Procedures for Submission of IRB Application

1. Prepare a cover letter requesting a review and a brief summary of study.

2. Proposal: The completed proposal shall contain the following information:

   - Body of Proposal:

     - Statement and a brief description of the area of the proposed study, including the hypothesis to be tested, where appropriate, and the information expected from the study.

     - Review of the literature – briefly summarize research already accomplished with emphasis on any significant contributions.

     - Study design – outline precisely what is to be studied, tests or instruments to be administered and what is to be done with the sample. This section should be sufficiently clear and complete to enable the IRBPH to arrive at an independent judgment of the scientific merit of the research. The investigator should include copies of little-known scales or tests, if their submission will facilitate review.

     - Possible risks and benefits to subject population. Particular attention should be given to the following factors in assessing risks and benefits:

       1. Interference with ongoing treatment programs.

       2. Inconvenience or psychological stress that might arise because of the nature of the subjects being studied.

       3. Depending on the nature of the data to be collected, what measures will be taken to protect the subjects from embarrassment or compromise of their rights to privacy.

       4. The procedures which the investigator and staff will follow to provide confidentiality of the information generated by the study and of the identity of the subjects must be precisely described and deemed by the IRBPH as adequate. The investigator must obtain consent of the subjects before furnishing information to organizations and to individuals other than the study staff. The investigator should pay special attention to audio or visual recordings of the subject, because of greater potential for violations of the subject's right to privacy, and the investigator must demonstrate to the IRBPH the provisions made to maintain confidentiality of the information in such recordings. The investigator must obtain the subject's consent for any long-term retention of the recordings, and for any showing of visual recordings or playing of audio recordings, including such use for educational purposes, to persons other than those conducting the study.

5. In the case of pharmacological research, a detailed outline of known or suspected risks must be presented. Information must be provided to document the competence of the facility and the investigators to deal with such complications as may be reasonably foreseen.

6. If significant physical or psychological risk is associated with the project, a statement as to the investigator's ability, and the institutional resources available, to provide adequate treatment to the subject should any complications occur, must be presented.

7. Whether benefits to the subject are likely to be immediate or whether they are anticipated as providing new knowledge which might, in the future, lead to improved treatment programs.

- Analysis of data
  1. State the use that will be made of raw data.
  2. Describe method by which findings will be evaluated.
  3. Outline statistical or other means of evaluation.
  4. State how the data will be stored.
  5. State how and when the data will be transported.
  6. State how and when the data will be destroyed.

3. Confidentiality Agreement. To be signed by any employee, staff, consultant, subcontractor, agent, representative or any other persons involved in the research who will have access to confidential data/information. It should include that he/she recognizes the individual responsibility to hold such data/information in confidence and is also aware of the potential legal penalties for unauthorized disclosure of confidential data/information. Bibliography. References to literature cited should be included. Copies of pertinent articles may be attached if their submission will facilitate review.

4. Curriculum Vitae. When submitting a proposal, the principal investigator and project supervisor (when appropriate) should provide information on education and training which attests to their scientific qualifications to conduct the proposed research.

5. Informed consent. It should address the method for approaching prospective subjects and obtaining consent. The investigator must attach a proposed informed consent form, unless the investigator is recommending that the IRBPH waive the requirement for a signed consent form.

6. Researchers partnering with DC Health Agencies must submit a letter of agreement to collaborate from partnering DC Health Agency.

NOTE:

- The Principal Investigator must be available to present if required to the IRBPH Board a 10-to-15-minute presentation of the project.

- DC Health partnering representative must be present at IRBPH meeting.

- The investigator is required to make any changes in the research activities which are necessary to eliminate immediate hazards to human subjects. Changes of this nature may be made without seeking prior IRBPH approval. The IRBPH must be informed of these and any changes in the research activity.

- In the case of proposals submitted for expedited review, the Chairperson of the IRBPH may waive some of the above requirements for research proposals if approval of the project can be given on the basis of a summary statement.

- Investigators are encouraged to consider the review criteria used by the IRBPH and consult with members of the IRBPH at any time during the development of a proposal. The IRBPH will provide investigators with copies of relevant publications and rules relating to research, and insofar as its resources permit, assist investigators in developing proposals that meet the requirements of this Policy.

- Research Protocol will be reviewed by the DOH IRBPH Board on the scheduled meeting date. The Board will deliberate and submit a written decision (Approval or denial) to the PI within 10 business days after the review.

Submit an electronic copy of the completed application packet 10 business days prior to the IRBPH meeting date to DOH-IRB (DOH) doh-irb@dc.gov

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Checklist of documents to be included in the application package:

Document Required	**Check**
Complete the IRBPH application form found on the website: https://dchealth.dc.gov/service/institutional-review-board-public-health	
Cover letter requesting review and a brief summary of the study	
Proposal	
Curriculum Vitae	
Informed consent	
Confidentiality Agreement	
Letter of agreement to collaborate from partnering DOH Agency	
All instruments that will be used in the research/project (including recruitment flyers, coupons, vouchers, etc.)	
All instruments must be submitted in the language(s) that will be used in the research/project, i.e. English, Spanish, Amharic, Chinese, Vietnamese, etc.	

If there are any questions, please feel free to send an email to doh-irb@dc.gov.