

SOP: 602C
OFFICE OF RESEARCH ADMINISTRATION - OUHSC

1. POLICY

The Office of Research Administration (ORA) shall serve as a central resource to promote the research, education, and service missions of the OUHSC. ORA shall provide information and administrative assistance to faculty and staff for preparing and submitting proposals to external sponsors and managing post-award administration of sponsored research awards. ORA requires that the Human Research Participant Protection (HRPP) requirements shall be addressed in all agreements with sponsors involving human participant research. ORA and HRPP shall work together to ensure all institutional and sponsor approvals and contracts are in place prior to the initiation of sponsored research involving human participants.

Specific Policies

1.1 Just-in-Time Policy for IRB Submissions

The NIH just-in-time policy that allows grant applications to be submitted to NIH for peer review without prior IRB approval has been extended by University policy to all OUHSC grant proposals where the granting agency does not require IRB approval at the time the proposal is submitted. Investigators are required to submit an IRB application only upon receipt of a favorable priority ranking from the granting agency. The investigator shall make sure IRB approval is obtained before the award is received and research begins.

1.2 Grant Proposals Lacking Definite Plans for Human Participant Involvement at the Time of Submission to Funding Agency

The IRB recognizes that certain types of grant applications, cooperative agreements, or contracts are submitted to funding agencies with the knowledge that human participants may be involved within the period of support, but definite plans are not set forth in the initial application or proposal. The IRB does not require review of these applications prior to an award being made; however, a supporting agency may require IRB review and certification.

Grant proposals lacking definite plans for human participant involvement may include the following:

- Research training programs or grants in which the activities involving human participants will be selected or designed during the course of the program.
- Research, pilot, or developmental projects in which the involvement of human participants depends on such things as the completion of pre-clinical animal studies.
- Research projects that are designed in collaboration with the funding agency only after the award has been made to HSC. Once the protocol has been designed by the investigator and funding agency, it shall be submitted to the IRB for the institutional review and approval process.

Involvement of human participants in any research project supported by these awards shall be permitted only after the IRB has reviewed and approved the research project.

1.3 Research Proposals Without the Initial Intent of Human Participant Involvement

Occasionally, research activities are designed without the intention of human participant involvement, but human participant research is proposed later. The newly proposed research activity involving human participants shall be reviewed and approved by the IRB before initiation of the research.

1.4 Research Requiring a Contract with the Sponsor or Funding Agency

All human participant research (approved under convened Board, expedited, or exempt criteria) at HSC that is sponsored and/or funded by industry (i.e., pharmaceutical and biotechnology companies) requires the execution of a contract detailing both parties' responsibilities prior to the initiation of the research protocol. In addition, human participant research funded by other agencies (i.e., state, foundation, federal) requires the execution of a contract between HSC and the other party prior to the initiation of the research protocol. When a contract between HSC and the other party is required by University policy, it shall be fully executed prior to the initiation of the human participant research.

1.5 Unique IRB Number Assignment For Each Funded Study

HSC policy requires that each study protocol involving human participants be submitted to the IRB for review and approval and be assigned a unique IRB number. Therefore, every funded study shall have a corresponding IRB application with a unique IRB number and individual approval, internally (departmental) or externally funded. Federal regulations under 45 CFR 46.103 (f) mandate that each federally-funded research project be reviewed and approved, in entirety, by an assured IRB.

1.6 Communication Mechanisms Between IRB and ORA

Regular communication between the IRB and ORA is essential in order for the IRB to fulfill its functions relative to human participant research.

The IRB shall notify ORA of the status of IRB approval for sponsored research projects. To assure compliance with University and federal policies, the IRB shall generate weekly status reports and provide them to ORA.

The IRB and ORA Access databases communicate by transferring IRB approval dates to ORA contract log.

1.7 Human Research Participant Protection Requirements with Sponsors

1.7.1 Adherence to Policies

The HSC requires a formal agreement between the HSC and the industry sponsor of a clinical trial. Agreements and other sponsored awards administered through ORA shall indicate that the HSC will conduct human research in accordance with the IRB-approved written protocol, applicable law, and ethical standards as outlined in its FederalWide Assurance with HHS.

Requests from sponsors for HSC HRPP to deviate from its policies and procedures shall not be accepted.

1.7.2 Medical Care for Research-Related Injury

ORA reviews each clinical trial agreement for subject injury language and notifies the investigator if the agreement language contradicts the consent form language. The IRB shall review each consent form document and require that it include an explanation of who to contact for answers to questions about the research, research participants' rights, and research-related injuries.

1.7.3 Reporting Requirements of the Sponsor

ORA reviews each clinical trial agreement for language indicating the sponsor will promptly report to the HSC HRPP any information contained within a monitoring report that could affect the rights or welfare of the research participants or their willingness to continue in the study or influence the conduct of the study, or alter the IRB's approval to continue the study. The Office of HRPP shall review each consent form document for required language that participants will be notified of new information relevant to their participation in the study.

1.7.4 Communication to Study Participants

The HRPP provides study participants with significant new findings developed during the course of the research, which may relate to their willingness to continue their participation.

The IRB notifies both current and past participants when they are at increased risk of a problem that was not identified at the time the study was initially designed. In order to fulfill this obligation, ORA shall request the sponsor include language in the clinical trial agreement indicating the sponsor shall promptly communicate significant or unexpected study results that may alter the willingness of study participants to continue participation in the study to the IRB.

1.7.5 Publications or Disclosure of Results

ORA shall review each clinical trial agreement for language detailing the publication rights of the investigator. Investigators retain the right to publish the data and/or results of a sponsored research study in accordance with the terms of the agreement.

1.7.6 Warranty or Disclaimer

ORA reviews each clinical trial agreement for warranty or disclaimer language and, if warranty or disclaimer language is found, ORA negotiates with the sponsor to remove or revise the language in compliance with IRB policy, as follows: The IRB shall review each consent form and shall not allow any language that disclaims or limits the warranty of drugs or devices. Exceptions to this policy will be handled on a case-by-case basis as described below in Section 7.7.6.2.

2. SCOPE

These policies and procedures apply to all human participant research projects performed at HSC.

3. RESPONSIBILITY

IRB and ORA staff are responsible for facilitating communication and notification between the offices.

4. APPLICABLE REGULATIONS AND GUIDELINES

NIH Notice OD-00-031 Release Date May 1, 2000

45 CFR 46.

45 CFR 46.118

45 CFR 46.119

21 CFR 56.

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301, Research Submission Requirements

SOP 302, Administrative Review and Distribution of Materials.

6. ATTACHMENTS

602C-A Contract-Hold Notification Email

602C-B Studies-Received Report

602C-C Studies Approved Report

602C-D Studies Inactivated Report

305-C New Study Approval Checklist

701-A Informed Consent Template

7. PROCESS OVERVIEW

7.1 Just-in-Time Policy for IRB Submissions

7.1.1 Upon receipt of a favorable priority ranking from the funding agency, the investigator submits an IRB Application, Grant Proposal, and other required submission documents per SOP 301, Research Submission Requirements to the IRB for review.

7.1.2 If the priority ranking of the project is unfavorable, it is not necessary for the investigator to contact the IRB.

7.2 Grant Proposals Lacking Definite Plans for Human Participant Involvement at the Time of Submission to Funding Agency

7.2.1 The IRB does not require review of grant applications lacking definite plans for human participant involvement prior to an award being made. If review is required by a supporting agency, the investigator submits an IRB Application, Grant Proposal, and other required submission documents to the IRB for review.

7.3 Research Proposals Without the Initial Intent of Human Participant Involvement

- 7.3.1 The IRB does not require review of research proposals when the initial intent of the research does not involve human participants. If proposed research activities are later revised to include involvement of human participants, the investigator submits an IRB Application and required documents to the IRB for review and approval before involvement of human participants in the research.

7.4 Research Requiring a Contract with the Sponsor or Funding Agency

- 7.4.1 HSC studies involving human participants that are sponsored and/or funded by pharmaceutical and biotechnology companies (industry sponsored) require both IRB review and approval and a fully executed contract between the HSC and the company prior to initiation of the research activities.
- 7.4.2 The investigator indicates on the IRB Application that the research project is industry-sponsored (i.e., providing drug, device, and/or funding). IRB staff enters this information into the IRB database and notes on the approval letter checklist.
- 7.4.3 Upon review and final approval of the project by the IRB, the IRB Administrator notifies the appropriate Sponsored Program Administrator in ORA via an email message of the project's approval.
- 7.4.4 The IRB Administrator maintains communication with ORA and monitors the execution of the contract and will not release the approval letter until ORA notifies the IRB office that the contract has been signed. ORA does not sign the contract until IRB approval is granted unless the contract indicates the research may not begin until IRB approval is obtained.
- 7.4.5 Upon execution of the contract, ORA sends notification via email to the appropriate IRB Administrator that the contract has been signed and the approval letter may be released to the Investigator.
- 7.4.6 If the contract is not fully executed within 7 (seven) months of the IRB Approval, the IRB Administrator contacts ORA for the status of the contract. If ORA indicates that the contract is anticipated to be executed, the study proceeds with Continuing Review. If ORA indicates that the contract is not anticipated to be executed, the IRB Administrator presents the study to the IRB Chair for Administrative Inactivation.
- 7.4.7 The IRB Administrator notifies the Investigator and ORA in writing of the Administrative Inactivation and the reason for the inactivation. ORA notifies the IRB of the status of the contract negotiations and when the contract is anticipated to be ready for signature.

7.5 Unique IRB Number Assignment Per Funded Proposal

- 7.5.1 The IRB Administrative Secretary assigns a unique IRB number as generated from the IRB database for every new IRB application submitted to the IRB.
- 7.5.2 The IRB number is used in all reports, minutes, agendas, correspondence with the investigator, and communications with ORA, sponsor, and federal agencies.

- 7.5.3 The Sponsored Program Administrator in ORA accesses the IRB database to verify that the IRB number, title, and sponsor designated in the IRB database correspond to the IRB number, title, and sponsor provided by the investigator to ORA on the grant proposal and ORA routing form.

7.6 Communication Mechanisms Between IRB and ORA

- 7.6.1 The IRB database is available to ORA for review of current IRB protocols and approval status.
- 7.6.2 The IRB staff generates status reports from the IRB database that facilitate communications and coordination between the IRB and ORA.
- 7.6.3 The IRB staff forwards copies of the IRB status reports to ORA on a weekly basis for review by ORA staff. The reports are as follows:
- a) IRB Study Received Report
 - b) IRB Study Approval Report
 - c) IRB Study Inactivation Report
- 7.6.4 After ORA has reviewed the reports for discrepancies with ORA information in sponsor, investigator, and project title information, the HRPP Director or designee is notified of any discrepancy by ORA.
- 7.6.5 If discrepancies in the sponsor, investigator, and project title cannot be resolved between the IRB and ORA, the IRB seeks clarification from the investigator.
- 7.6.6 If necessary, the IRB requests the investigator to submit a protocol modification form as outlined in SOP 302, Administrative Review and Distribution of Materials.

7.7 Human Research Participant Protection Requirements with Sponsors

7.7.1 Adherence to Policies

- 7.7.1.1 Requests to the IRB or ORA from sponsors for the HSC HRPP to deviate from HRPP policies and procedures are not accepted and are brought to the attention of the HRPP Director or ORA Associate Director for response to the sponsor.

7.7.2 Medical Care for Research-Related Injury

- 7.7.2.1 The Sponsored Program Administrator of ORA reviews each clinical trial agreement for inclusion of subject injury language. ORA notifies the investigator if the agreement language does not agree with the informed consent form language.
- 7.7.2.2 The IRB Member reviews each informed consent form for inclusion of the following elements as described in the IRB consent form template: an explanation of whom to contact for answers to questions about the research, research participants' rights, and research-related injuries.

7.7.3 Reporting Requirements of the Sponsor

- 7.7.3.1 The Sponsored Program Administrator of ORA reviews each clinical trial agreement for language indicating the sponsor must

promptly report to the HSC HRPP any information contained within a monitoring report that could affect the rights or welfare of the research participants or their willingness to continue in the study or alter the IRB's approval to continue the study.

7.7.3.2 The IRB Administrator reviews each informed consent form for inclusion of language, as described in the consent form template, that participants will be notified of new information relevant to their participation in the study.

7.7.4 Communication to Study Participants

7.7.4.1 The investigator provides study participants with significant new findings developed during the course of the research, which may relate to their willingness to continue their participation.

7.7.4.2 In order to fulfill this obligation, the sponsor is requested to notify the IRB through the investigator when new findings developed during the course of the research which may relate to the participants' willingness to continue their participation.

7.7.4.3 The IRB requires the investigator to notify both current and past participants when they are at increased risk of a problem that was not identified at the time the study was initially designed.

7.7.4.4 ORA requests that the sponsor include language in the clinical trial agreement indicating the sponsor shall promptly communicate significant or unexpected study results that may alter the willingness of study participants to continue participation in the study to the IRB.

7.7.5 Publications or Disclosure of Results

7.7.5.1 The Sponsored Programs Administrator of ORA reviews each clinical trial agreement for language detailing the publication rights of the investigator.

7.7.5.2 Investigators retain the right to publish or disclose the data and/or results of a sponsored research study in accordance with the terms of the agreement.

7.7.6 Warranty or Disclaimer

7.7.6.1 The Sponsored Programs Administrator of ORA reviews each clinical trial agreement for warranty or disclaimer language. The IRB reviews each consent form and does not allow any language that disclaims or limits the warranty of drugs or devices, in compliance with IRB policy. If the Sponsored Programs Administrator of ORA finds warranty or disclaimer language in the clinical trial agreement, ORA negotiates with the sponsor to remove the language.

7.7.6.2 Exceptions to this policy are handled on a case-by-case basis through a subcommittee comprised of the Associate Director of ORA or designee, Director of the IRB or designee, and the IRB Chair. The Office of Legal Counsel may be consulted.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012