Rules of  
Patients for Patient Safety, action area of the World Health Organization  
Patient Safety Programme

SECTION I  
INTRODUCTION

1.01 Introductory

The rules set forth in this document have been adopted by Patients for Patient Safety ("PFPS"), an action area of the World Health Organization ("WHO") Patient Safety Programme, formerly known as the WHO World Alliance for Patient Safety.

SECTION II  
PURPOSES

2.01 Purpose

The purposes of PFPS are:

(i) To advance the vision set forth in the London Declaration of Patients for Patient Safety, World Alliance for Patient Safety, adopted January 17, 2006, which states:

We, Patients for Patient Safety, envision a different world in which healthcare errors are not harming people. We are partners in the effort to prevent all avoidable harm in healthcare. Risk and uncertainty are constant companions. So we come together in dialogue, participating in care with providers. We unite our strength as advocates for care without harm in the developing as well as the developed world.

We are committed to spread the word from person to person, town to town, country to country. There is a right to safe healthcare and we will not let the current culture of error and denial, continue. We call for honesty, openness and transparency. We will make the reduction of healthcare errors a basic human right that preserves life around the world.

We, Patients for Patient Safety, will be the voice for all people, but especially those who are now unheard. Together as partners, we will collaborate in:

- Devising and promoting programs for patient safety and patient empowerment.
- Developing and driving a constructive dialogue with all partners concerned with patient safety.
- Establishing systems for reporting and dealing with healthcare harm on a worldwide basis.
- Defining best practices in dealing with healthcare harm of all kinds and promoting those practices throughout the world.

In honor of those who have died, those left disabled, our loved ones today and the world’s children yet to be born, we will strive for excellence, so that all involved in healthcare are as safe as possible as soon as possible. This is our pledge of partnership.

(ii) To provide opportunities for PFPS participants to be involved in furthering the goals of WHO Patient Safety.
SECTION III
ACCOUNTABILITY

3.01 Responsibilities

PFPS shall have the responsibilities as stated in these Rules or as subsequently provided or assigned by WHO Patient Safety.

3.02 Accountability

PFPS shall be accountable for its decisions and actions to the WHO Secretariat responsible for overseeing WHO Patient Safety.

3.03 Designated Lead

The Lead of the PFPS action area shall be appointed by and accountable to the WHO Secretariat responsible for overseeing WHO Patient Safety. The Lead serves at the discretion of the WHO Secretariat.

SECTION IV
OFFICES

4.01 Offices

As an action area of WHO Patient Safety, the principal office of PFPS is WHO. PFPS may maintain other offices in such places as are provided or designated by the WHO Secretariat to whom the Programme is accountable.

SECTION V
PARTICIPATION

5.01 Classes of Participation

PFPS shall have three classes of participation:

(i) Individual persons who qualify as PFPS Champions;
(ii) Individual persons who qualify as PFPS Associates; and
(iii) Organizations that qualify as PFPS Collaborating Organizations.

PFPS Champions are individuals who have attended a PFPS facilitated or approved workshop and have committed to principles of the PFPS Collaborative Agreement.

PFPS Associates are individuals who have not attended a PFPS facilitated or approved workshop, but have committed to the principles of the PFPS Collaborative Agreement and met any additional eligibility requirements determined by the Steering Committee.

PFPS Collaborating Organizations are organizations that support the London Declaration, have committed to the principles of the Collaborative Agreement and met any additional eligibility requirements determined by the Steering Committee.

Additional classes may be created only by amendment of these Rules.

5.02 Eligibility

A requirement for each class of participation is support for the London Declaration set forth in Section II. Additional eligibility criteria for each class of participation, including requirements for maintaining the status of PFPS Patient Safety Champion, PFPS Associate or PFPS Collaborating Organization shall be determined by the PFPS Steering Committee. Any questions of interpretation about participation criteria shall be determined by the PFPS Steering Committee. No participant of any class may voluntarily or involuntarily transfer his, her or its participation designation, certification of
participation or any other title, document or status arising from participation in PFPS to another person or organization.

5.03 No Membership or Voting Rights

PFPS participants are not members of WHO Patient Safety or the PFPS action area, nor do they have voting rights. Certificates issued by PFPS designating status as PFPS Patient Safety Champion, PFPS Associate or PFPS Collaborating Organizations shall not be construed as certificates creating membership.

5.04 Termination of Participation

Any participant may resign his or her participant designation at any time. The acceptance of such resignation shall not be necessary to make it effective.

Participation may be terminated by the PFPS Steering Committee by providing the participant with written notice of the proposed termination and the reasons for it, and with an opportunity to be heard, orally or in writing, in accordance with the processes and procedures set forth in Section IX of these Rules.

SECTION VI
STEERING COMMITTEE MEMBERS

6.01 General Powers

PFPS affairs shall be managed by or under the direction of the Steering Committee. The Steering Committee shall specifically have the power to:

(i) Draft PFPS statements, plans, policies, rules, and procedures;
(ii) Hold meetings;
(iii) Determine eligibility requirements for qualifying as a PFPS Patient Safety Champion, PFPS Associates or PFPS Collaborative Organizations;
(iv) Support, mentor and develop PFPS Patient Safety Champions, PFPS Associates or PFPS Collaborative Organizations; and
(v) Handle complaints;

in addition to all of the other powers, authority and duties prescribed or imposed by these Rules or the WHO Secretariat to whom the PFPS action area is accountable.

6.02 Number of Steering Committee Members

The number of Steering Committee Members shall not be fewer than five (5) at any time, nor more than fifteen (15). There should always be a member of the WHO Secretariat on the Steering Committee. Although not required, the Steering Committee shall always strive to include at least one person who lives in or represents each of the six WHO regions.

6.03 Qualifications

Each Steering Committee Member must support the purposes of PFPS as set forth Section II and agree to advance the goals of WHO Patient Safety. At the discretion of the Steering Committee, these promises may be required to be made in a written instrument.

6.04 Elections

At each annual meeting, Steering Committee Members shall be elected for a two (2) year term. There is no limit to the number of successive terms a Steering Committee Member may serve.
6.05 **Nominations**
The Steering Committee shall nominate members of the Steering Committee.

6.06 **Elections**
A quorum of the Steering Committee shall elect members of the Steering Committee.

6.07 **Resignation**
A Steering Committee Member may resign at any time by written notice delivered to the Lead or the WHO Secretariat. A resignation is effective when the notice is delivered unless the notice specifies a certain date. The pending vacancy may be filled before the effective date, but the successor shall not take office prior to such effective date.

6.08 **Removal of a Steering Committee Member**
A Steering Committee Member may be removed by the affirmative vote of a majority of the Steering Committee Members then in office present and voting at a meeting of the Steering Committee. A Steering Committee member is entitled to the following due process:

(i) Written notice of the reasons for removal, provided not less than 60 days before the day any vote is scheduled to be taken;
(ii) Upon request of the Steering Committee Member provided notice of removal, a right to file a written response; said response must be submitted at least 14 days prior to the day any vote is scheduled to be taken;
(iii) Upon request of the Steering Committee Member provided notice of removal, a right to a hearing before a quorum of the Steering Committee before the vote of the Steering Committee is taken; said hearing may be conducted in a telephone or videoconference meeting of the Steering Committee; and
(iv) Written findings that set forth the rationale or circumstances upon which a Steering Committee action to remove a Steering Committee Member is taken; said findings shall be maintained in the minutes of the Steering Committee where any action to remove a Steering Committee member is taken.

Any vacancy occurring on the Steering Committee, or any position to be filled by reason of an increase in the number of Members, shall be filled through election by a majority vote of the Steering Committee Members then in office. Nominations for vacancies shall be made by sitting Steering Committee members. The new Steering Committee Member so elected to fill the vacancy shall serve for the unexpired term of his or her predecessor in office.

6.09 **Meetings**
The Annual Meeting of the Steering Committee shall be held annually at a place designated by the Lead, provided that such meeting shall be held on a date on or before the last day of the calendar year. The Steering Committee may schedule at its discretion the time and place for the holding of additional regular meetings.

6.10 **Quorum**
A majority of the Steering Committee then in office shall constitute a quorum. The act of the majority of the Steering Committee Members present at a meeting at which a quorum is present shall be the act of the Steering Committee, unless the act of a greater number is required by these Rules.

6.11 **Place of Steering Committee Meetings**
Meetings of the Steering Committee may be held in person, by telephone or by videoconference. If held in person, provision should be made wherever possible to enable participation by telephone or videoconference for those members who do not attend in person.
6.12 Notice

Notice of the time and place of any meeting of the Steering Committee shall be given at least (3) days in advance thereof by written notice delivered personally or sent by mail or email, provided however that Notice of the Annual Meeting of the Steering Committee is given at least ten (10) days before the meeting date. If mailed, such notice shall be deemed to be delivered when deposited in the mail in a sealed envelope so addressed, with postage prepaid. If notice given by electronic means, it shall be deemed delivered when transmitted by electronic means to the address that appears on PFPS records.

6.13 Waiver of Notice

Attendance at any meeting shall constitute waiver of notice thereof unless the person at the meeting objects to the holding of the meeting because proper notice was not given.

6.14 Informal Action

Any action required to, or which may, be taken at a meeting of the Steering Committee, may be taken without a meeting if approved in writing before the meeting or if subsequently approved at a later Steering Committee meeting.

SECTION VII
COMMITTEES

7.01 Creation of PFPS Committees

A quorum of the Steering Committee may create one or more committees or working groups and appoint to those committees/groups:
(i) Steering Committee Members;
(ii) PFPS Patient Safety Champions,
(iii) PFPS Associates,
(iv) Representatives of PFPS Collaborating Organizations, or
(v) Such other persons as the Steering Committee may designate.

7.02 Appointments to non-PFPS Committees

A quorum of the Steering Committee may appoint or nominate:
(i) Steering Committee members,
(ii) PFPS Patient Safety Champions,
(iii) PFPS Associates,
(iv) Representatives of PFPS Collaborating Organizations, or
(v) Such other persons as the Steering Committee may designate

to participate in the activities of another WHO Patient Safety action area, or a committee, commission, advisory body or other such body external to the WHO or WHO Patient Safety that requests or provides for PFPS representation.

SECTION VIII
OFFICERS

8.01 Roster of Officers

The Officers of the Steering Committee will consist of the following:
(i) The Lead, 
(ii) a Secretary; and
(iii) such other Officers as the Steering Committee shall determine.
Two or more offices may be held by the same person, except one person may not serve simultaneously as Lead and Secretary.

8.02 Selection of Officers

The Lead shall be appointed by the WHO Secretariat to whom the programme is accountable. Each of the other Officers shall be elected annually by the Steering Committee at the Annual Meeting.

8.03 Lead

The Lead shall be in charge of the business and affairs of PFPS, and accountable therefore to the WHO Secretariat to whom the Programme is accountable. The Lead will further perform all other duties incident to such office and such other duties as may be provided in these Rules.

8.04 Secretary

The Secretary will keep minutes of all meetings of the Steering Committee, will be the custodian of PFPS records, and generally will perform all other duties incident to such office and such other duties as may be prescribed from time to time by the Steering Committee.

8.05 Removal of Officers

Any Officer other than the Lead may be removed by an affirmative vote of a majority of the Steering Committee for cause, whenever in their judgment the best interests of PFPS are served by such removal. A record of the rationale or circumstances upon which this action is taken shall be maintained in the minutes of the Steering Committee meeting where such action was taken.

SECTION IX
COMPLAINTS PROCESS

9.01 Complaints

Any person may file a complaint against a PFPS Patient Safety Champion, Associate or Collaborating Organization. Complaints will be considered that state an act that, if true, is inconsistent with requirements or responsibilities set forth in the PFPS Collaborative Agreement and PFPS rules. If uncertain about whether an act is sufficient to justify a complaint, the person complaining is encouraged to contact PFPS.

9.02 Filing a Complaint

A person making a complaint must submit the complaint in writing and must sign it. No anonymous complaints will be considered. The form should be completed within three (3) months from the occurrence of the alleged violation and contain the following information:

i. Description of the act which justifies the complaint, including nature and location of act(s), date and time, person(s) or organization responsible for the acts, including name or other type of information for identification

ii. Identifying information for the person making the complaint, including name, phone, e-mail, best time to be contacted, date of complaint submission

A complaint form to be used as a guide is available by request from PFPS.

9.03 Notice to the Regional Focal Point, Investigation and Mediation

Upon receipt of a complaint, the PFPS Lead will notify the World Health Organization Regional Office patient safety “focal point” for the region in which the person complained against lives.
The PFPS Lead will conduct the following operations:

i. Review the complaint;
ii. Interview the complainant and collect evidence if available;
iii. Seek input from the appropriate Regional Office focal point;
iv. Make an initial determination as to whether the complaint would have merit if proven to be true;
v. Identify the specific PFPS Collaborative Agreement clause, rule or other requirement that may have been breached;
vi. Notify the person(s) or organization against whom the complaint was made;
vii. Interview the person(s) or organization complained against and collect additional evidence if possible;
viii. Further investigate the complaint via interviews with the person who complained, the person(s) or organization complained against or others with relevant knowledge; and
ix. Determine if the complaint can be resolved through mediation between the parties.

If, after these operations, the PFPS Lead determines that there is cause for concern that cannot or should not be resolved by mediation, the person(s) or organization complained against will be asked to file a response in writing.

9.04 PFPS Steering Committee Review and Decision

Based on the investigation set forth in Section 9.03, the PFPS Lead, in consultation with the Regional Office focal point and, if appropriate, the WHO Patient Safety Secretariat, shall make a recommendation for action on the complaint to the PFPS Steering Committee.

The PFPS Steering Committee shall discuss at a meeting and make a decision to accept, not accept or modify the recommendation of the PFPS lead. If a consensus cannot be reached, majority vote will rule. If a Steering Committee member is the complainant or otherwise has a conflict of interest, he or she will be excused from voting. If the Steering Committee makes a decision that finds a violation, it will establish the appropriate corrective action or remedies that will be sought from the respondent.

Reasons for the decision shall be included in the minutes of the Steering Committee meeting. After the Steering Committee decision, the office of the PFPS Lead will forward the decision to the Regional focal point to ensure that they are aware of it.

9.05 Opportunity to Be Heard

Either the person making the complaint or the person or organization complained against can request an opportunity to be heard if they disagree with the Steering Committee decision. Requests to be heard should be made within thirty (30) days of the time the person or organization requesting the opportunity to be heard was received from Steering Committee.

9.06 Remedies

PFPS reserves the right to pursue any of the following remedies, where appropriate and provided by law for a violation of its rules, Collaborative Agreements or other requirements:

i. Written Warning;
ii. Corrective action, typically a WHO Patient Safety decision that a PFPS Champion, Associate or Collaborating Organization must take appropriate steps to rectify the violation;
iii. Revocation of PFPS Champion or Associate credentials and right to use the designation of PFPS Patient or Associate; or
iv. Any other action the PFPS Steering Committee deems to be fair and reasonable.
9.07 Process for Being Heard

A quorum of the Steering Committee shall schedule a time to hear from the party requesting it, in person, by telephone or by teleconference, at the discretion of the Steering Committee.

The Steering Committee shall have the power to manage the proceedings to maintain order. After hearing from the party requesting the opportunity to be heard and any others the Steering Committee decides to interview, the Steering Committee will deliberate in private in an attempt to reach consensus. If a member of the Steering Committee is the person complaining, the person complained about, or otherwise has a conflict of interest, that member shall be excused from participating in the decision.

Whether or not the Steering Committee reaches private consensus, a vote shall be taken and documented in minutes of the Steering Committee meeting at which the final decision is made.

9.08 Notification

A notification of final decision shall be issued to the person complained against, the person making the complaint and the Regional Office focal point.

9.09 Enforcement of Remedies, Warnings and Final Notice

If the Steering Committee does request or require a rectifying action to be done by a PFPS Champion, Associate or Collaborative Organization, and it is not completed within the timeframe determined in the Steering Committee’s Notification, a warning letter shall be sent. The Warning Letter shall specify a time certain, typically 30 days, with which to perform the required actions. Additional time shall be allowed at the discretion of the PFPS Lead.

If the rectifying action requested/required by the Warning Letter is not completed within the timeframe set forth, a final notice stating that the person(s) or organization who has refused to perform the rectifying action is non-compliant. The final notice shall also state that the non-compliant person(s) or organization shall be deprived of PFPS Champion, Associate or Collaborative Organization status immediately. Additional time shall be allowed at the discretion of the PFPS Lead.

If the requested/required actions set forth in the final notice are not completed within the time specified, the PFPS Lead shall remove the name of the non-compliant person from the roster of PFPS Champions. The Regional Office focal point shall be notified of this decision. The complaint process is then closed.

SECTION X
RECORDS

10.01 Financial Records

PFPS will keep correct books and records of account if instructed to do so by the Lead or the WHO Secretariat.

10.02 Minutes

PFPS will keep minutes of the proceedings of the Steering Committee.

10.03 Custody of Records

Books, records of account and minutes shall be kept at the PFPS principal office or at such other place as the Lead in consultation with the WHO Secretariat shall determine.
11.01 Modification of Rules

The vote of a two thirds (67% or higher) majority of the Steering Committee then in office is required to amend, repeal, alter or add to these Rules. Such action may be taken at a regular or special meeting of the Steering Committee, provided written notice of the purpose the meeting shall be given in accordance with these Rules.

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