

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
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Approved By: ORI Director	Signature	Date	Date First Effective: 10-15-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	
Approved By: SURE IRB representative	Signature	Date	Revision Date: 11-01-08

OBJECTIVE

To describe the procedures for the coordination between the Institutional Review Board (IRB)/Office of Research Integrity (ORI) and the Subject Use and Research Ethics (SURE) Committee on protocols to be conducted through the University of Kentucky (UK) Psychology Department

GENERAL DESCRIPTION

Both the SURE Committee and the IRB are committed to ensuring the protection of human subjects involved in research. They have enacted a number of coordination activities in significant areas including: joint committee membership; protocol review; training for SURE Committee/IRB personnel; complaints and alleged noncompliance; quality assurance/improvement findings; and joint policy/procedures.

RESPONSIBILITY

Execution of SOP: SURE Committee, SURE IRB representative or designee, IRB Members, ORI Staff, ORI Research Compliance Officer (RCO), ORI Director, Principal Investigator (PI)/Study Personnel

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PROCEDURES

Joint Committee Membership

1. The SURE IRB representative serves as the primary liaison for ensuring coordination between the SURE Committee and the IRB with respect to nonmedical protocol review and modification requests.
2. The SURE Committee consists of three (3) faculty members, one of whom is also an IRB member. The SURE IRB representative is a member of the IRB and serves as the IRB expedited and exempt reviewer for SURE protocols.
3. The ORI Director or designee serves as an ex officio non-voting member of the Nonmedical IRB and as primary liaison in the development of joint SURE IRB policies and procedures.

Protocol Review Procedures

1. The PI makes a preliminary determination that a protocol is eligible for review by the SURE IRB representative. The SURE Committee and the IRB make the final determination regarding whether a protocol is eligible for IRB or SURE review. (To be eligible for review by the SURE IRB representative, a protocol must meet the criteria for either exempt or expedited review and enroll subjects from the PSY100 Introductory Psychology subject pool only.)
2. The PI submits a completed expedited or exempt IRB application to the SURE IRB representative.
3. Upon receipt of the application, the SURE IRB representative screens the application to determine whether the application meets the criteria for SURE and IRB exemption or expedited review. If the application does not meet the criteria for expedited or exempt review, the SURE IRB representative advises the PI that he/she could consider resubmitting to the full IRB for review. For example, the IRB representative may determine the study involves greater than “minimal risk” as defined in 45 CFR 46.102(f). If appropriate, the SURE IRB representative may choose to send studies to full IRB review if they involve deception, questions about illegal behaviors, or questions about other sensitive issues such as abuse, suicide, and/or sexual behaviors.
4. If the SURE IRB representative has any questions regarding whether a project meets the exempt or expedited criteria, he/she contacts ORI staff or the IRB Chair for a second opinion.

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5. The SURE IRB representative issues a letter describing requested revisions and assumes the responsibility for reviewing revision responses submitted by the PI. The SURE IRB representative forwards documentation to the ORI after completing review and approving the study.
6. Following receipt of a SURE Committee approval, ORI staff enter the application into the ORI computerized tracking system and set up an application file. Once the study information has been added to the tracking system, ORI staff provide the SURE IRB representative with the IRB protocol number assigned by the computerized system.
7. ORI staff retain records of such approval using standard operating procedures. ORI staff list the exemption or expedited review on the agenda for a full review IRB meeting.

Modification Review Procedures

1. The PI may not initiate any changes in research procedures or consent/assent form(s) without prior IRB and SURE Committee review and approval, except where necessary to eliminate apparent immediate hazards to the subject. Examples of modifications that require review include, but are not limited to, changes in: study personnel; advertising materials (flyers, radio spots, etc.); research procedures; subject populations (e.g., age range); location where research will be conducted; consent/assent form; recruitment procedures; date for completion of study.
2. The PI is responsible for submitting a modification request prior to the implementation of any change. To submit the request, the PI completes the Modification Request Form and submits the designated number of copies with required attachments to the SURE IRB representative, who serves as the IRB Chair designee. The SURE IRB representative conducts the review in accordance with the Modification, Deviations, and Exceptions—IRB Review of Changes SOP.
3. If the SURE IRB representative is not available, ORI staff send the modification request to the IRB Chair or to a voting member of the IRB through the ORI using standard operating procedures.
4. Also, if the SURE IRB representative recommends full review, ORI staff place the modification request on an agenda following procedures outlined in the Initial Full Review SOP.
5. If the IRB approves the modification, the approval period remains the same as that assigned at initial or continuation review.

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Continuation Review Procedures

1. The IRB conducts substantive and meaningful continuing review (CR) at intervals appropriate to the degree of risk, but not less than once per year, in accord with the Continuation Review SOP.
2. If the PI submits the modification with a CR application, the IRB handles the modification following procedures outlined in the Continuation Review SOP. ORI staff process the modification as part of CR, i.e., amendments. (See the Continuation Review SOP.)

Appeals

1. If the PI has concerns regarding the IRB decision, he/she may submit his/her concerns to the IRB in a written document that includes justification for changing the committee decision.

Complaints and Alleged Noncompliance

1. If the SURE IRB representative receives a complaint from a subject, subject family member, staff, or researcher concerning subject rights and welfare or alleged noncompliance, the SURE IRB representative immediately (i.e., within 2 days) notifies the ORI Research Compliance Officer. The SURE IRB representative handles subject complaints about class credit.
2. If the ORI receives a complaint from a subject, subject family member, staff, or researcher concerning alleged noncompliance or subject rights and welfare regarding a SURE protocol, the RCO immediately (i.e., within 2 days) notifies the SURE IRB representative. The RCO initiates an inquiry following standard ORI/IRB operating procedures if complaints involve noncompliance with IRB approved procedures/informed consent process.
3. The IRB has the authority to make final determination on the outcome of review of any complaint regarding subject rights and welfare or alleged noncompliance.
4. The IRB is also responsible for determining whether the incident meets requirements for reporting to the federal regulatory agencies. In making the determination, IRB follows standard ORI/IRB operating procedures for reporting. (See the Mandated Reporting to External Agencies SOP.)
5. After the IRB has completed its review of the complaint/alleged noncompliance, the RCO is responsible for providing the SURE IRB representative with a copy of the final deliberations. If the IRB determines that the incident is reportable to a federal regulatory agency, the RCO is responsible for sending a copy of the federal report to the SURE IRB representative. The

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SURE IRB representative is responsible for disseminating copies of the final outcome and, if applicable, the federal report to the SURE Committee.

Personnel Training Requirements

1. The SURE IRB representative is responsible for ensuring all study personnel have completed UK's mandatory education requirements before issuing approval. The SURE IRB representative contacts ORI prior to requesting revisions (or issuing approval if no other revisions are necessary) to verify proper completion of human subjects' protection (HSP) training for all personnel listed on the study.

Joint Policy/Procedures

1. The ORI Director, when appropriate, is responsible for initiating efforts to establish joint IRB/SURE policy, procedures, and submission forms.
2. The SURE IRB representative, ORI staff, the IRB, or UK researchers or administrators may submit suggestions or recommendations for the joint policy/procedure/form initiatives to the ORI Director.

REFERENCES

Not applicable