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SIU Southern Illinois University
CARBONDALE

OFFICE OF SPONSORED PROJECTS ADMINISTRATION

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RESEARCH COMPLIANCE

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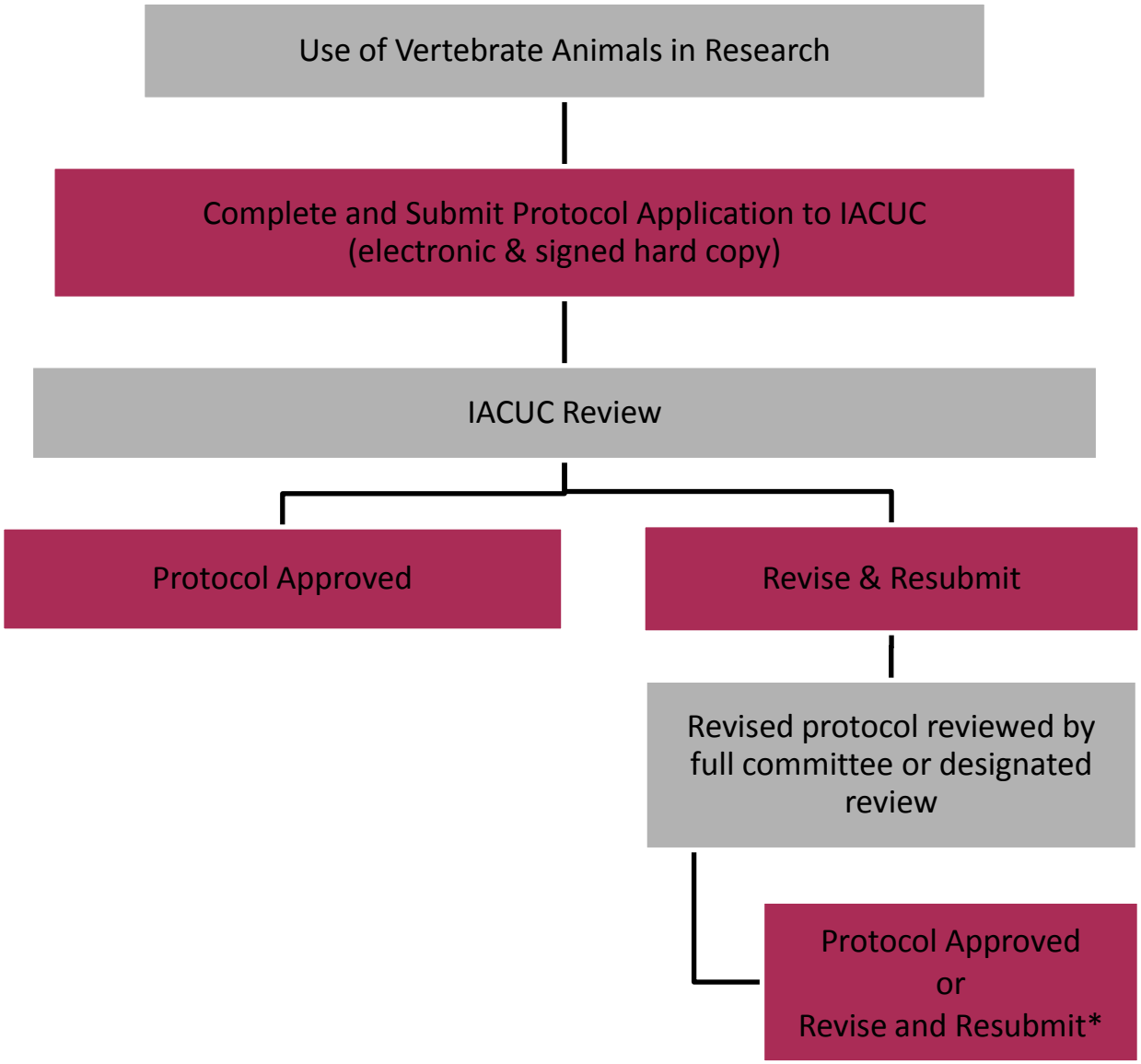
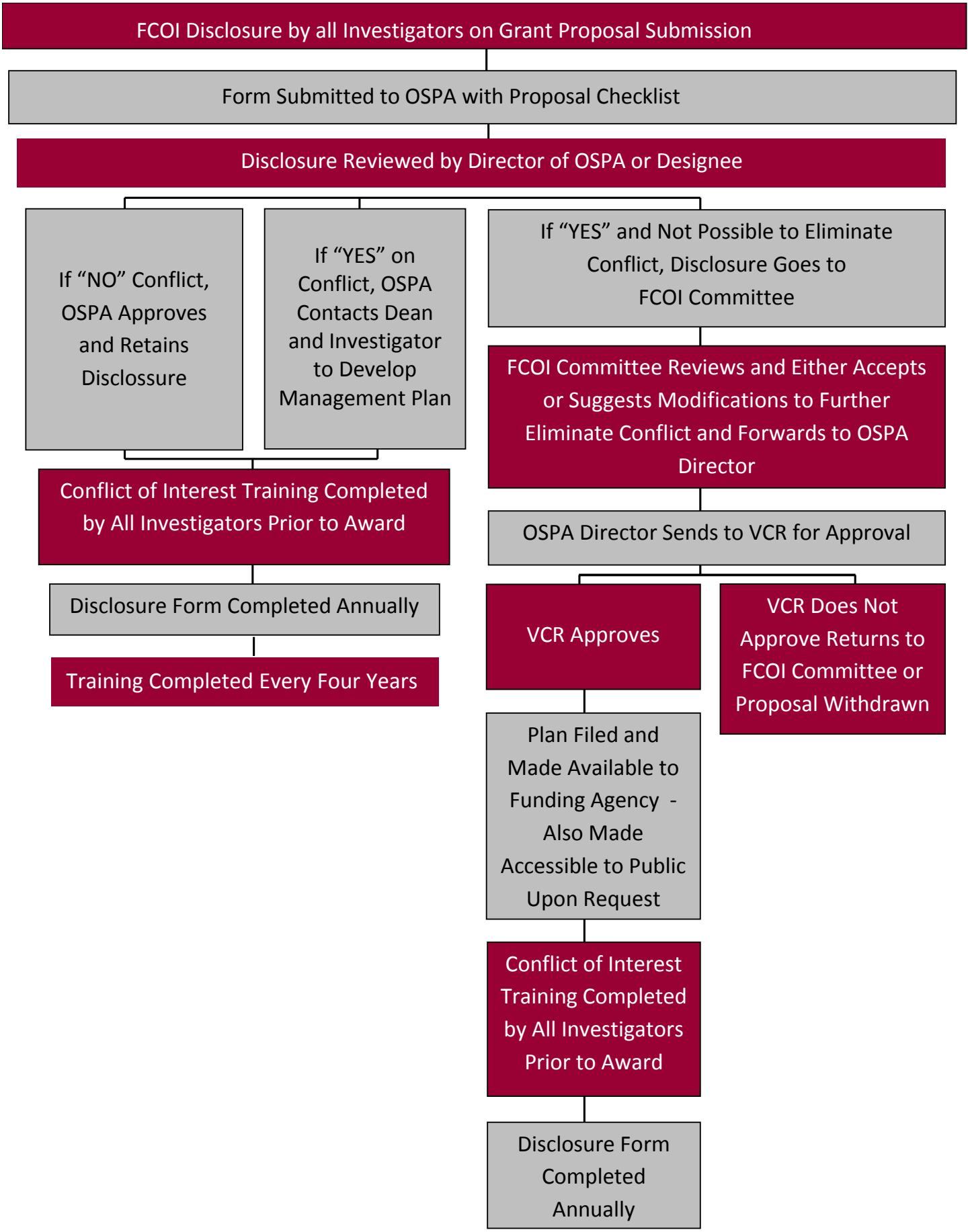
SIUC's Office of Sponsored Projects Administration oversees several research compliance areas to ensure all research (sponsored and un-sponsored) is conducted according to University, local, state, federal and funding agency regulations. Faculty, staff, and students need to be aware of their responsibilities relating to ethical conduct of research, including the following federally mandated research compliance areas. Also see Research Policies and Procedures, for more information on policies governing research at SIUC.

- ANIMAL RESEARCH
- HUMAN SUBJECTS RESEARCH
- FINANCIAL CONFLICT OF INTEREST
- RESPONSIBLE CONDUCT OF RESEARCH
- EXPORT CONTROL
- UNMANNED AIRCRAFT SYSTEMS
- HAZARDOUS MATERIALS


Use of Vertebrate Animals in Research
Complete and Submit Protocol Application to IACUC
(electronic & signed hard copy)
IACUC Review
Protocol Approved
Revise & Resubmit
Revised protocol reviewed by full committee or designated review
Protocol Approved
or
Revise and Resubmit*


FCOI Disclosure by all Investigators on Grant Proposal Submission
Form Submitted to OSPA with Proposal Checklist
Disclosure Reviewed by Director of OSPA or Designee
If "NO" Conflict, OSPA Approves and Retains Disclossure
If "YES" on Conflict, OSPA Contacts Dean and Investigator to Develop Management Plan
If "YES" and Not Possible to Eliminate Conflict, Disclosure Goes to FCOI Committee
Conflict of Interest Training Completed by All Investigators Prior to Award
Disclosure Form Completed Annually
Training Completed Every Four Years
FCOI Committee Reviews and Either Accepts or Suggests Modifications to Further Eliminate Conflict and Forwards to OSPA Director
OSPA Director Sends to VCR for Approval
VCR Approves
VCR Does Not Approve Returns to FCOI Committee or Proposal Withdrawn
Plan Filed and Made Available to Funding Agency - Also Made Accessible to Public Upon Request
Conflict of Interest Training Completed by All Investigators Prior to Award
Disclosure Form Completed Annually

SIU CARBONDALE
SOUTHERN ILLINOIS UNIVERSITY
OFFICE OF SPONSORED PROJECTS ADMINISTRATION

Human Subjects Committee Procedures

The SIUC Human Subjects Committee (HSC) reviews all research involving human subjects, including research that is considered "exempt" in CFR 46.101. Exempt research is classified by the HSC as Category I. Expedited research is classified as Category II and receives a higher level of review. Research applications that do not fit into either Category I or II are classified as Category III applications and require review by the convened HSC with a quorum of the members present.

The SIUC Human Subjects Committee Office is staffed by one part-time secretary and one part-time administrator who report to the director of the Office of Sponsored Projects Administration. The office is located at OSPA, Woody Hall C-214, Mail Code 4709. It also can be contacted at 618-453-4533 or siuhsc@siu.edu.

To begin the review process, researchers should complete the appropriate Human Subjects Application (see Human Subjects Compliance main page) and mail or hand-carry it to the HSC Office.

Initial Review

The secretary for the HSC reviews the application to be sure that it is complete. Materials that must be included are the full protocol, a proposed consent document, any brochures or web pages the investigator may use, and recruitment materials or scripts, including advertisements intended to be seen or heard by potential subjects.

For Category I projects, those that represent minimal risk to human subjects, the HSC uses a primary reviewer system. Either the chair of the HSC or the HSC administrator or their designee reviews the Category I applications. The HSC secretary forwards half of the Category I applications to the chair and half to the Administrator or to their designees. The primary reviewer verifies the level of review. If the primary reviewer considers it a Category II proposal, that reviewer notifies the secretary, who then sends the proposal to a second primary reviewer for a Category II review.

For Category II projects, those that meet the federal guidelines for Expedited Review, the HSC secretary forwards the application to the chair and the administrator or their designees. At

least two individuals review Category II projects. If either one of the reviewers thinks that the project does not fit into the Expedited Review category, the application is classified as a Category III proposal and is then reviewed by the full HSC.

The full HSC meets once a month to review applications, usually the first Friday of the month. The secretary mails all of the Category III applications to the members so that they have a complete packet of materials to review and to use as reference at the monthly meeting. These materials should be received by members sufficiently in advance of the meeting date to allow review of all the materials, usually a week before the meeting. At the meetings, all members are given a written report that briefly describes the Category I and Category II applications that have been reviewed and approved by the primary reviewers since the last meeting of the full committee.

Initial and continuing reviews of Category III applications must be conducted at convened meetings with a majority of the members present, including at least one member whose primary concerns are in nonscientific areas. Approval of research is by a majority of this quorum.

The full committee often sets conditions under which a protocol can be approved. When the committee stipulates specific revisions requiring simple concurrence by the investigator, the HSC chair and the HSC administrator may approve the revised protocol on behalf of the HSC. Some proposal revisions may be reviewed by one or more committee members with special expertise in the areas of the proposed research. When the full committee requests substantive clarifications or modifications, HSC approval will be deferred pending subsequent review by the convened HSC of the responsive materials.

Conflict of Interest

Federal regulations (21 CFR 56.107) require that "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB." (IRB, or Institutional Review Board, refers to the Human Subjects Committee.)

This regulation is interpreted by the HSC to mean that, except to provide information requested by the HSC, no member will be in attendance during the review and vote of any proposal for which the member is a researcher or contributor to the research in any capacity (including chair, committee member, or advisor for a student project); has a superior or subordinate relationship with the researcher; or has a financial, personal, or other conflict of interest.

Reporting Findings to Researchers

After reviewing the Category I applications, the primary reviewer sends written comments about the applications to the secretary, who then writes memos to the researchers requesting that they make any changes needed. For Category II applications, both reviewers send written comments to the Secretary, who then writes memos to the researchers describing any changes that are needed in the application. Due to the large number of applications, the Category I and II reviews may take as long as two or three weeks from the time they are submitted.

For Category III applications, the secretary tape-records the discussions by the full committee. At the meeting, the chair verbally summarizes the changes that the committee requires, and the committee votes to (1) approve the project as described in the initial application, (2) require specific revisions that the chair and administrator may approve with or without consultation with a member who has relevant expertise, or (3) require substantive modifications and a subsequent review by the full committee. After the meeting, the secretary sends a memo to each researcher. Based on the HSC vote, the memo will either give approval for the research to begin or it will describe the modifications that the committee requires before they will approve the project. If the changes are minor, the committee may ask that the chair and the administrator, and possibly selected members, review and approve the changes. If the changes are major, the committee may ask that approval be deferred so that they can review the changes at the next meeting before they vote to approve it.

Review of Modifications to Approved Protocols

The HSC application and the HSC approval memo inform researchers that any modification to their protocols must be submitted to the committee for review and approval before those modifications are implemented. An exception would be that rare occasion when a change would be necessary to eliminate immediate hazards to subjects.

Minor changes in previously approved research protocols may be reviewed under an expedited review procedure. If the protocol was originally approved as a Category I, only one reviewer, typically the chair or the administrator, needs to review the changes. If the protocol was originally approved as a Category II or III, the chair and the administrator or their designees review the modifications.

If either reviewer thinks that the modification of a Category II or III is a major change, the full committee reviews the modified protocol. If the modification of a Category I protocol is major enough to change the research into a Category III project, the full committee reviews it. In both cases, the secretary will ask the researcher to provide additional copies for the full committee.

Requests for Extension of Protocols

All HSC protocols expire one year from the initial protocol review date. Researchers must submit a Request for Extension to continue the project. (See the Human Subjects home page for the appropriate forms.) The secretary sends reminders to the researchers a few months before their protocols are due to expire.

The primary review system is used for continuations or extensions of Category II research. Exempt or Category I research extensions are not required. The full committee must review requests for an extension of Category III protocols at a regularly convened meeting. The Request for Extension asks (1) how many subjects the project has accrued, (2) if there have been any modifications to the project, and (3) if any subjects have complained about the research, reported any injury, or withdrawn from the project. Researchers are also asked to send a copy of the consent form they are currently using. During the review process, all committee members have a copy of the Request for Extension and the consent form.

Policy on Extension of Approved Protocols

As noted above, researchers submit an "Application for Approval to Conduct Research Involving Human Subjects" to the HSC for initial review of their proposed research. The HSC reviews and approves applications to conduct research for a specified duration. Federal regulations limit this duration to no more than 12 months. The time period begins when the HSC first reviewed the protocol as a convened committee. Some Category III protocols may have to be reviewed more often. If the HSC decides that the research poses an unusual risk to subjects or that the researcher may have problems with the procedures, the committee will require the researcher to submit a Request for Extension (see preceding section) more frequently so that the results can be reviewed earlier. The twelve month review cycle does not apply to exempt studies (policy revision effective 9/2/2011).

Researchers with Category III protocols will be notified by the HSC prior to the expiration of their approved time limit and inquire whether they wish to continue the research past the approved time limit. Researchers who have an approved application may submit a "Request for Extension" form to continue their research after the initial time limit has elapsed. The HSC will consider the request for extension, which, if granted, typically is for one additional year. Researchers also may request a modification of the research any time during the approval period by submitting a memo to the HSC specifying the modifications.

Extensions will not be required to continue work on an approved project when all the data has been collected, there will be no more interaction or intervention with human subjects, and **subject identifiers have been removed** (e.g., during the data analysis or report writing stages).

Researchers who want to continue their research beyond the first extension (i.e., typically for a third year) will be required to submit a new "Application for Approval to Conduct Research Involving Human Subjects" to the HSC. When preparing the new application, researchers should

take into consideration any new scientific information that would affect the research, as well as any new federal and HSC policies concerning human subjects protections.

Researchers who have an approved modification to their research and want to submit a second modification also might be asked to submit a new "Application for Approval to Conduct Research Involving Human Subjects." The HSC will make that determination based on the nature and number of additional modifications proposed, consideration of their risk to human subjects, new human subjects protection policies, and clarity of the entire written proposal. Minor changes that present minimal risk to human subjects (e.g., adding a researcher, expanding advertising for subjects, recruiting subjects in another location, etc.) and that maintain the clarity of the application might not require reapplication. Multiple modifications and those that involve direct interaction or intervention with human subjects might require submission of a new application.

Complaints or Concerns

All complaints or concerns regarding human subjects research should be made to the HSC chair or administrator. (Contact information may be obtained from the HSC office; see top of page.)

The HSC chair and administrator will review any allegations of noncompliance by gathering as much information as possible through meetings and conversations with the involved parties. A satisfactory resolution will be sought based upon the approved protocol, federal and state regulations and guidance, and the SIUC Human Subjects Guide. The HSC chair may bring the complaint to the attention of the HSC for the purpose of seeking members' recommendations if an immediate resolution is not reached. During the process of complaint review, committee members shall ensure confidentiality to the best of their abilities.

Complaints will be formally documented along with resolutions and formal actions taken. This information will be placed with the protocol files. The complainants and respondents will also receive copies of final decisions. If the complaint is considered an adverse event, the HSC will be required to report the matter to the U.S. Department of Health and Human Service's Office of Human Research Protection.