

Long-Term Agreement for the Provision of Global Research Ethical Review Facility and Quality Assurance Services for Evidence Generation.

Question 1 : is there any guidance on the acceptable range of hourly fees and other staff compensation levels so our proposal is “within bounds” of UNICEF procurement standards?

Answer:

There is currently no defined acceptable range of fees per deliverable, we expect vendors to offer their most competitive rates.

Question 2 : we understand that UNICEF, depending on the proposals received, may award different parts of the total review work to different bidders [I.e. ethics review work vs quality assurance reviews]. May we submit a single integrated proposal which distinguishes between these two areas [in terms of staff and cost], or should we submit separate proposals?

Answer:

Please submit separate financial proposals, one for the quality assurance activities and the other for the ethical review, using the templates provided as annex C.

Question 3: is there any guidance on whether the service from the help desk is expected to be 24/7 and/or what the response time standard might be?

Answer:

The help desk facility would preferably be available 24/7 in order to account for the global nature of the service. However, a reasonable specification of availability could be determined, with a clear indication of hours and that if staff contact outside those hours that they note a preferred time within those hours to discuss the issues. Vendors should however, respond within 24 hours. It should also be noted, that requests may also be in writing and again, this would require a written response in 24 hours.

Question 4: Financial Proposal – Annex C: The Financial Proposal Response Sheet requests a daily rate for each staff resource, but Annex B, p.6 h) requests unit costs for each item (other than help desk which is priced hourly). Should we provide unit costs in the Financial Proposal Response Sheet or daily rates or both?

Answer:

Please provide the costs as requested in the Financial Response Sheets provided.

Question 5: Technical Proposal – Under the US Code of Federal Regulations IRBs receiving authorization must have a minimum of 5 people in their rosters. However, for an authorized IRB to meet it must only have a quorum which can be as few as 3 persons as long as one of those is non-scientific in nature. Is it your intention to require IRBs who are authorized in accordance with an FWA to only conduct reviews when all 5 members are present?

Long-Term Agreement for the Provision of Global Research Ethical Review Facility and Quality Assurance Services for Evidence Generation.

Answer:

The requirement should be in accordance with US Federal Regulations and therefore, if the requirement for a particular project only demands 3 persons – this will be adequate.

Question 6: Technical Proposal – You are asking for Full Board IRB reviews only. IRBs operating with FWA are also authorized to conduct expedited reviews and exemption determinations. Are you also interested in having information on those types of services?

Answer:

Yes, please include the cost of doing an expedited review, if applicable.

Question 7: Technical Proposal - On page 5 of Annex B one of the factors listed under “Desirable” is a pool of qualified reviewers. Do you want detailed information for all qualified reviewers who might conduct reviews under this LTA or a representative sample of some of the potential reviewers?

Answer:

Please provide detailed information for the project manager and key essential personnel who will be involved in managing and operationalising the LTA (i.e development of relevant materials and reports, designing or altering templates etc..). For all other reviewers please note:

- Name,
- Title and Professional role,
- Institutional Affiliation,
- Geographical Location,
- Subject and Geographical expertise, and,
- Very brief outline of experience in ethical review or QA reviews of research proposals (bullet points will suffice)

Question 8 : Technical Proposal - On page 5 of Annex B, 8.c. you ask for CVs of “the specialists who will undertake draft and potentially update the templates as required, undertake the quality assurance and ethics reviews and provide real time trouble shooting and technical assistance.” Do you want all CVs for anyone who will potentially work on any of these components, or a representative sample? We have a panel of over 20 potential reviewers so that we can find an appropriate expert given the subject matter and timing. We do not want to burden our response to the RFPS with 20+ CVs unless this is what you require.

Answer:

See answer to Question 7

Question 9: Technical Proposal – Is there any value or benefit in being able to commit to completing the described tasks in fewer days than specified in Annex B?

Answer:

Please note that UNICEF will be paying for the deliverable (not the rate per day per se) so a shorter time frame for providing reviews will certainly be favorably looked upon.

Long-Term Agreement for the Provision of Global Research Ethical Review Facility and Quality Assurance Services for Evidence Generation.

Question 10 : Technical Proposal -- We have had inquiries from regional offices regarding IRB exemptions. We are authorized to grant exemptions to on-going review in cases where risks to subjects are negligible (e.g., reviews of existing anonymous data, desk reviews, etc.). Would UNICEF be interested in this also? We would be willing to negotiate a rate lower than a usual review, but since some review is necessary there is a cost.

Answer:

See Answer to question 6 above. Regional Offices will determine if an exemption is possible under the UNICEF Procedure for Ethical Standards.

Question 11:

Please can you clarify the evaluation process that will be followed by UNICEF

Answer:

Proposals will be reviewed following a three-step process:

- A. An initial administrative check for completeness and compliance
- B. Technical evaluation (70 points)
- C. Evaluation of financial proposal (30 points)

A. Administrative check

Proposals will first be reviewed for their completeness in terms of the information requested in the RFPS (Section 7) and their compliance with its requirements. Only proposals that successfully pass the administrative check will be subject to technical evaluation.

B. Technical evaluation (70 points)

Technical evaluation will be conducted for each category of service separately. Only those proposals that score 55 points and above will be considered technically compliant and will proceed to the financial evaluation. All other proposals will be disqualified.

C. Evaluation of the financial proposal

The financial evaluation of all technically compliant proposals will be determined according to all relevant deliverables. Where the vendor holds an FWA this will include the unit costs of:

- 1) Undertaking an ethical review of individual inception reports/research protocols or evidence generation proposals with 5 reviewers (for organisations that have FWA accreditation)
- 2) Reviewing a proposal that meets the requirements for expedited review, in accordance with the Final Rule.

Where the vendor does not hold an FWA, the financial evaluation will be exclusive of the above.

The total USD price for all the relevant deliverable will be used for the ranking of the financial evaluation. FWA holders will be assessed separately in recognition of the additional services provided. The proposals will be ranked from the lowest to the highest based on the average cost per service category area.

Following the technical and financial evaluation, awards will be made to the proposals that offer best value for money and are in the best interests of UNICEF.

Please Note. Awards may be made to multiple vendors.

Long-Term Agreement for the Provision of Global Research Ethical Review Facility and Quality Assurance Services for Evidence Generation.

Question 12:

Can you provide an indication of the amount of work that may go through these LTAS once established?

Answer: It is estimated that on an annual basis approximately 100-150 proposals will require ethical review with a similar number for quality assurance of both research protocols and final reports.

However, the total number of *proposals* and mature draft research reports to be reviewed per year will be contingent on (a) the number of successful institutions selected by UNICEF (b) whether the successful institution/s bid for (a) just the research reviews (b) just the ethics reviews (c) both (d) whether UNICEF decides to allocate successful institutions to either research reviews, ethics reviews or both, dependent on the qualifications and experience of these institution/s.