

**SYRACUSE UNIVERSITY
HUMAN RESEARCH PROTECTION PROGRAM
STANDARD OPERATING PROCEDURES**

TITLE: IRB COMMITTEE DETERMINATIONS/ MOTIONS		DOCUMENT NUMBER: 010	
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Title: IRB COMMITTEE DETERMINATIONS/MOTIONS

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the Syracuse University (SU) Institutional Review Board's (IRB) operating policies and procedures for rendering of the IRB Committee determinations/motions following the review of applications for proposed research activities.

2.0 Policy:

The SU IRB has the implicit authority to approve, require modifications in, or disapprove all research involving human participants. All human participants research at SU, whether conducted by university faculty, staff, or students, must be prospectively reviewed and approved by the IRB unless determined to be exempt from review by application to the IRB. Approval from the IRB must be obtained prior to the formal recruitment of participants, obtaining informed consent, or initiation of research activities. The IRB is guided by a policy of proportionality. Within the discretionary decision-making permitted by the federal regulations, the IRB attempts to carefully weigh protections against risks. The greater the potential risks to participants, the greater the oversight that will be exercised by the IRB and the greater the protections that it will impose on Investigators whether or not required by the federal regulations. All applications to the IRB must be in writing and on approved forms available on the ORIP website and submitted to the ORIP office. All IRB determinations are sent to the Principal Investigator designated on the application or in the case of a Student Investigator, to the Faculty Advisor via campus mail to the address included on the application. When requested an email is sent in addition to the hard copy.

It is the policy of SU, ORIP and the IRB that all policies and procedures for rendering motions/determinations are in accordance with Federal regulations, state and local laws, other SU policies and procedures, and standards of regulatory, accrediting, and funding agencies. The written procedures are to be used to guide personnel through various procedural steps and to standardize practices to ensure the protection of human participants in research and promote the responsible conduct of research.

- 2.1 Approved.** An approval is granted if the research activity proposed in the application meets the criteria for approval as defined in 45 CFR 46.111 and no changes to the application are recommended.
- 2.2 Modifications Required.** Modifications required is determined if the research meets the criteria for approval as defined in 45 CFR 46.111, and the modifications required by the full IRB, or in the case of expedited or exempt research, the IRB Chair, are specific and only require basic modifications by the Investigator and the IRB does not request substantive clarifications or modifications that are directly relevant to the determinations required by the IRB. The application is subsequently approved if the modifications to the application have been made by the Investigator and reviewed and confirmed by the IRB Chair, or designated IRB member via written memorandum. If any of the requested modifications have not been made, or additional modifications have been made that were not requested, the application will continue to be deemed to be provisionally approved.

- 2.3 Disapproved (Withheld).** The research is disapproved if the study referred for full IRB review does not meet the criteria for approval as defined in 45 CFR 46.111 or the IRB recommends substantial revisions to the application, informed consent document(s), or other pertinent documents rendering it unable to assess the risk/benefit ratio without the completed revisions.
- 2.4 Sponsor-Imposed Suspension.** A sponsor-imposed suspension is when the IRB receives written notification that the sponsor has suspended the research study. This will be acknowledged via a memorandum by the ORIP Director in consultation with the IRB Chair when the IRB Chair determines the suspension is appropriate.
- 2.5 Suspension of IRB Approval.** An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB, the Investigator, or study personnel. A currently approved study may be suspended when evidence of a possible increase in risk to participants or non-compliance by the Investigator has been determined by the IRB. Suspensions of IRB approval are made by the full IRB or by the IRB chair or designee through the Administrative Hold process. (See *SOP 029*).
- 2.6 Closed.** A currently approved study is closed when continuing review has not been conducted and approved prior to the study's expiration date.
- 2.7 Termination of IRB Approval.** An action initiated by the IRB to stop permanently some or all research procedures. A currently approved study may be terminated if the study is not being conducted in accordance with the IRB policies, is not in compliance with Federal regulations, or has been associated with unexpected serious harm to participants. Terminations of IRB approval are made by the full IRB.

3.0 References and Reference Documents:

45 CFR 46.111

45 CFR 46.102(h)

SOP 012 on IRB Review of Human Subjects Research: Expedited

SOP 013 on IRB Review of Human Subjects Research: Full Board

SOP 029 on Suspension or Termination of IRB Approval

4.0 Procedure:

This procedure describes the process for the rendering of the IRB Committee determinations/motions following the review of proposed research activities.

4.1 IRB Responsibilities.

4.1.1 Approved.

If approval is granted, the research activity meets the criteria for approval as defined in 45 CFR 46.111 and no changes to the research application are recommended.

4.1.2 Modifications Required.

If "modifications required" is determined, the research meets the criteria for approval as defined in 45 CFR 46.111, and the modifications required by the full IRB, or in the case of expedited or exempt research, the IRB Chair, are such that they only require basic modifications by the Investigator. The recommended modifications are made to the IRB Application and the informed consent document(s), or other pertinent documents before final IRB approval can be granted. The IRB provides a letter to the Investigator stipulating the specific modifications required for approval.

4.1.3 Disapproved (Withheld).

If the research is disapproved, the study referred for full IRB review does not meet the criteria for approval as defined in 45 CFR 46.111 or the IRB recommends substantial revisions to the IRB Application, informed consent document(s), or other pertinent documents rendering it unable to assess the risk/benefit ratio without the completed revisions. The Investigator's response is reviewed by the full IRB. The IRB may also invite the Investigator to address the concerns of the IRB at the next convened meeting.

4.1.4 Sponsor-Imposed Suspension.

If a sponsor imposes a suspension the IRB receives written notification that the sponsor has suspended the research study. This will be acknowledged by the IRB Chair or designee when the appropriate level of review determines the suspension is appropriate. The IRB may impose additional criteria for suspension, if needed, to protect the participants from potential harm.

4.1.5 Suspension of IRB Approval.

The IRB initiates an action to stop temporarily some or all research procedures pending future action by the IRB, the Investigator, or study personnel. A currently approved study may be suspended when evidence of a possible increase in risk to participants or non-compliance by the Investigator has been determined by the IRB. Suspensions of IRB approval are made by the full IRB or by the IRB Chair or designee through the Administrative Hold process (See *SOP 029*).

4.1.6 Closed.

If a currently approved study is closed, continuing review has not been conducted and approved prior to the study's expiration date.

4.1.7 Termination of IRB Approval.

The IRB initiates an action to stop permanently some or all research procedures. A currently approved study may be terminated if the study is not being conducted in accordance with the IRB policies, is not in compliance with Federal regulations, or has been associated with unexpected serious harm to participants. Terminations of IRB approval are made by the full IRB (See *SOP 029*).

4.2 Investigator Responsibilities.

4.2.1 Approved.

If approval is granted, upon notification of approval the Investigator may begin the research.

4.2.2 Modifications Required.

4.2.2.1 If "modifications required" is determined, the Investigator responds to the IRB's recommendations in a memorandum outlining the changes requested and the rationale for any changes not incorporated. The Investigator includes in the response a copy of any revised documents in their entirety (See *SOP 012* and *SOP 013*). Clean copies of consent document(s) are included for date stamping upon final approval.

4.2.2.2 Amendments receiving provisional approval may not be implemented until a satisfactory response by the Investigator has been received and final approval has been granted in a written letter of approval by the IRB.

4.2.2.3 The Investigator may not start the research until all conditions outlined in the memorandum from the IRB Chair have been met and the IRB Chair or designee has signed a final written approval letter.

4.2.3 Disapproved (Withheld).

4.2.3.1 If the research is disapproved, the Investigator responds to the IRB's recommendations in a memorandum outlining the changes and the rationale for any changes not incorporated. The Investigator includes in the response a copy of

any revised documents in their entirety. Clean copies of consent documents are included for date stamping upon final approval.

4.2.3.2 Amendments which are disapproved are not implemented until a satisfactory response by the Investigator has been received and final approval has been granted in a written letter of approval by the IRB.

4.2.3.3 The Investigator may not start the research until all conditions outlined in the memorandum from the IRB Chair have been met and the IRB Chair or designee has signed a final written approval letter.

4.3 ORIP/IRB Administrator Responsibilities.

4.3.1 The ORIP/IRB Administrator captures in the minutes the determinations and motions made during the full IRB meetings.

4.3.2 The ORIP/IRB Administrator prepares all letters, correspondence and memoranda pertaining to the IRB's determinations.

4.3.3 The ORIP/IRB Administrator tracks the follow-up dates for Investigator responses based on the determinations and sends reminders of the impending expiration date of applications to the Investigator.

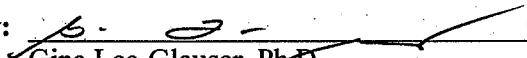
4.3.4 The memorandum from Investigators and the applications given provisional approval are reviewed and changes are verified. The ORIP/IRB Administrator completes final approval letters. Upon completion, the determination letter is sent to the Investigator and a copy placed in the IRB protocol file.

4.3.5 Responses from Investigators for motions of disapproval are prepared for the full IRB for further review and determination.

4.3.6 The ORIP/IRB Administrator makes appropriate database entries into *InfoEd* for motions and responses to determination letters.

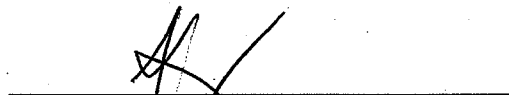
SOP 010: IRB COMMITTEE DETERMINATIONS/MOTIONS

Approved by:



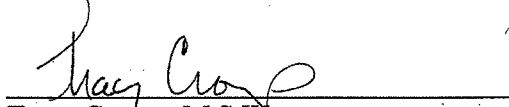
Gina Lee-Glauser, Ph.D.
Institutional Official
Vice President for Research
Syracuse University

6-14-2010
Date



Kathleen King, Ph.D.
Chair of the Institutional Review Board
Syracuse University

11 June 2010
Date



Tracy Crop, M.S.W.
Director of Office of Research and Integrity Protections
Syracuse University

6-11-2010
Date