results, will not extend to any indirect damages or losses, or to any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity (whether direct or indirect), even if the party bringing the claim has advised the other of the possibility of those losses, or even if they were within the other party’s contemplation.

Limitation on Amount of Damages - The aggregate liability of each party to all of the others for any or all breaches of this Agreement, any negligence, or arising in any other way out of the subject matter of this Agreement, the Project or the Results, will not exceed in total [that party’s Financial Contribution][the portion of the External Funding allocated to that party].

Liability Not Excluded - Nothing in this Agreement limits or excludes any party’s liability for:

(i) death or personal injury;
(ii) any fraud or for any sort of liability that, by law, cannot be limited or excluded;
(iii) [any breach of the Funding Conditions;] or

(iv) any loss or damage caused by a deliberate breach of this Agreement or any breach
of confidentiality obligation.

Example text

Liability - The Recipient hereby agrees to indemnify the Supplier and their respective affiliates
as the case may be from and against all claims, demands, causes of action, damages or costs
(including without limitation reasonable outside attorneys’ fees and all costs associated with the
defense of the matter) arising out of (i) the breach by the Recipient or its Representatives of any
provisions of this Agreement, (ii) the use by or on behalf of Recipient of the Material and Data
Set(s) or other Confidential Information, except to the extent any such claims, demands, causes
of action, damages or costs have been caused by the breach by the Supplier of any provisions
of this Agreement.

Example text

Liability - Each Party shall be solely responsible for the manner in which it carries out its part of
the collaborative activities under this Memorandum of Understanding. Thus, a Party shall not
be responsible for any loss, accident, damage or injury suffered or caused by the other Party, or
that other Party’s staff or sub-contractors, in connection with, or as a result of, the collaboration
under this Memorandum of Understanding.

In the event that liability insurance for activities associated with this Agreement has not been
obtained by a Party at the time of the signature of this Agreement, that Party shall obtain
reasonable liability insurance for the activities they conduct, such insurance to be (a) reasonably
acceptable to [partner] (b) name [partner] among the parties insured and (c) obtained before the
commencement of the activities.

Example text

University Liability - The University’s total liability for any and all causes of action arising in
connection with this agreement or the transactions contemplated by this agreement, in
aggregate, and regardless of the form of action, whether in contract or in tort, including
negligence, or otherwise will be limited to direct damages not exceeding in the aggregate one
hundred percent of the amounts paid to the University. Licensee waives and disclaims any right
to recover any damages in the aggregate in excess of such amount from the University.

Example text

Except to the extent prohibited by law, the Recipient Institution assumes all liability for damages
which may arise from its receipt, use, storage or disposal of the Material. The Donor Institution
will not be liable to the Recipient Institution for any loss, claim or demand made by the Recipient
Institution, or made against the Recipient Institution by any other party, due to or arising from
the use of the Material by the Recipient Institution, except to the extent the law otherwise
requires.

Neither party will be liable for any loss or damage resulting from its failure nor delay in
performing its obligations hereunder to the extent that such failure or delay arises from
circumstances beyond its control.

The liability of either party for any breach of this Agreement, or arising in any other way out of
the subject matter of this Agreement, will not extend to loss of business or profit, or to any
indirect or consequential damages or losses.

Example text
Except to the extent prohibited by Law and subject to [clause], the Recipient Institution assumes
all liability for damages which may arise from its receipt, use, storage or disposal of the Material.
The Provider Institution will not be liable to the Recipient Institution for any loss, claim or
demand made by the Recipient Institution, or made against the Recipient Institution by any
other party, due to or arising from its use, storage or disposal of the Material by the Recipient
Institution, except to the extent the law otherwise requires.

The liability of either party for any breach of this Agreement, or arising in any other way out of
the subject matter of this Agreement, will not extend to loss of business or profit, or to any
indirect or consequential damages or losses.

Example text
Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages that
may arise from its use, storage or disposal of the MATERIAL. The PROVIDER will not be liable
to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the
RECIPIENT by any other party, due to or arising from the use of the MATERIAL by the
RECIPIENT, except to the extent permitted by law when caused by the gross negligence or
willful misconduct of the PROVIDER.

Example text
Recipient understands that the Biological Material delivered hereby is experimental in nature
and should be used with prudence and appropriate caution since not all of its characteristics are
known. Recipient assumes all liability for damages, which may arise from the use, storage,
handling or disposal of the Biological Material or its derivatives.

Example text
The recipient organization is responsible for the proper handling and use of the material. The
recipient or both the provider and recipient are accountable for any misuse or consequences of
use of the material. Parties must agree on liability.

Governing Law

Example text
Governing Law: This MTA shall be governed by and construed in accordance with the laws of
(country).

Example text
This Agreement shall be governed by [English] Law, and the [English] Courts shall have
exclusive jurisdiction to deal with any dispute which may arise out of or in connection with this
Letter Agreement.

Example text
This Agreement shall be governed by [English] Law, and the [English] Courts shall have
exclusive jurisdiction to deal with any dispute which may arise out of or in connection with this
Letter Agreement.
This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the [District of Columbia].

The MTA should state the governing law. Such laws may be the laws of the provider’s and recipient’s country or both. Whatever the case may be, the MTA should be prepared taking into consideration the governing laws of the provider’s and recipient’s countries.

This Agreement shall be governed by the laws of [England] and the parties submit to the exclusive jurisdiction of the [English] courts.

Settlement of Disputes

If a dispute cannot be resolved through negotiations or other non-binding means of the parties’ choice, disputes shall be subject to binding arbitration on conditions that are mutually agreed by the parties.

Breach of agreement

Breach: Any breach of this Agreement by the Recipient, including but not limited to a breach of the scope of use will entitle the Provider to immediately cease or cause to cease any transfer or shipment of samples to the Recipient and to seek temporary or permanent relief against the Recipient. Third Parties Beneficiaries to this Agreement shall be notified promptly of such decision by Provider and shall cooperate fully to prevent further transfer of samples to Recipient.

The aggregate liability of each party to all of the others for any or all breaches of this Agreement, any negligence, or arising in any other way out of the subject matter of this Agreement, the Project or the Results, will not exceed in total [that party’s Financial Contribution][the portion of the External Funding allocated to that party].

Consistency

In the event of any inconsistency between the terms of this MTA on the one hand, and the protocol for the study on the other hand, the terms of this MTA will take precedence

The provisions of this [agreement] shall be given precedence in interpretation in the event of any conflict between this [agreement] and the Implementing Letter.
When preparing MTAs care should be taken not to contravene provisions of other existing agreements pertaining to the human material in question. If, for example, the human material is to be used together with a material governed by a separate MTA, care should be taken under such circumstances to avoid granting two or more parties conflicting rights to the same material or product. Usually before negotiating a MTA, parties correspond by mail to reach consensus on particular issues regarding the material. Such correspondences, which include, for example, signed letters indicating consent or willingness to exchange, transfer or acquire the material, may be attached as annexes to the MTA. Where parties have a memorandum of understanding (MoU) to exchange, transfer or acquire human materials within a given research programme over a specified period of time, the MTA should be prepared within the framework of the MoU. The MoU usually does not specify details of the human materials, but allows in principle, the exchange, transfer or acquisition of the human materials.

15. Headings, amendments, waivers, and further assurances

Heads

The headings and subheadings in this Materials Transfer Agreement are inserted for convenience of reference only and will not be used in interpreting or construing the provisions of this Materials Transfer Agreement.

Amendment

No amendment or variation to this Materials Transfer Agreement will operate to change or vary the terms, obligations or conditions hereof except upon mutual agreement by both parties signed by an authorized representative of each Party.

Waivers

No condoning, excusing or overlooking by any Party of any default, breach or non-observance by any other Party at any time(s) regarding any terms of this Materials Transfer Agreement operates as a waiver of that Party’s rights under this Materials Transfer Agreement. A waiver of any term or right under this Materials Transfer Agreement will be in writing signed by the Party (or [third party]) entitled to the benefit of that term or right, and is effective only to the extent set out in the written waiver.
Further assurances

Example text
The parties will promptly do such acts and execute and deliver to each other such further instruments as may be required to give effect to the intent expressed in this Materials Transfer Agreement.

Example text
The Parties agree that this Agreement and any rights and obligations under this Agreement are not transferable whether by operation of law or otherwise. Any attempted assignment of this MTA by the Recipient to a third party will be void and of no force and effect.

17. Duration and Surviving Provisions

Example text
This Agreement shall come into effect on the Effective Date and continue in force until completion of the Purpose, including the reporting of the results of the work performed by Recipient to the supplier, or earlier termination of this agreement, whichever occurs sooner. Notwithstanding expiration or earlier termination of this agreement, the rights and obligations of the parties set forth in Articles … shall survive such expiration or termination.

Example text
Confidentiality - During implementation of the Action and for [number of] years after the completion of the Action, unless another term is agreed upon, any Beneficiary (the “Receiving Beneficiary”) must keep confidential any Confidential Information that is disclosed by or on behalf of another Beneficiary (the “Disclosing Beneficiary”) during the course of the Action and identified as confidential at the time it is disclosed. If information has been identified as confidential only orally, it will be considered to be Confidential Information only if this is confirmed in writing within [number of] Days of the oral disclosure.

Example text
Term - The obligations of [articles] shall remain in effect for each subject disclosure of Confidential Information during the Disclosure Period for a period of [number of] years from date of the termination of the appertaining Projects for which Confidential Information has been transferred.

Example text
Discontinue Use and Destroy Confidential Information Upon Request - The Receiving Party agrees to discontinue its use of the Confidential Information and destroy or return to the Disclosing Party all written Confidential Information received hereunder or Confidential Information that has been reduced to a written form upon completion of its use in accordance with this [agreement] or upon request by the Disclosing Party that supplied such Confidential Information (which ever shall occur first); provided, however, one (1) copy of such Confidential Information may be retained by the Receiving Party to preserve an archival record of the same.

Example text
Termination of the Confidential Disclosure Agreement - The Confidential Disclosure Agreement will terminate in its entirety upon the termination of the Project of either the Disclosing Party or the Receiving Party or if the Receiving Party is in breach of any of the conditions of this Master CDA.
Unless different period is stipulated by the Supplier, the obligations of this [Article] shall continue for a period of ten years after the expiration or termination of this Agreement.

Upon completion of the aforesaid Purpose, each Party shall (unless otherwise agreed by the Parties in writing) cease all use and make no further use of the Information disclosed to it hereunder. Upon written request from the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or destroy all of the Information received, except that each Party may retain one copy of the Information in its files to determine any continuing obligations hereunder.

This Agreement shall commence on the date of last signature below and will (subject to earlier termination pursuant to [clause]) continue for the duration of the Research Project.

The Donor Institution may terminate this Agreement if the Recipient Institution is in material breach of any of the terms of this Agreement and, where the breach is capable of remedy, the Recipient Institution has failed to remedy the same within one month of service of a written notice from the Donor Institution specifying the breach and requiring it to be remedied.

Upon completion of the Research Project or earlier termination under [clause] the Recipient Institution will discontinue all use of the Material, and upon the Donor Institution's direction, return or destroy the Material, unless permission to retain the Material is specifically provided in writing by the Donor Institution to the Recipient Institution.

The Provider Institution has the right to terminate this agreement forthwith at any time by means of written notice to Recipient Institution if the ethical approval is withdrawn or if the Recipient Institution is in breach of this Agreement. In the case of any termination, the Recipient Institution shall immediately discontinue all use of the Material and, at the Provider Institution's discretion, promptly return or destroy (at the Recipient Institution's own cost) all unused Material and provide written confirmation that this has been completed. If requested, the Recipient Institution must certify that it has complied in full with any such requirement of the Provider Institution. Should an individual donor or their next of kin rescind their consent, the Provider Institution will require and the Recipient Institution agrees to discontinue using the appropriately identified sample and return or destroy it in accordance with the Provider Institution's instructions.

This Agreement will terminate on the earliest of the following dates: (a) when the MATERIAL becomes generally available from third parties, for example, though reagent catalogs or public depositories or (b) on completion of the RECIPIENT's current research with the MATERIAL, or (c) on thirty (30) days written notice by either party to the other, or (d) on the date specified in an implementing letter, provided that:

   i. if termination should occur under 13(a), the RECIPIENT shall be bound to the PROVIDER by the least restrictive terms applicable to the MATERIAL obtained from the then-available resources; and
ii. if termination should occur under 13(b) or (d) above, the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS;

and

iii. in the event the PROVIDER terminates this Agreement under 13(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the PROVIDER will defer the effective date of termination for a period of up to one year, upon request from the RECIPIENT, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS.

[p]atent applications], [warranties], and [liability] shall survive termination.

Example text
When the Research Project is completed or three (3) years have elapsed, whichever occurs first, the Research Material will be disposed of as directed by Provider.

Example text
This agreement will terminate on the earliest of the following dates: (a) XXX years from the date of signing this agreement, or (b) on completion of the Recipient’s current Research with the Biological Material, or (c) on thirty (30) days written notice by either party to the other.

On termination for any reason, Recipient agrees to return or dispose of any remaining Biological Material, in accordance with the Provider’s directions.

Example text
This contractual agreement shall remain in force until [date] and shall be automatically renewed until [date] unless the [body] decides otherwise.

Applicability: [agreement] shall cease to be applicable only upon suspension or revocation of designation or recognition by [organization] or upon formal withdrawal by the laboratory of its participation in the [network] or upon mutual agreement of the [organization] and the laboratory. Such a suspension, revocation or withdrawal shall not relieve a laboratory of pre-existing obligations under [agreement].

Example text
A date for termination of use of the material may be set to avoid indefinite use of the material by the recipient organization. This date may be extended by written mutual consent of the parties. At the termination date, the provider organization may ask for the return of the material or its destruction. It should be noted that terminating use of the material does not render null and void other provisions of the MTA. It should be mentioned if the material would be stored for future unknown uses.
A disposal plan for the materials must be described in the MTA, including methods of disposal.
Disposal of material must be sufficiently documented.

The MTA may be terminated by either party providing a written notice in an agreed time frame.
Parties must, however, make provisions for benefit sharing of any accruing or anticipated future benefit at the point of termination.