SOUTHWEST
TENNESSEE COMMUNITY COLLEGE

General Directions:

Review of Subsequent Events is required if an approved study is being modified, renewed, or reported as completed. These guidelines are also used when an Investigator reports an Adverse Event to the IRB. This review is necessary if the investigator wishes to make any change to the IRB approved protocol. This review is also required to renew IRB approval prior to the expiration date listed on the original approval letter. At this time, the researcher can request a modification, renewal and report an adverse event or report the study's completion in one submission by completing the appropriate sections listed below. The sections required are as follows:

- Modification - complete sections 1, 2 and 4.
- Renewal - complete sections 1, 2, and 3.
- Renewal with Modifications – complete sections 1 through 4.
- Adverse Events – complete sections 1, 2 and 5.
- Completion – complete sections 1, 2, and 6.

Provide answers that are clear, complete and succinct. Do not simply attach sections of research proposals or grant applicants. Avoid unnecessary jargon and define terms that are specific to your discipline, but not likely known to a competent reviewer. Finally, please provide a complete application. Unless otherwise noted, all sections of the application must be completed. This application must be complete before the IRB reviews the request.
Please use the IRB glossary in the policies manual for clarification of terms used in these guidelines.

Directions by Section

1. BASIC INFORMATION

a) *Lead Investigator ("LI")*. This section refers to the person who has overall responsibilities for the study. It is also the person who has primary responsibility for communicating to the IRB. Official IRB correspondence will be sent only in writing via e-mail to University sponsored e-mail accounts of the LI, Contact person, and faculty advisor where applicable.

b) *Contact Person*. For some projects the Lead Investigator will have a person who will manage correspondences. This person might be an administrative assistant or lab manager. Messages to the Lead Investigator will be sent via this contact person.

c) *Faculty Advisor*. Student investigators must identify a faculty advisor. This advisor is responsible to review and approve the Initial Review Request before it is submitted to the IRB. Faculty advisors are required to have a current CITI certification on file with the IRB prior to approving a student's submission. This section is only required if the lead investigator is a student.

d) *Study Information*. The lead investigator must provide an estimate of the likely number of participants required to address the project's questions. Listing co-investigators is optional. A co-investigator is considered someone who shares responsibility for the study as a whole. Any person who needs to listed on the IRB's approval letter needs should be here as a co-investigator.

e) *Affirmations.* Read carefully. Questions should be addressed to the IRB via effectivness@southwest.tn.edu.

2. Required Information for Review of all Subsequent Events:

This section must be completed in order for the IRB to review study related events that are subsequent to the IRB's most recent approval.

3. Study Renewal

All research projects must retain IRB approval or must be registered with the IRB as completed (see #6 below). IRB approval of non-exempt research lasts, at most, 12 months from the date of the previous approval. In order to

renew the IRB's approval, the investigator must submit a request to renew their study at least 30-60 days prior to the expiration of IRB Approval.

4. Study Modification

Prior to enacting any change to an approved study the investigator is required to submit a request to the IRB to review the proposed changes. For example, changes in data collection sites, investigators, sample size, exclusion or inclusion criteria, and assessment tools, and methods. For each study modification, the IRB reevaluates the determination of risk, consent documents, recruitment materials, and study methods and procedures as appropriate.

5. Adverse Events

What is an adverse event? *adverse event* in general is used very broadly and includes any event meeting the following definition:
Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

When these events occur the investigator must report the event to the IRB within 3 working days.

6. Study Completion

When should a study completion be filed? The lead investigator and/or the IRB may close approved protocols under certain circumstances. The lead investigator is responsible for promptly closing out an IRB approved study if any of the following conditions exist:

a) All research/clinical investigation activities including data analysis and reporting are complete;

b) The lead investigator never initiated the study;

c) Subject accrual is finished, all data collection is complete and the only remaining activity is analysis of the data, and there are no identifying links or codes to the de-identified data;

d) The lead investigator plans to leave the University and intends to continue the research activities at another institution;

e) The study has been open for a period of three or more years and the LI has enrolled no subjects in the study.

Please send the completed form via email to effectivness@southwest.tn.edu.

Institutional Review Board
Office of Institutional Effectiveness

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