Instructions & Guidelines for Expedited or Full IRB Review

Research or projects that do not qualify as being Exempt from IRB review require more detailed information about the procedures of a study.

To determine whether your study can qualify for an **Expedited IRB Review** (two reviewers) it must satisfy both of the following:

1. Pose no more than "minimal risk" to subjects and
2. Qualify within one of the Expedited Categories

Decisions or requests for additional information for **Expedited IRB Review** applications are made within 2-3 weeks. If you are asked to submit more information, the same reviewers and/or the IRB chairperson will re-review your application considering the additional information and respond promptly. Incomplete applications and/or delays by the PI in providing the requested information will add additional time needed for protocol approval.

- Applications for **Expedited IRB Review** can be submitted at any time.
- Submit completed application along with attachments to the IRB Administrator, Jamie Hirota (jhirota@samuelmerritt.edu).

If your study does **NOT** qualify for an expedited review, your application will require **Full IRB Review**. This means that the application will be reviewed by a quorum of the IRB committee members. This is usually 5 to 6 reviewers. The IRB convenes every month except for August and December.

- Applications for **Full IRB Review** need to be submitted the first few days of the month for distribution to committee members in preparation for discussion of the protocol at the scheduled meeting.
- Submit completed application along with all required attachments to the IRB Administrator, Jamie Hirota (jhirota@samuelmerritt.edu). Please note: *to facilitate an efficient review process, attachments could be consolidated into a single pdf file and titled with your name or if each remains separate, group into a single folder titled with your name.*

You can download the *Word* version of the **Expedited or Full Review Application** that articulates the specific information needed within each section of the application and includes checkboxes to facilitate. Insert your responses directly into the document within the sections and subsections. All section items need to be addressed on the application, however it is possible that an item is not applicable to your study. In this case, indicate "N/A" to inform the reviewers that you have considered all the required components for human subject research.

- *Note: An electronic form is being developed and will be available Fall, 2023*

Overview of Application Content for Expedited or Full IRB Review
(see Application for complete details)

Section 1: Study Personnel
Section 2: Review Type and General Information

- Review Type
- Data being gathered
- Location of data gathering
- Funding

Section 3: Protocol Information

- Purpose and Research Questions/Hypotheses
- Brief explanation of the study (<300 words)
- Study design

Section 4: Study Procedures

- All events and activities

Section 5: Subject Population

- Expected age & estimated maximum number of subjects
- Involvement of potentially vulnerable subjects or SMU students or employees
- Subject Recruitment
- Subject Population Inclusion and Exclusion Criteria
- Subject Compensation

Section 6: Risks and Discomforts

- No greater than minimal risk or Greater than minimal risk
- Description of potential risks and and procedures to reduce the risk.
- Adverse effects of participation
- Subject deception

Section 7: Benefits/Alternatives

- Description of potential benefits
- Description of any alternative treatments and procedures available

Section 8: Procedures to Maintain Confidentiality

- Subject Identity
- Data Security

Section 9: Informed Consent

- Description of informed consent process
- Description of how subject consent will be obtained

Section 10: HIPAA
Section 11: Potential Conflict of Interest
Section 12: Attachments

- Recruitment notices; email communication script; project flyers
- Data collection instruments
- Any materials to be distributed to subjects during study procedures
- Letters of support from institutions or agencies where data is being collected
- Informed Consent
- Human subjects training (CITI training documents completed within past 3 years)
- *If available*, a full proposal with reference list