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 prior to finalizing the agreements. ORA and HRPP shall work together to ensure all University 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 a new study application only to the IRB through the electronic information system and promptly upon receipt of a favorable priority ranking from the granting agency. The investigator shall ensure IRB approval is obtained before the award is accepted 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 at the time of submission 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 research project has been designed by the investigator and funding agency, it shall be submitted to the IRB for a determination.

Involvement of human participants in any research project supported by these awards shall be permitted only after the IRB has 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 approved by the IRB before initiation of the research involving human participants.
1.4 **Research Requiring a Contract with the Sponsor or Funding Agency**

All human participant research projects approved by the IRB at HSC that are sponsored and/or funded by industry (i.e., pharmaceutical and biotechnology companies) require the execution of a contract detailing both parties' responsibilities prior to the initiation of the research project. In addition, human participant research projects funded by other agencies (i.e., state, foundation, federal) require the execution of a contract between HSC and the other party prior to the initiation of the research project. When a contract between HSC and the other party is required by University policy, the investigator shall not begin research project activities prior to the execution of a contract through ORA.

1.5 **Unique IRB Number Assignment For Each Funded Research Project**

HSC policy requires that each research project involving human participants be submitted to the IRB for approval and be assigned a unique IRB number. Therefore, every funded research project shall have a corresponding IRB application with a unique IRB number and individual approval, whether 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 ORA shall have access to the electronic information system in order to check the status of a research project.

1.7 **Human Research Participant Protection Requirements with Sponsors**

1.7.1 **Adherence to Policies**

The University 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 participant research in accordance with the IRB-approved protocol, and applicable law.

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**

Contracts and/or funding agreements must indicate who will provide care and who is responsible to pay for it. ORA reviews each clinical trial agreement for research participant injury language and notifies the investigator if the agreement language contradicts the informed consent document language. If research participant injury language is included in a clinical trial agreement, such language shall not refer to billing a research participants’ insurance company first for the injury or require the research participant to be financially responsible for the research-related injury. The HRPP will not include such language in the informed consent form or permit sponsor to do so. ORA shall notify the investigator if the informed consent document contains language that contradicts the agreed upon language in the clinical trial agreement.

The IRB shall review each consent 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 (within 30 days) to the HSC HRPP any information contained within a routine or urgent data and safety monitoring report that could affect the rights, safety, or welfare of the research participants or their willingness to continue in the research project, influence the conduct of the research project or alter the IRB’s approval to continue the research project.

The HRPP shall review each informed consent for required language that participants will be notified of new information relevant to their participation in the research project. Clinical trial agreements shall also indicate the time frame after closure of the study during which the Sponsor will communicate such findings to the University but shall not be any less than two years after closure.

1.7.4 Communication to Research Project Participants

The HRPP through the investigator provides research project participants with significant new findings developed during the course of the research that may affect their willingness to continue their participation.

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

1.7.5 Publications or Disclosure of Results

ORA shall review each clinical trial agreement for language providing for the publication rights of the investigator. ORA shall make every effort to ensure that investigators retain the right to publish the data and/or results of a sponsored research project 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 that goes to the study drug or device (other than efficacy), ORA negotiates with the sponsor to remove or revise the language in compliance with IRB policy, as follows: The IRB shall review each consent document and shall not allow any language that disclaims or limits the warranty of drugs or devices except with regard to the efficacy of the drug or device. Exceptions to this policy will be handled on a case-by-case basis as described below in Section 7.7.6 (B)

2. SCOPE

This SOP applies to all human participant research projects performed at HSC.

3. RESPONSIBILITY

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

4. APPLICABLE REGULATIONS AND GUIDELINES

NIH Notice OD-00-031 Release Date May 1, 2000
45 CFR 46
21 CFR 56
REFERENCES TO OTHER APPLICABLE SOPS
SOP 301: Research Submission Requirements

ATTACHMENTS
701-A Informed Consent Template (HSC)
701-A-1 Informed Consent Template (NC)

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. If the priority ranking is favorable, the investigator shall promptly submit the research project to 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 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 research projects involving human participants that are sponsored and/or funded by pharmaceutical and biotechnology companies (industry sponsored) require both IRB 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). Upon final approval of the project by the IRB, the approval date of the project is available for review by ORA in the IRB’s electronic information system.
7.4.4 The IRB approval letter instructs the investigator that they are not to begin the project until the contract is signed by ORA. ORA does not execute the contract until IRB
approval is granted unless the contract indicates the research may not begin until IRB approval is obtained.

7.5 Unique IRB Number Assignment Per Funded Proposal

7.5.1 The IRB’s electronic information system assigns a unique IRB number upon receipt by the IRB of a research project submission 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, the sponsor, and federal agencies.

7.5.3 The Sponsored Program Administrator in ORA accesses the IRB electronic information system to verify that the IRB number, title, and sponsor designated in the IRB electronic information system 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 electronic information system is available to ORA for review of IRB research project status.

7.6.4 ORA notifies the HRPP Director or designee of any discrepancy discovered 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 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

Requests to the IRB or ORA from sponsors for the HSC HRPP to deviate from HRPP policies and procedures are not accepted by ORA. ORA must bring such requests 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

A. The Sponsored Program Administrator of ORA reviews each clinical trial agreement for inclusion of research participant injury language. ORA notifies the investigator if the agreement language does not agree with the informed consent document language.

B. The IRB Member reviews each informed consent document for inclusion of the following elements as described in the IRB informed consent templates: 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

A. 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 research project or alter the IRB’s approval to continue the research project. Each clinical trial agreement shall be reviewed for language indicating the time frame after closure of the study during which the Sponsor will communicate such findings to the University.
B. The IRB Administrator reviews each informed consent document for inclusion of language, as described in the consent form templates, that participants will be notified of new information relevant to their participation in the research project.

7.7.4 Communication to Research Project Participants

A. The investigator provides research project participants with significant new findings developed during the course of the research that may affect their willingness to continue their participation.

B. In order to fulfill this obligation, the sponsor is required via contract to notify the IRB through the investigator when new findings developed during the course of the research may affect the participants’ willingness to continue their participation.

C. 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 research project was initially designed.

D. ORA requires that the sponsor include language in the clinical trial agreement indicating the sponsor, through the investigator, shall promptly communicate significant or unexpected research project results that may affect the willingness of research project participants to continue participation in the research project to the IRB. The clinical trial agreement shall indicate the time frame after closure of the study during which the Sponsor will communicate such findings to the University which shall not be any less than two years after closure.

7.7.5 Publications or Disclosure of Results

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

B. ORA shall make every effort to ensure that investigators retain the right to publish or disclose the data and/or results of a sponsored research project in accordance with the terms of the agreement.

7.7.6 Warranty or Disclaimer

A. The Sponsored Programs Administrator of ORA reviews each clinical trial agreement for warranty or disclaimer language. The IRB reviews each consent document and does not allow any language that disclaims or limits the warranty of drugs or devices other than of efficacy, in compliance with IRB policy. If the Sponsored Programs Administrator of ORA finds warranty or disclaimer language beyond efficacy in the Phase III or IV clinical trial agreement, ORA negotiates with the sponsor to modify or remove the language.

B. 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: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020