Institutional Review Board
1204 Marie Mount Hall ● 7814 Regents Drive ● College Park, MD 20742 ● 301-405-4212 ● irb@umd.edu

INITIAL APPLICATION GUIDE

(A) IRB LIAISON SIGNATURE: The Application must be "shared with the IRB Liaison." The Application **must be electronically signed by the IRB Liaison or Alternate IRB Liaison** unless there is a conflict of interest. If the Department or Unit does not have an IRB Liaison, the Department Head, Unit Head or Designee should electronically sign the application.

(B) CITI TRAINING: The IRB Office **requires** all individuals engaged in human participant research at University of Maryland College Park to complete CITI Training every three (3) years. Individuals are **required** to take one of the following Basic Courses under Question 1 - Human Subjects Research depending on the scope of their research:

- Biomedical Research Investigators - 14 Modules
- Social and Behavioral Research Investigators - 11 Modules

Please visit www.citiprogram.org and create a username and password to begin the training. If you have any questions, please contact the IRB Office at irb@umd.edu or (301)-405-4212.

Please provide the following information in a way that is intelligible to lay persons/non-specialists in your specific subject area. Please use the Initial Application – Part 2 Template Document.

1. **ABSTRACT:** Provide an abstract (roughly 200 words) that describes the purpose of this research and summarizes the strategies used to protect human subjects.

2. **SUBJECT SELECTION:**

   a) **Recruitment**: Please state the population you plan to enroll and how you plan to recruit. If you plan to advertise (flyer, web, email, letter, phone script, etc.) for subjects, a copy of all advertisements must be uploaded as a **Supporting Document**.

   b) **Eligibility Criteria**: Please outline any Inclusion and Exclusion Criteria (e.g., age, sex, race, ethnic origin, religion, or any social or economic qualifications).

   c) **Rationale**: State why the selection will be made on the basis or bases given in 2(b).

   d) **Enrollment Numbers**: State the total number of subjects you plan to enroll (e.g., all groups, adults, adolescents, etc.). If unsure, provide an estimate of the maximum number of participants.

   e) **Rational for Enrollment Numbers**: Provide rationale for selecting the enrollment numbers stated in 2(d).

3. **PROCEDURES:** Describe in detail your methods and procedures in terms of what participants will be asked to do. State the amount of time participants will spend participating on each visit and in total.

    - If subjects will complete surveys and/or other instruments on more than one occasion, state the number of visits/follow-up contacts.

    - If you are using a questionnaire or survey, a copy must be included as a **Supporting Document**.

    - If you are conducting interviews/focus group/etc., a list of the questions/topics for the interviews/focus group must be included as a **Supporting Document.**

    - If you are collecting or studying existing data, describe the dataset and list the data elements that you will extract from the dataset.

    - If you plan to collect or study existing data, documents, records, pathological specimens or diagnostic specimens, state whether the sources are publicly available and if the information will be recorded in such a manner that subjects can be identified (directly or through identifiers linked to the subjects).

4. **RISKS:** State any potential risks to participants. If there are known risks, please list them. If not, please state that there are no known risks.

5. **BENEFITS:** State any potential direct benefits to participants. If none, please state no direct benefits. Please also state the potential overall benefits to be gained from this research (new knowledge, improving practices, etc.)

    - If there are known risks associated with the subject's participation in the research, please state what potential benefits will accrue to justify (outweigh) taking these risks.

    - Incentives and compensation are not considered benefits. Please add this information to Section 3 – Procedures.

6. **CONFIDENTIALITY:** Adequate provisions must be made to maintain the confidentiality of identifiable information and data collected. Explain what measures are in place to maintain confidentiality. This information must include: data storage (locked file cabinets/offices, password protection, etc.), data location and duration, description of persons with access to the data, and the method of destroying the data when completed.

    - If the research involves audio taping, videotaping or digital recordings, state who will have access to the tapes or recordings, where the tapes or recordings will be kept, and state the final disposition of the tapes or recordings. If tapes or recordings will be destroyed, please state when this will occur.

7. **CONSENT PROCESS:** State how participants will be presented with informed consent. For example: written informed consent form, information sheet, oral script, introductory paragraph before survey, etc. The appropriate consent document(s) must be included

as a **Supporting Document**. State how and when informed consent will be obtained. Please see the **Consent Form Template** to create a consent document.

- State how all participants will receive a copy of the consent form for their records.
- State the measures in place to protect participant privacy during the consent process (behind closed doors, private area, away from others, etc.).
- If participants will not sign a consent form (via physical or typed signature) and will instead verbally agree to participate or click a button to consent, address at least one of the Waiver of Consent Documentation criteria.
- State if any part of this project involves deception, such as presenting participants with a false purpose of the study or providing false information about the procedures. If so, refer to the Deception Resource section on What to include in a study with deception. Please note that this requires addressing all of the Alteration of Consent criteria.
- If participants will not be approached at all for consent, address the Full Waiver of Consent criteria.

NOTE: The consent forms in your approved IRBNet PACKAGE must be used. When creating or editing your consent form, please provide the most recent IRBNet package number at the bottom, right corner of the consent form. This ensures you are using the most "up-to-date" version of the form.

To find your IRBNet package number, go to the MY PROJECTS tab and click on the title of your project. In the PROJECT OVERVIEW page, your IRBNet package number will be listed at the top, next to your project title.

8. **CONFLICT OF INTEREST:** If there is no anticipated conflict of interest, please state "No conflict of interest."

   Describe the potential conflict of interest, including how such a conflict would affect any potential risk to study participants. Please consult the University of Maryland policy on conflict of interest as defined by the University of Maryland Policies and Procedures III-1.11and II-3.10.

   These may be viewed at: Policy on Conflict of Interest in Research and Development.

9. **HIPAA COMPLIANCE:** If you are not using HIPAA protected health information, please state "Not Applicable."

   If you are using PHI, please state what data elements you will be collecting and how they will be used. If a HIPAA Form will be used, it must be included as a **Supporting Document.** For more information on HIPAA and obtaining authorization, please visit the IRB Website: HIPAA.

10. **RESEARCH OUTSIDE OF THE UNITED STATES:** If you are not conducting research outside the U.S., please state "Not Applicable."

If you are conducting research outside of the U.S., please provide responses to the following questions. Separate responses are required for each country where the research will be conducted.

a) Has the investigator(s) previously conducted research in the country where the research will take place? Briefly describe the investigator's knowledge and experience working with the study population.

b) Are there any regulations, rules or policies for human subjects research in the country where the research will take place? If so, please describe and explain how you will comply with the local human subject protection requirements. The United States Department of Health and Human Services, Office for Human Research Protections (OHRP) has an International Compilation of Human Subject Research Protections with a listing of the laws, regulations and guidelines of over 131 countries. This compilation can be accessed on the OHRP website: International Compilation of Human Research Standards. The OHRP website also provides a List of Social Behavioral Research Standards, which includes information on 27 social behavioral research laws, regulations, and guidelines from around the world.

c) Do you anticipate any risks to the research participants in the country where the research will take place, taking into account the population involved, the geographic location, and the culture? If so, please describe, including any physical, psychological, social, legal and financial risks. Do you anticipate that subjects who participate in this research will be placed at risk of criminal or civil liability? If so, please describe.

11. RESEARCH INVOLVING PRISONERS: If you are not conducting research involving prisoners, please state "Not Applicable."

If you are conducting research involving prisoners, please provide responses to the following additional IRB criteria for research involving prisoners. For more information, see: Prisoner Involvement in Research.

a) The research under review represents one of the categories of research permissible described below:

i) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

ii) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

iii) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or

iv) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

b) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

c) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

d) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

e) The information is presented in language which is understandable to the subject population;

f) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and if there is a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Supporting Documents:
The application must include Document Wizard – IRB Initial Application Part 1 (On-Line Document), Initial Application Part 2 (Please use the Initial Application – Part 2 Template which contains the information required in items 1-11 above), and all relevant Supporting Documents including: Consent Forms, Information Sheets, Recruitment Materials (letters, telephone scripts, advertisements, etc.), surveys/questionnaires, and any other material that will be presented, viewed or read to human subject participants.

Minimal Risk:
If the protocol presents no greater than minimal risk, it will be processed via Exempt or Expedited Review. This means the protocol will not be reviewed by the Full Board. The protocol will be reviewed and approved by the IRB Chair or designee. **Please Note:** The IRB Office reserves the right to take any submitted application to the Full Board for review.

Greater than Minimal Risk:
If the protocol presents greater than minimal risk, please check the IRB Website for the submission deadline for the next IRB Meeting. Full Board reviews are required for initial applications involving greater than minimal risk to the subjects (i.e., more risk than subjects would generally encounter in their daily activities or a routine doctor visit).