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

READ ME FIRST

STEPS TO SUBMIT INSTRUCTIONS: Review your respective in-depth steps to submit instructions on the IRB Process page.

HUMAN SUBJECT RESEARCH DETERMINATION FORM
INITIAL APPLICATION
AMENDMENT/CONTINUING REVIEW/REPORTABLE EVENT

HUMAN SUBJECT RESEARCH DETERMINATION FORM

Complete and upload this form and have the Principal Investigator sign off on the package. This Form can be submitted without Initial Application Part 1 or an IRB Liaison signature.

THIS IS NOT AN IRB APPLICATION. THIS IS TO DETERMINE IF YOUR PROJECT NEEDS IRB REVIEW IF YOU ARE UNSURE.

INITIAL APPLICATION

1. **PART 1:** If this is an **Initial Application** IRBNet you must complete **Initial Application Part 1**:
   - **Where?** – Click **Designer** tab and then **Start a Wizard** button. Select **UMCP – IRB Initial Application Part 1** from the drop down box near the lower middle of the page.
   - This will create a "Smart Form" document online that captures necessary reportable information for the IRB to conduct their review.
   - Once Initial Application Part 1 is complete, it will be automatically added to the Documents list under Designer as a PDF.
   - **Only Once:** Initial Application Part 1 is only required to be completed once. Future packages (transactions) under the project only need the application form and any relevant supporting documents.

2. **UPLOAD PART 2 AND OTHER MATERIALS:** Once Initial Application Part 1 is complete, upload your completed Initial Application Part 2 and any supporting documents (recruitment materials, consent forms, surveys, etc).
   - **How?** - Click Designer and then Attach New Document to upload a new document.

- **Templates:** These can be found under the **Forms and Templates** tab. Then select the library from the drop down box: **UMCP IRB – Documents for Researchers**. This library is also located on the top of the Designer page.

3. **SHARE THIS PROJECT:** Share with those who need to have access to this project. An Initial Application must be shared with and signed by your **IRB Liaison** in order for the IRB to begin reviewing your project.
   - Click Share this Project, and then click Share. Select University of Maryland College Park and Search for a User.
     - Colleagues at other institutions can create an IRBNet account under their institution in order to have a UMD project shared with them. If this is the case, you will select their institution (not UMD).
   - If a User cannot be found, that User does not have an IRBNet account. He/She must register for an account in order to have a project shared with them.
   - **Access Tips:** IRB Liaisons should receive "Signature Only (Read)" access. "Full" access should be given to those responsible for submitting packages, sharing access with others and making requested changes.

4. **LINK TRAINING:** All members of the research team (Investigators and Advisors if applicable) must link their **CITI Training Completion Report** to each project they are a part of.
   a. Save your CITI Training Completion Report as a PDF to your computer. www.citiprogram.org
   b. Click User Profile (upper right corner) in IRBNet and click Add a New Training & Credentials Record.
   c. In your un-submitted or unlocked project, click Designer and click **"Link/Unlink Training"** near the middle of the page (the text is small).
   d. Users must have FULL or WRITE access to link.

5. **SIGN THIS PACKAGE:** The Principal Investigator's signature and the required IRB Liaison signature must be present before the application will be accepted by the IRB Office. Please note: **If you are a student**, you must have your Faculty Advisor sign off on your submission.
   - Click **Sign this Package** and follow the instructions.

6. **SUBMIT THIS PACKAGE**: Click **Submit this package** and follow the instructions. Please note: be sure to select the IRB as the Board as opposed to the IACUC.

AMENDMENT/CONTINUING REVIEW/REPORTABLE EVENT

NEW PACKAGE: If you are submitting an Amendment/Continuing Review/Reportable Event to a currently approved project in IRBNet you must **Create a New Package**:

1. Go to My Projects and click on the title of the project you wish to update.
2. Click the Create a New Package button on the left of the screen under the Project Administration heading. This will create a new package so you can upload and submit your new documents.
    a. A new package number will be added. For example, you will have 123456-1 and 123456-2 and so on.
3. Upload the new package documents (Amendment Application and any revised materials, Continuing Review Application and the most up-to-date consent form, Adverse Event Form, Deviation Report).
4. Click Sign this Package. Follow the instructions.
5. Click Submit this Package. Follow the instructions.