

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

## **IRB** Submission Tips

(1) **IRB Liaison Signature**. All initial application submissions have to be "signed" by the IRB Liaison for the Department in IRBNet before the IRB will review it. If you sign and submit it to the IRB before that, the IRB will send it back and request that your Department Liaison sign it first. Please give the IRB Liaison "Read" status when sharing. "Read" status (rather than "Full") prevents the Liaison from getting emails every time there is a change to the submission's status.

The IRB recommends including a message to the Liaison when sharing the submission with them to let the Liaison know that the project is ready for their signature.

The Liaison will then review the submission materials and you should receive a notification from IRBNet via email when they have signed off.

(2) **Required Training**. A completed CITI training certificate is required for anyone listed on the Part 1 Application (Principal Investigator, Faculty Advisor, and Co-Investigators). This will be titled either "Social and Behavioral Research" or "Biomedical Research." CITI training certificates need to be linked to your User Profile in IRBNet and then linked to each individual package. Instructions can be found <u>here</u>.

(3) **Required Materials.** There will be some exceptions to this (such as secondary data analysis studies), but for most studies that involve engaging with human participants, there are four types of files that need to be submitted in a complete IRB application:

(i) Initial Application Part 1: This is a form filled out on IRBNet that describes some basic information about the study.

(ii) Initial Application Part 2: This is a document uploaded to IRBNet that describes the study's purpose, participants, procedures, risks, and benefits. The audience is IRB Staff and IRB Committee members, who are well-educated and experienced with IRB submissions but most likely not experts in your particular area of work. The template is available on IRBNet and on the <u>IRB website</u>. A <u>completion guide</u> is also available to assist with preparing the document.

(iii) Consent Form: This is a document uploaded to IRBNet that helps participants understand what will be asked of them if they decide to participate in the research. Therefore, the audience of the consent form is potential participants of the study. You can find a template consent form on IRBNet and on the <u>IRB website</u>. A <u>completion guide</u> is also available to assist with preparing the document.

(iv) Any materials participants or prospective participants will engage with: Common examples include recruitment flyers, recruitment emails, and surveys.



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(4) **Tips for Preparing Materials.** Some general advice on IRB submissions that can help speed along your review:

- → Advisor Review. For students, advisors should carefully review all materials before signing off in IRBNet. Advisors will have expertise in the area of study and can provide content-specific feedback that Liaisons and the IRB Office may not be able to provide.
- → Consider the Audience. Readers will not likely be members of your field, and participants will not likely be trained researchers. Avoid field-specific jargon and avoid abbreviations/acronyms that are not essential. In the consent form specifically, use language that a layperson can understand. Make the procedures of the study very clear and make it very clear what participants will actually be signing up to do. Describe everything that their participation will involve.
- → Consistency. Between the Initial Application Part 2 and the Consent Form, there must be consistency in the inclusion/exclusion criteria, procedures, risks, benefits, and confidentiality measures. The language may differ because they are designed for different audiences, but the same things categorically need to be described in both documents. This is a very common modification that the IRB Office will send, if for example there are risks disclosed in one document that are not included in the other. This is also why the IRB does not recommend reusing previously approved documents for new projects. This can lead to discrepancies in the materials, resulting in more modifications.
- → Potential Risks. Unless the project is an anonymous survey of a non-controversial topic, be sure to consider potential risks such as: breach of confidentiality, discomfort, or being reminded of a past trauma. Be sure to state how each listed risk will be mitigated.
- → Potential Benefits. Many studies will have no direct benefits to participants, which is permissible as long as the potential overall benefits outweigh any risks. In the Initial Application Part 2 and in the Consent Form, if there are no direct benefits, be sure to also describe any potential overall benefits, such as new scientific knowledge or practices.