

**University of Maryland School of Medicine
Office of Student Research**

Proposed Research Initiated by Students and Mentors (PRISM) Program

IRB and IACUC Instructions

Human Participants/Data and Animal Subjects

If your research involves human participants or data or animal subjects, please see instructions below regarding required additional documents to be submitted to the program. You should consult your research mentor. If necessary, contact the [Human Research Protections Office](#) or the [Office of Animal Welfare Assurance](#) for clarification.

A. Required Documents

1) Human Participants or Data

If human participants or data will be involved in the proposed research, you must provide a copy of the approval letter issued by the Institutional Review Board (IRB) which shows 1) the protocol review number for the approved procedure to be used in the research and 2) the approved period that covers the duration of the proposed research. If a protocol falls under an exempt category of IRB review, an IRB exempt determination letter must be provided. If a protocol involves human participants or human data but does not require IRB review, the determination of whether IRB review is required must be made by the IRB, and an IRB determination letter or determination email must be provided.

2) Animal Subjects

If vertebrate animal subjects will be involved in the proposed research, you must provide a copy of the approval letter issued by the Institutional Animal Care and Use Committee (IACUC) which shows 1) the protocol review number for the approved procedure to be used in the research and 2) the approved period that covers the duration of the proposed research.

3) Addition onto the Protocol

If appropriate according to IRB or IACUC requirements, you must be formally added to the applicable protocol before you can begin the research.

B. Submission Deadlines

1) Existing, Currently Approved Protocols

For existing protocols that are currently approved, the approval letter or determination letter must be submitted **by the program application deadline**.

- If the IRB or IACUC protocol is currently approved at the time of application submission but the approval will expire by the application deadline or shortly thereafter before the summer (before the start of the program):
 - a) Both the existing current approval letter showing the expiration date and proof that the protocol has been submitted for renewal or modification must be submitted **by the program application deadline**, AND
 - b) The updated approval letter must be submitted **by noon on April 23, 2021**.

- If the IRB or IACUC protocol is currently approved at the time of application submission but the approval will be expired during the summer (during program period):
 - a) The existing current approval letter showing the expiration date must be submitted **by the application deadline**. AND
 - b) Proof that the protocol has been submitted for renewal or modification must be submitted **by noon on April 23, 2021**. AND
 - c) The updated approval letter must be submitted **before the expiration date**.

2) Pending Protocol Approvals

If the applicable IRB or IACUC protocol approval is pending at the time of application due to a new protocol or the modification or renewal of an existing protocol, you must provide proof that the protocol has been submitted by the program application deadline and provide the required approval or determination letter **by noon on, April 23, 2021**.

- If the IRB or IACUC protocol had previously been approved (with current approval letter that is not expired) but the protocol is being modified at the time of the application or the approval is in the process of being renewed through continuing review:
 - c) Both the existing current approval letter showing the expiration date and proof that the protocol has been submitted for renewal or modification must be submitted **by the program application deadline**. AND
 - d) The updated approval letter must be submitted **by noon on April 23, 2021**.

3) Exclude from Consideration

If the required IRB or IACUC documentation is not provided by the applicable deadline, the application will not be considered for the program or removed from the program.