HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

Preparing your eResearch Application for IRB Review
August 12, 2020

This guidance is intended to assist researchers to prepare their eResearch applications such that it moves through the IRB review process as effortlessly and promptly as possible.

Please also consult the IRB-HSBS website https://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs which has helpful information and templates for use in preparing your application.

Some key information has been provided below and you are encouraged to read through this guidance prior to starting your eResearch application.

ALL IRB-HSBS APPLICATIONS

1. Each IRB application is for a specific research project with unique aims and goals. After approval of the main application, if you plan to do a sub-study or add a new cohort, you may want to discuss this first with your IRB staff liaison. The IRB will evaluate whether the change is consistent with the stated aims and goals for the approved research. If the research aims and goals change, you may be asked to do a new application for the new research.

2. Ensure that you have completed the required Human Subjects research module in the U-M PEERRS system (http://my.research.umich.edu/peerrs/). This module is required for all key personnel (PI, Co-I, FA, or Study Coordinator). Please note that anyone "engaged" in the research (i.e., those consenting subjects, interacting/intervening with subjects, or who will have access to identifiable subject data), must also complete the Human Subjects module in PEERRS.

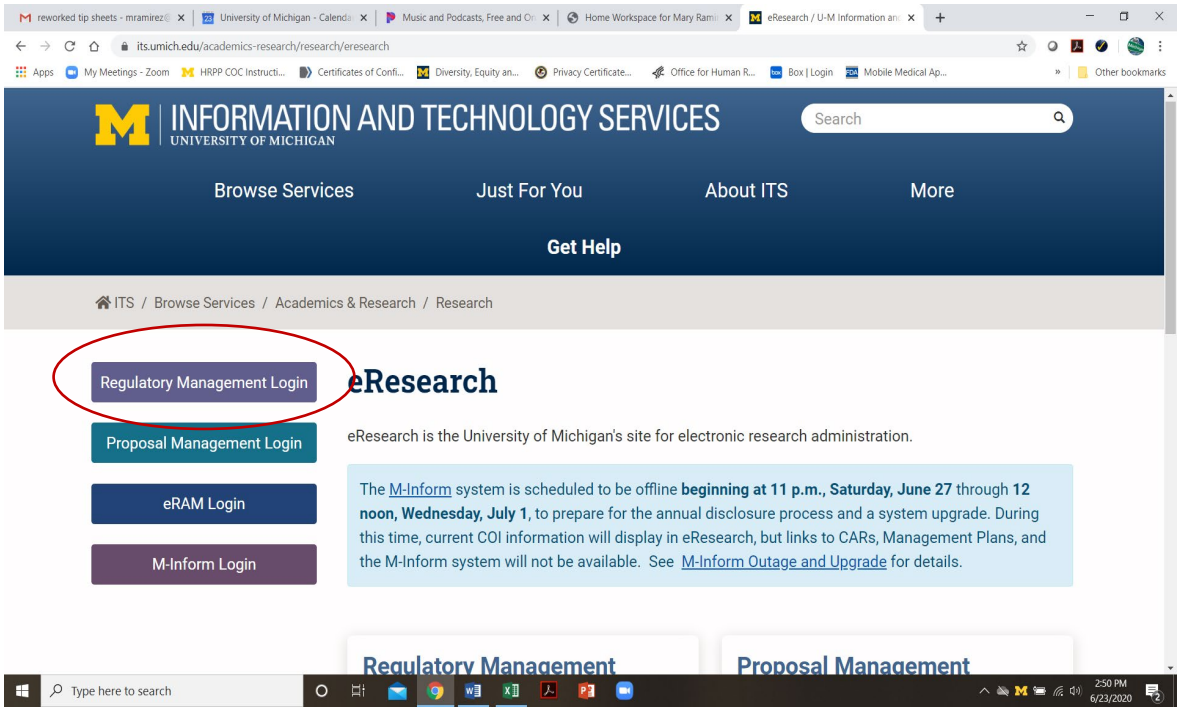
Administrative Staff are not required to have PEERRS certification since, typically, they are not engaged in the conduct of the research; their role is primarily clerical/administrative, with limited to no direct contact with subjects.

If you have human subjects training from another institution or agency (e.g., CITI), you can submit a waiver request to the PEERRS office to meet the U-M requirement.

3. All students and other trainees who are acting as the PI (e.g., post-docs) are required to have a Faculty Advisor listed in the study team in 1.3. If you are unsure about this requirement, consult with your IRB staff liaison.

4. ***CREATING A NEW APPLICATION***

Logging into eResearch: If you have never logged into the eResearch Regulatory Management system go to https://its.umich.edu/academics-research/research/eresearch and find the purple Regulatory Management Login button found on the screen's upper left side. Click this button and you will be taken into your specific eResearch workspace.



To start a new application: Look to your left for the My Roles area. Confirm that your role is highlighted as "Study Team Member". Once you do this, look just below and find the Create New area. Click the button to 'Create a New Application'.

Navigating within the application: Use the on-screen **CONTINUE button** (located on the screen's lower right) to both move through your application, and to save your information.

The eResearch system is set up on conditional logic, so that as you respond to questions the eResearch system will route you to other specific sections based on your previous responses.

CAUTION: If you do not use the **CONTINUE button** to advance through the application, (e.g., you rely on the "jump to" menu), you could re-route yourself away from required sections. In general, SAVE often!

EXEMPT APPLICATIONS

Please go to the IRB-HSBS website directory and find the Exempt Consent Template and Exempt Studies: Brief Protocol including Data Management and Security Questionnaire documents.

Download and complete these two documents. Upload them into your application where instructed.

NOTE: Exempt 2 applications are limited in what they cover and do not permit secondary data use as part of the research.

NOTE: Exempt 3 applications that may include deception/concealment: Please include a statement in your consent form, telling subjects that they may be misled as part of the research, yet will learn the reason for this deception/concealment in a debriefing that you will provide them at the end of the data collection. If debriefing occurs at the end of the study, please briefly describe your justification within the IRB application. Upload a copy of your debriefing script/statement to your application.

EXPEDITED APPLICATIONS

Please do not upload your dissertation or grant proposal. Either upload a concise stand-alone protocol into section 5.1 or enter the information into section 5-1.5. A simple research methodology/protocol template can be found on pages 5-6 below. By the time you submit your IRB application, you should have a clear idea of your research and procedures, and your application should tell us what you will do; not what you might do.

Please describe in your protocol whether you will be limiting your recruitment to those potential subjects located within the US; if not, other regulations may come into effect.

On all of your documents, recruitment flyers, consent, debriefing forms please leave a 1 inch margin at the top, which allows us to effectively date/stamp your documents. Once final approval is issued, you will find the IRB approved documents under the Documents tab on the front page of your HUM. You should only use the IRB approved documents found under the Documents tab.

The eResearch IRB application works best with WORD documents. Ensure that any documents that are uploaded into sections 5.1, 8-1.8, or 10-1.1 are WORD documents.

5. *IF USING THE PSYCH SUBJECT POOL*

If applicable for your consent form please include, "You can also meet your Introductory Psychology methods requirement by completing alternative assignments or other studies within the pool. For more information, please contact subjectpool@umich.edu." This is a department requirement.

6. *WHEN CREATING AN AMENDMENT TO AN EXPEDITED APPLICATION*

Please see the documents, Amendment: What Study Teams should Do when Amending the Application (guidance with graphics) AND Amendment: eResearch Instructions for Creating Submission found at the IRB-HSBS website directory. An amendment is required for most changes to your application. If you are unsure as to when to submit an amendment, please post a correspondence to your staff liaison and be sure to select the staff name so that they receive the system notification of your message.

NOTE: Changes to currently approved applications must be reviewed and approved by the IRB before the study team may implement the changes, UNLESS changes are necessary for subject safety.

NOTE: Exempt applications typically do not require amending IF the changes continue to meet the requirements of the Exemption category. If you are unsure, please consult with your IRB-HSBS staff liaison.

SIMPLE PROTOCOL for NON-EXEMPT PROJECTS

This simple protocol is only suggested; it is not required for IRB review.

This checklist and template serves as a guide for how to layout the scientific design of your research within the eResearch application. The information you provide should provide the overall view of your protocol and describe all research procedures and subject interactions. Once you draft the protocol, you may either copy and paste the information into section 5-1.5 or upload the stand-alone protocol document into section 5.1.1.

NOTE: Copy and paste relevant information from the protocol into specific sections of the eResearch application to ensure consistency.

Generally, you will explain the research as a step-by-step process following this order:

- Subject sample
- Recruitment & Screening
- Consent Process
- Description of what happens to the subject during the research
- Description of data storage, security, and plans for sharing
- Description of the type of compensation & method of distribution

NOTE: If procedures vary between subject populations, you should structure your description so that the procedures for each group are addressed within each category.

SUBJECT SAMPLE – Describe who will be the subjects of the research

- Who are the subjects of the research? (e.g., children, adults, students)
- How many subjects for each subject group will you seek to enroll into the research?

RECRUITMENT – Describe how you will recruit subjects for the research

- How, when & where recruitment will be conducted and by whom
- Methods of recruitment (i.e. flyers, emails, SONA)
- Describe how the subject will respond to the recruitment materials (i.e. phone, email, etc.)
- Upload documents for every interaction from first communication to just before consent (oral scripts, screeners, flyers, emails, SONA screen shot) in 8-1.8

SCREENING – Describe how you will screen for eligibility

- Provide a detailed description of how and when the screening will take place
- Describe whether the data you collect for screening will be used for any analyses (for both eligible and non-eligible subjects)
- Upload your screening script into section 8-1.8

CONSENT/ASSENT - Describe the process to obtain consent/assent

- Describe when the process will take place and who will obtain consent/assent
- Describe the manner in which consent/assent will be obtained (e.g., full written, oral)
- Describe the use of a translator, if applicable

- Describe how subject questions will be addressed
- Describe how subjects will be given a copy of the consent/assent document

NOTE: PIs should plan procedures for obtaining signed consent/assent that allow for providing subjects with a copy of the entire document. The PI should also plan to keep copies of the entire signed document as part of their records.

- Describe how much time the subject has to consider whether they want to participate in the study
- Upload a copy of the consent form into section 10-1.1

SUBJECT PARTICIPATION - Describe the details of what the subject will be doing during the course of their participation.

- Provide a detailed description of what the subject will do after you obtain consent/assent, how often specific procedures will be conducted; describe any biospecimen or biomeasures that will be obtained/taken
- Describe the data collection methods
    - Survey instruments: on-line, paper and pencil, CATI or other similar tools
    - Interviews: include when and where they will be conducted
    - Interventions (describe what it is and how it will be administered)
    - Describe video or audio recordings that the subject will see or hear
    - Describe whether video or audio recordings will be made of the subjects
    - Limit the screening questions to the eligibility criteria. Do not collect additional data in this document. End a screening survey at the first disqualifying response

NOTE: Videotaping refers to physical tapes/films, video recording refers to digital files; be specific as this has implications for the protection of data and subject identifiabilty. Also consider adding transcription, who/when/ how will subjects be identified in the transcripts, and how long original recordings be retained.

- Describe how the compensation will be managed (amounts, payment form, and process)
- Upload all survey instruments and interview questions in section 29
- Upload screenshots of any A-V materials in section 31

DATA STORAGE - Describe how the data will be transmitted, protected, and stored. Your IRB staff liaison may request that you complete the IRB-HSBS Data Management and Security Template for inclusion in section 44. Discuss whether you will collect or maintain any directly identifiable data. Discuss whether you will collect or maintain any data that Linking document, where stored, how subject ID is derived via a Data Management plan. Provide a description of any plans to share data after the research, including with non-UM collaborators on this research.

IMPORTANT: All sections of the application must be consistent with the methodology you provide in 5.1 or 5-1.5. Therefore, it is a good idea to copy sections of the methodology into the appropriate sections of the IRB application. For example, Recruitment & Screening will go in section 8-1. Consent will go into 10-1.1. Data Storage & Security will go into section 11/11-1. Compensation will go into section 13.