Proposal Review Committee

Terms of Reference

1. Terms of reference

The Proposal Review Committee (PRC) is an independent, impartial team of experts who provide scientific, public health, health systems, programmatic, country implementation, market dynamics and health economics expertise to Unitaid on proposals submitted for funding (hereinafter Proposals) and draft grant agreement documents (hereinafter GAD documents).

1.1 Specifically, the PRC:

- Reviews Proposals according to established criteria;
- Participates in the Joint Review Committee (JRC)[1] meetings;
- Provides recommendations to the Unitaid Executive Board (EB) as part of the JRC, based on the review of the Proposals and
- Reviews the GAD documents to ensure that the JRC and the EB recommendations and comments have been duly addressed during the GAD process.

1.2 The PRC is an advisory body that does not have decision-making authority.

2. Membership

The PRC is broadly constituted and comprises Members with a firm commitment to Unitaid and the requirements of PRC membership, including:

- Serving in a personal capacity without respect to professional or institutional affiliation and without acting upon advice or representation of the interests of governments, organizations, or other third-party representatives;
- Complementary and cross-cutting expertise in areas outlined in Paragraph 2.5 below;
- Commitment to the highest standard of compliance with the Declaration of Interest Policy and Confidentiality Undertaking;
- Regular attendance and participation in PRC/JRC in-person meetings, teleconferences;
- Active, independent and high-quality engagement in discussions and processes related to the PRC mandate;
- High quality of input/recommendations;
- The total estimated average time requirement per PRC Member and per year of 17 full working days[2].

[1] JRC is composed of the PRC and the Secretariat review teams.

[2] PRC Core Member yearly time commitment for attendance of at least 2 two-day JRC in-person meetings (plus in-depth review of 3 proposals per PRC Member on average per meeting with estimated 5-7 hours of total review time per proposal), 2 one-day virtual/teleconference JRC meetings on average (plus in-depth review of 1 proposal per PRC Member on average with estimated 5-7 hours of review time per proposal) and an average of 8 GAD reviews per PRC Member per year with 3-5 hours of average review time for regular GADs that have gone through the competitive selection process and 5-7 hours of average review time for atypical (enabler) GADs and grant extensions.

2.1. Types of Members

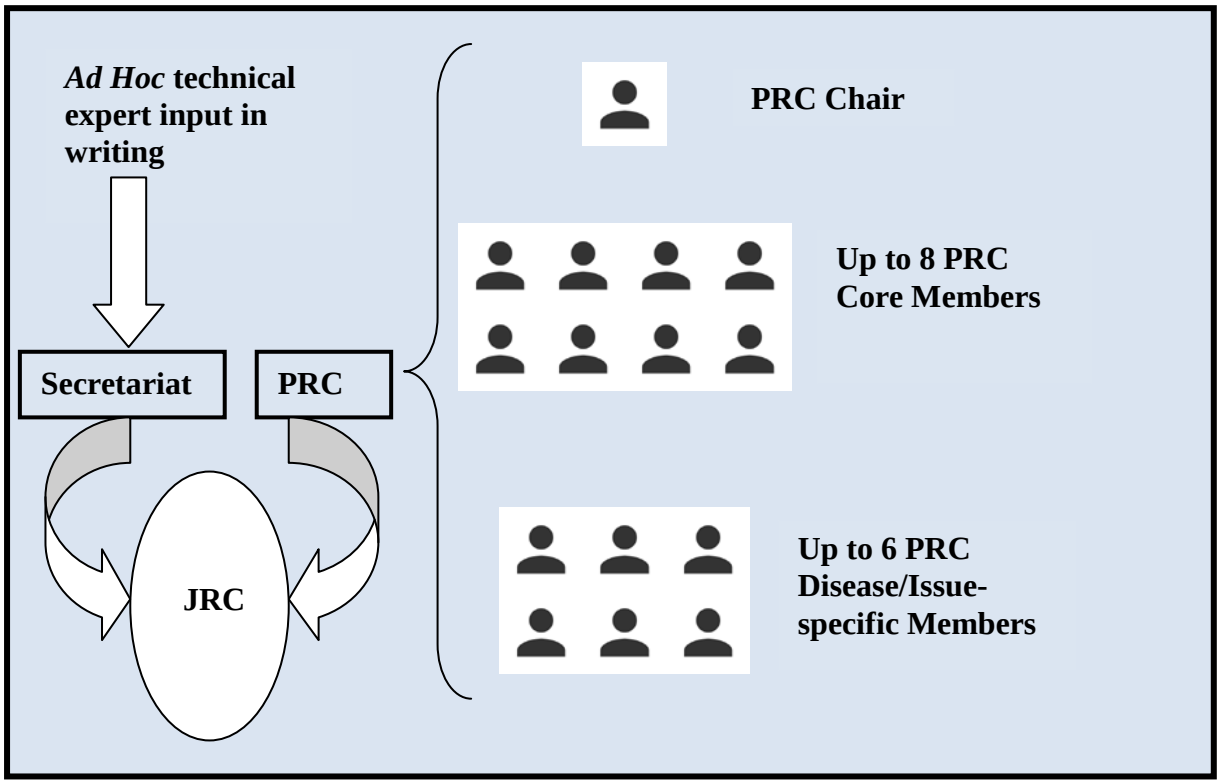
There are two types of PRC Members:

- Core Members – have broad cross-cutting expertise and are engaged in all proposal and GAD reviews/meetings;
- Disease/issue specific Members – have focused expertise in one area outlined in Paragraph 2.5 and are engaged only in those proposal and GAD reviews/meetings that pertain to their specific area of expertise[3].

2.2 Size of the PRC

The PRC comprises up to 8 Core Members and up to 6 Disease/issue specific Members, in addition to the Chair. The PRC Chair will review the composition of the PRC at the end of each calendar year based on PRC Member performance assessment and request EB approval of any recommended adjustments to the PRC size and composition, if deemed necessary.

Graph1: PRC Composition within broader JRC context



[3] The PRC Chair will determine the engagement of Disease/issue- specific PRC Members for the purposes of each specific Call for Proposals after the EB approval of the Area for Intervention (AfI).

2.3 PRC Chair and Vice-Chair

The Unitaid EB selects the PRC Chair. The choice of whether to nominate a Vice Chair is at the discretion of the PRC Chair. The Vice Chair is nominated by the Chair in consultation with the other PRC Members.

In the absence of the PRC Chair, or in any other circumstance where the Chair cannot effectively perform his/her duties, the Vice Chair will chair the PRC.

The PRC Chair and/or the PRC Vice-Chair will attend EB meetings and represent the PRC as observers and shall take the floor upon request from the EB Chair.

2.4 Selection of Members

PRC Members are selected from a pool of applicants based on their training, skills, experience and ability to advise on areas of expertise related to the PRC mandate (see Paragraph 2.5).

The following sequential steps are followed in selecting the PRC Members:

- Unitaid Policy and Strategy Committee recommends to the EB the approval of the candidature of the PRC Chair;
- EB appoints the PRC Chair;
- Secretariat issues a call for applications;
- PRC Chair and Secretariat review applications and produce a shortlist of 20 – 24 names;
- The PSC recommends to the EB a shortlist of up to 8 PRC Core Member candidates, up to 6 PRC Disease/issue specific Members candidates and 4 alternate candidates[4] ;
- EB approves the new PRC composition.

The composition of the PRC reflects a geographical and gender balance, assuring representation from those resident in, or with experience of working in low and lower-middle income countries.

2.5 Expertise of PRC Members

Members of the PRC are high-level senior experts with advanced experience in their fields of work. Members have significant, demonstrated expertise and leadership in the skill sets described below. The selection of the PRC Members should ensure that all of the below areas of expertise are represented on the PRC.

[4] 2 alternate members of Core PRC Members and 2 alternate members of Disease/issue specific Members are considered in case the EB objects to any of the proposed candidates.

Disease-specific areas of expertise

1.	**HIV/AIDS**	Expertise in HIV, including prevention, diagnosis and treatment. This may include expertise in HIV with a perspective on future trends, and expertise in HIV-related global health policy and public health. Experience designing/implementing interventions to benefit (i) people living in developing countries, with particular attention to low-income, and lower middle-income countries; (ii) underserved groups, which are to be defined based on the specific disease context.
2.	**Tuberculosis**	Expertise in TB, including prevention, diagnosis and treatment. This may include expertise in TB with a perspective on future trends, and expertise in TB-related global health policy and public health. Experience designing/implementing interventions to benefit (i) people living in developing countries, with particular attention to low-income, and lower middle-income countries; (ii) underserved groups, which are to be defined based on the specific disease context.
3.	**Malaria**	Expertise in malaria, including prevention, diagnosis and treatment. This may include expertise in malaria with a perspective on future trends, and expertise in malaria-related global health policy and public health. Experience designing/implementing interventions to benefit (i) people living in developing countries, with particular attention to low-income, and lower middle-income countries; (ii) underserved groups, which are to be defined based on the specific disease context.
4.	**HIV Co-Infections and Cross-Disease Integration**	Expertise in HIV co-infections, including prevention, diagnosis and treatment. This may include expertise in HIV co-infections with a perspective on future trends, and expertise in HIV co-infection-related global health policy and public health; Experience in enabling access to health products that address more than one disease or condition (e.g., polyvalent diagnostic platforms); Experience addressing the needs of people affected by more than one disease (e.g., treatment of co-infections); Experience reaching people for one health issue through a different program or clinical interaction (e.g., leveraging child health programs to diagnose malaria in children).
5.	**RMNCH**[5]	Expertise in RMNCH with a perspective on future trends, and expertise in RMNCH-related global health policy and public health. Technical expertise and skills on the principles and application of standard and innovative practices, methods and techniques in the field of RMNCH. Experience designing/implementing interventions to benefit (i) people living in developing countries, with particular attention to low-income, and lower middle-income countries; (ii) underserved groups, which are to be defined based on the specific disease context.

[5] Reproductive, maternal, newborn and child health (RMNCH)

Access-specific areas of expertise

6.	**Market Dynamics and Health Economics**	Expertise in the market dynamics of health commodities, including price reduction strategies and market analysis. High level experience in the health economics of the pharmaceutical and/or health commodity[6] industries, including regulatory and legal issues, research incentives, competition, subsidy, costing, contracting, demand side and social marketing, public private interface.
7.	**Product Development**	Expertise in product development issues in relation to the pharmaceutical and health commodities industries, including process and product development, commercialization and product launch.
8.	**Intellectual Property**	Expertise in intellectual property issues, including international legal and policy frameworks (such as the TRIPS Agreement) and their implications for access to health commodities for HIV/AIDS, TB and malaria.
9.	**Supply Chain**	Expertise in supply chain management, pharmaceutical supply, procurement of pharmaceutical products and medical devices and related health commodities, in particular in developing countries.
10.	**Regulation**	Expertise in the regulation of health products, including work with Stringent Regulatory Authorities (SRAs) or the WHO pre-qualification process.
11.	**Scalability and Country Implementation**	Experience of scaling up successful projects and ensuring transition after the end of the project. Experience of programmatic implementation in developing countries, good understanding of their political and institutional systems and experience collaborating with civil society and development partners (including in demand creation).

Cross-cutting areas of expertise

12.	**Health Systems**	Expertise in health systems, including health policy, health systems strengthening, public and private sector healthcare and human resource development.
13.	**M&E/Impact:**	Experience in M&E systems, including design and appraisal of M&E indicators and systems; selection and definition of indicators and baselines; verification; reporting; evaluating market impact; evaluating public health impact and value for money, impact assessment at a strategic level and assessment of efficiency and effectiveness on operational level.

[6] Health commodity is intended to include medical devices and *in vitro* diagnostic devices.

2.6 Term of Office

PRC Members are appointed for an initial term of office of three years that is renewable subject to satisfactory performance. To ensure continuity, the PRC Member replacements shall not exceed 50% of the PRC membership at any one replenishment occasion.

2.7 Remuneration and Reimbursement of Expenses

The PRC Chair and Core PRC Members will receive an annual honorarium for their services. The Disease/issue specific Members will be paid for the number of days spent for rendering their services, as estimated by the Secretariat. The travel and per diem of PRC Members will be paid in accordance with established WHO rules and procedures.

2.8 Resignation or Withdrawal from the PRC

A PRC Member may withdraw from the PRC at any time upon written notification to the PRC Chair. In cases of resignation, the PRC Chair and the Secretariat go back to the shortlist of 20-24 names presented to the PRC Nominations Sub-Committee and make a recommendation to the EB for replacement. The EB will confirm the nomination by electronic vote.

PRC Membership may be terminated at any time upon written notification by the PRC Chair in consultation with the Secretariat and the EB Chair.

2.9 Ad Hoc Supplemental Technical Input

PRC Members' expertise in the 13 skill areas defined above in Paragraph 2.5 will ensure the committee's capacity to review the entirety of most Proposals developed for EB consideration. However, in a minority of cases – particularly where Proposals involve new products or novel intervention types – there will be a need for *ad hoc* supplemental technical input to the JRC review process.

Any need for such *ad hoc* supplemental technical input will be identified as early as possible and usually at the time of issuing a call for proposals. The selection and appointment of providers of such supplemental technical input (hereinafter referred to as "Technical Consultants") will be done by the Secretariat, in consultation with the Chair of the PRC. All Technical Consultants will be appointed in accordance with WHO's financial rules and regulations and their names included in the PRC summary record.

The focus and parameters for any supplemental technical input will be elaborated in proposal-specific TOR. The Technical Consultants' input will be provided to the JRC in the form of a written report designed to inform the JRC's wider review and deliberation.

The JRC itself remains ultimately responsible for all recommendations it makes to the EB. Technical Consultants will not participate in JRC meetings during which final recommendations are formulated by JRC Members. Technical Consultants will be

held to the same standards governing conflict of interest and confidentiality as JRC Members.

2.10 Performance Assessment

A yearly performance assessment of PRC Members will be conducted by the Chair of the PRC based on the following simple criteria of assessment:

- Regularity of attendance/ participation in PRC/JRC in-person meetings/teleconferences/discussions
- Level of participation/engagement/responsiveness
- Quality of input/recommendations
- Compliance with DOI and Confidentiality policies

The PRC Chair will share the performance assessment with the Secretariat in writing. In cases of performance assessment revealing non-performance on any of the assessment criteria, the PRC Chair may recommend withholding the end-of the year payment of PRC Member honorarium/ end of the contract payment.
Performance assessments will be used as a criterion for PRC membership renewal.

3. Working procedures

3.1 PRC Members review Proposals and GAD documents made available to them by the Secretariat and provide advice based on assessment criteria and on specific issues raised by the JRC, EB and /or the Secretariat.

3.2 JRC Meetings

The PRC will participate in the JRC meetings which will be organized on a needs basis, on average twice annually in person. The JRC may meet face-to-face, or by telephone/video conference, as is most appropriate for the work of the JRC at that time. Where meetings are held by conference call, JRC Members should make every effort to ensure that a secure line is used and that persons not approved by the JRC Co-Chairs[7] do not listen to the proceedings.

JRC meetings will be co-chaired by the PRC Chair and the Deputy Executive Director of Unitaid.

The JRC discussion will be based on pre-meeting assessments done by the PRC Review Teams[8] and the Secretariat Review Team separately. Both PRC and Secretariat Review Teams will use the Assessment Tool to note their scores, rationales and overall assessment of each Proposal.

The Secretariat will introduce the discussion at a JRC meeting by summarizing the call intent, specific requirements of the Area for Intervention (AfI), the outcomes of the

[7] PRC Chair and the Deputy Executive Director of Unitaid serve as JRC Co-Chairs.
[8] Usually 3 PRC Members constitute a PRC Review Team. The composition of the review teams is determined by the PRC Chair based on the analysis of declarations of interest, available expertise and taking into account equal distribution of workload amongst all PRC Members.

Intention to Submit Proposal (ISP) screening, the outcome of the initial Level 1 and Level 2 reviews done by the Secretariat, the outcome of the partner consultations organized by the Secretariat and, if relevant, the input from technical experts as described in the Paragraph 2.9.

Both the PRC and Secretariat Review Teams will then introduce their assessments, proposal by proposal, followed by an open discussion per proposal and per assessment area[9], moderated by the JRC Co-Chairs with the aim of arriving at agreed consensus scores, rationales and final recommendation to the EB.

The agenda for JRC meetings will be developed by the Secretariat in collaboration with the JRC Co-Chairs.

3.3. JRC Recommendations

The JRC will aim to arrive at its recommendations based on consensus. The JRC meeting agenda will contain a separate special session to review and agree on the exact final recommendations to the EB. In the unlikely and exceptional event that consensus cannot be achieved, the positions of the PRC and Secretariat will be conveyed to the EB.

3.4 Summary Record

The Summary Record of the JRC meetings will be compiled and maintained by Unitaid's Secretariat. The Summary Record will be considered and endorsed by JRC Members. In the unlikely and exceptional event that consensus cannot be achieved, the positions of the PRC and Secretariat will be conveyed to the EB.

3.5 GAD Reviews

The GAD document reviews are usually performed by the same PRC Review Team members who reviewed the initial proposal. The PRC Chair will constitute special PRC Review Teams in cases of atypical/enabler proposals and grant renewals that have not undergone the process of competitive selection under the current Unitaid Operating Model. The PRC Review Teams will perform the reviews based on deskwork and teleconference/web-meetings may be organized by the PRC Review Team members at their discretion to arrive at agreed opinion/recommendations.

4. Transparency and Confidentiality

4.1 The membership, terms of reference and operating procedures of the PRC are published on the Unitaid website.

4.2 PRC Members in their advisory capacity linked to the proposal review process, may have access to certain information relating to proposal review or grant making processes, which Unitaid considers to be confidential. PRC Members are therefore

[9] The assessment areas include rationale and strategic alignment, impact, organizational capacity, proposal design and alignment, budget, compliance and risks.

required to complete and sign a general Confidentiality Undertaking form upon signing their contract and are also required to complete and sign specific Confidentiality Undertaking forms against the list of proponent organizations and their consortium members for each specific round of review.

4.3 JRC meetings will be closed to the public.

5. Declarations of Interests (DOI)

5.1 To ensure the highest integrity and public confidence in its activities, Unitaid requires that PRC Members disclose any circumstances that could give rise to a potential conflict of interest related to the proposal review process in which they will be involved.

5.2 PRC Members are required to complete and sign a general DOI form upon signing their contract and are also required to complete and sign specific DOI forms against the list of proponent organizations and their consortium members for each specific round of review.

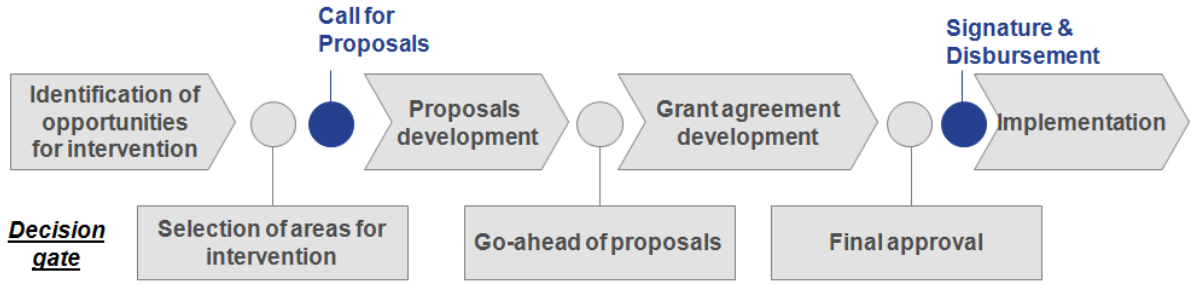
5.3 Unitaid Secretariat will analyse the submitted DOI forms and together with the PRC Chair decide on appropriate actions to manage the declared interests in order to avoid conflict of interest situations[10].

5.4 The Secretariat will summarize all declarations made and the suggested management actions in a presentation made at the beginning of each JRC meeting. Subject to agreement of the JRC Co-Chairs, this information will then be reflected in the JRC Summary Record.

[10] E.g. PRC Chair allocates PRC Members to PRC Review Teams only following thorough analysis of the declarations made.

Annex 1
Unitaid Proposal Process

Unitaid's operating model aims to make the grant agreement development process fast, focused and efficient, while ensuring that grant agreements are fully consistent with global health goals and help other global health partners achieve more with scarce resources.



1. Areas for Intervention (AfIs)

Unitaid identifies opportunities and areas for intervention, through internal analysis and engagement with partners and countries. Multiple targeted Calls for Proposals within selected areas for intervention are launched per year.

2. Intention to Submit Proposal (ISP)

Once a Call is issued, applicants may communicate their ISP within 30 days of the launch of the Call, unless the call announcement specifies otherwise. They can do so by filling in the electronic form, available on Unitaid's web site at http://www.unitaid.org/calls. While submission of an ISP is not a mandatory requirement, it is highly recommended as it allows the Unitaid Secretariat to provide initial feedback on the fit of the suggested proposal within the intent of the call. PRC Members have no role during the ISP process.

3. Proposal submission

Proposals are submitted within 3 month from the call announcement date, if not specified otherwise. Complete proposals consist of the following documents:

- Proposal form with scanned version of signed Front page
- Annex 1: Log frame
- Annex 2: Timeline GANTT chart
- Annex 3: Budget details
- Annex 4: Organizational details and CVs of key team members
- Annex 5: Support Letters (not mandatory)
- Annex 6: Declaration of relevant interest
- Annex 7: Applicable ethics, anti-discrimination and environmental policies

- Annex 8: Declaration regarding tobacco entities

4. Proposal Assessment

Proposal assessment is done in three levels. The first two levels are done by the Secretariat and only those proposals that have reached the level three stage are assessed by both the PRC and Secretariat Review Teams in parallel with the final discussion and recommendation during a JRC meeting.

The proposals are assessed based on the following criteria:

- Level 1
  General fit

- Level 2
  Technical criteria
  Potential feasibility

- Level 3
  Rationale and strategic alignment
  Impact
  Organizational capacity
  Proposal design and alignment
  Budget
  Compliance
  Potential risks

5. EB "Go-Ahead" Decision

Based on the JRC recommendation, which may contain conditions to be addressed early in the GAD process, the EB grants its "Go- Ahead" decision, which allows successful proponents to start the grant agreement development process with the Secretariat. The EB "Go-Ahead" decision involves no financial commitment from the EB.

6. Grant Agreement Development (GAD) Process

Following notification of the "Go-Ahead", applicants will work with the Unitaid Secretariat to develop a grant agreement based on Unitaid's Standard Terms and Conditions. The grant agreement includes, but may not be limited to, a Project Plan, Budget and Logical Framework.

The PRC Members are engaged in the GAD process usually after the second iteration to ensure that the comments, conditions and recommendations made by the JRC and the EB have been addressed during the GAD process. The PRC opinion at this stage is final and no further clarifications or responses are examined.

7. The EB Funding Decision

At the end of the GAD process, the EB makes the final funding decision following which the grant implementation starts.