Check list for required documents:

The applicant should fulfill the requirements of the below checklist. This checklist is part of application form. Applicant should tick in the applicant column as appropriate.

ITEM	Applicant	IRB-Committee
COMPLETED APPLICATION FORM FOR ETHICAL REVIEW		
Original signed and complete application form		
Proof of payment		
Proof of registration/NOC (?)		
Letter of support/collaboration, as necessary		
EACH OF THE FOLLOWING DOCUMENTS SHOULD BE SUBMITTED ALONG WITH APPLICATION		
Study Protocols		
Project Proposal		
Tools/Questionnaires (Original tools, not just consent procedure) (If tool is in SurveyCTO, send the tool in a readable MS Word format)		
Translated Data collection tools (tick): Questionnaires, FGD Guides, IDI guides, Other		
Consent form/procedure (Depending on study location, please include translated consent form) ; (Must include basic information about organization/study, designated space for participant signature, consent for recording/picture-taking (if applicable), information on data storage/retention procedures, time duration of survey/interview, right to withdraw consent during/after survey, contact information of research team for complaints/queries.)		
Curriculum vitae and other relevant documents evidencing qualifications of investigators (Principal Investigator and Co-PIs)		
Any other relevant documents that require approval		
Detailed study budget		
Proof of availability of funding		
Other supporting documents (specify)_____		

Please fill this form to the best of your knowledge and ability. This information will help the members of RADS Institutional Review Board in reviewing the protocol.

Research Study Title	
Type of Project	
Funding Organization	
Principal Investigator's name	
Title/Position	
Name of Organization implementing study	
Signature	

Address of the study implementing organization:

Street Address	
City	
Country	
Postal Code	
Email	
Phone (1)	
Phone (2)	
Website	

Contact details of Principal Investigator (if different from organizational address):

Street Address	
City	
Country	
Postal Code	
Email	
Phone (1)	
Phone (2)	
Website	

Name of co-investigators:

Name	Designation	Organization	Signature

Undertaking: The Principal Investigator is responsible for the following:

1. Ensuring that the rights of study participants are protected during the study
2. Ensuring the welfare of study participants
3. Complying with all national and international standards of research ethics
4. Informing the IRB about any changes in the research protocol once approval has been granted
5. Ensuring that every study participant should have the right to withdraw from the study at any time without any pressure on the participant
6. Reporting any adverse events related to the conduct of the study to the IRB within four weeks of the event, in writing
7. Ensuring that the information provided in this form and the study protocol is correct to the best of their knowledge and ability

Declaration by Principal Investigator:

As Principal Investigator, I am responsible for the ethical conduct of this study and will adhere to any stipulations of the RADS-IRB, protect the rights and welfare of research subjects. I agree to conduct the research as presented in this application and as approved by the RADS-IRB, and I am qualified to perform the procedures described herein.

I will submit any proposed changes/modifications for review and approval before these are implemented. I agree to notify the IRB of any adverse events that may occur during the study.

I certify that the information provided in this application is complete and accurate.

Declaration by Organizational Head (If any):

I have reviewed this proposal and agree that it is ethically sound. I feel that facilities/resources are adequate for research. I recommend the participation of the concerned personnel of my department in this study.

Signature of the Principal Investigator (PI)	**Signature of Organizational Head (OH) (if different from PI)**
Name of PI: **Dated:**	**Name of OH:** **Dated:**

Research Questions:

Are Human Subjects involved?	
If yes, please indicate the type of research (Qualitative/ Quantitative)	
What is/are the objective(s) of the study?	
What is the rationale/purpose of the study?	
What is the duration of the study?	
Briefly describe the methodology (Sampling, interview type etc.)	
How are the study participants defined?	
What are the inclusion criteria?	
What are the exclusion criteria?	

What will be the sample size? Include the sample size calculation as well.	
What is the age range of participants?	
Are children involved in the study?	
What is the gender of participants?	
How much time on average will each study participant spend in the study?	
Will participants be compensated for their participation?	
If yes, how?	
Where will the study take place?	
Any other relevant information	
What will be the consent procedure?	
How will the confidentiality of the study participants be maintained? Data management issues (data management plan, analysis and storage)	
Potential risks to the participants and the enumerators	
What measures will be taken to handle any anticipated adverse events experienced by the enumerator and the participants?	
Potential benefits to the participants	
If the interviews require asking for high-risk behaviors (e.g. violence, family planning, decision making in households) what measures will the investigator(s) take to ensure that the interview is conducted in complete privacy?	
How will the findings of the study be presented?	
What could be any other possible ethical issues?	
Any other pertinent information with reference to the local context:	

For IRB Official Use Only:

RADS ethical committee decision:

This request for ethics approval has been:	
a. Approved (no additional ethics form is necessary)	☐
b. Approved with conditions (see below comments)	☐
c. Declined	☐
Comments:	

For Official Use:

Date of Application Received:	Protocol No.	
Full Review	Expedited Review	Renewal or Modifications