

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>			
<b>Revision #10</b>	<b>TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination</b>		<b>Page 1 of 11</b>
Approved By: ORI Director	Signature	Date	Date First Effective: 06-17-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair			
Approved By: OSPA Director	Signature	Date	Revision Date: 04/30/19

## **OBJECTIVE**

To describe procedures for coordination between the Office of Sponsored Projects Administration (OSPA), the Institutional Review Board (IRB), and the Office of Research Integrity (ORI) in administering sponsored research agreements at the University of Kentucky (UK)

## **GENERAL DESCRIPTION**

OSPA, the IRB, and ORI are committed to ensuring the protection of human subjects involved in sponsored research. OSPA and the IRB/ORI coordinate activities in significant areas of sponsored research including: proposal submission; negotiation of award agreements; negotiation of clinical trial agreements (CTAs); subaward agreements for off-site research; establishing accounts; IRB fees; coordination of complying with the NIH Genomic Data Sharing (GDS) Policy; terminations and lapses of approval.

### *Definitions*

*Sponsors* are the agencies, institutions, companies, organizations, foundations, or other grantors responsible for funding a research study. The term *sponsor* is understood to include any intermediaries, such as contract research organizations or coordinating centers, acting as agents of the sponsor in carrying out the responsibilities above. All research falling under these types of agreements are considered *sponsored projects*.

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #10</b>	<b>TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination</b>	<b>Page 2 of 11</b>

## **RESPONSIBILITY**

Execution of SOP: OSPA Research Administrators (RA), OSPA College Grant Officers (CGO), OSPA Director, OSPA Subaward Administrators (SA), OSPA Conflict of Interest Administrator (COIA), OSPA Administrative Staff (AA), ORI Staff, ORI Director, ORI Research Compliance Officer (RCO), ORI Off-Site Research Coordinator, Principal Investigator (PI), Study Personnel

## **PROCEDURES**

### *Proposal Submission*

1. Before OSPA submits a proposal to an extramural sponsor, the PI completes the UK electronic Internal Approval Form (eIAF) clearly indicating the involvement of human subjects, if applicable, and submits it to OSPA.
2. The eIAF includes questions designed to verify whether the project involves human subjects and whether the PI has obtained IRB approval.
3. The CGO screens each proposal and the associated eIAF. When appropriate, the CGO advises the PI of sponsor requirements for submission of the certification of IRB approval and/or completion of mandatory human research training. The CGO refers the PI to the ORI in cases where the PI requires additional clarification or assistance with human research protections.
4. OSPA submits certifications of IRB approval or mandatory education requirements to the agency in accordance with agency requirements. ORI staff prepare agency certifications for the PI upon request. The OSPA Director signs the agency certifications.
5. When the OSPA RA receives the IRB protocol number, OSPA staff enter it into the OSPA electronic database. OSPA identifies all sponsored proposals involving human subjects and/or clinical trials in the electronic database so that RAs or the OSPA Director may generate reports of all research involving human subjects or of all clinical trials.
6. Initial IRB review and continuation review submissions prompts the PI to provide information identifying the sponsor and, if funded, the OSPA account number.
7. The CGO ensures that investigators, as defined in the Administrative Regulations 7:2 (AR 7:2), have completed an annual financial conflict of interest disclosure prior to the submission of a proposal to an external funding agency. The COIA reviews financial disclosures and determines whether an investigator has or could potentially have a financial

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #10</b>	<b>TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination</b>	<b>Page 3 of 11</b>

conflict of interest with their sponsored research. Once a proposal is funded, the OSPA RA confirms that all investigators included on the proposal have completed a financial disclosure and the Financial Conflict of Interest training information, and confirms with the COIA that there is no financial conflict of interest on the project. Should an investigator have a financial conflict of interest on the project, the conflict of interest is managed according to University procedures outlined in AR 7:2.

#### *Negotiation of Award Agreements*

1. OSPA provides investigators with up-to-date information on institutional policy in negotiating the terms of sponsored research agreements to ensure compliance with applicable law, university policy, and good business practice. OSPA publishes information resources on the OSPA web site, including regulatory resources, sample research study agreements, and specific information on clinical trial agreements.
2. Once UK receives an extramural award, the OSPA RA reviews the proposed research agreement and negotiates acceptable terms between the sponsor and the institution. For projects including human subjects research, the agreement includes provisions for human research protections in compliance with all applicable laws, institutional policies for ethical conduct of research, and the written research protocol. The PI receives a copy of the completed agreement from OSPA.
3. The OSPA Director's signature signifies acceptance of a research agreement for which the RA has obtained appropriate administrative approvals and/or a completed eIAF
4. The OSPA RA negotiates the terms of the research agreement to allow for publication of the research results in accordance with sponsor and university policies and acknowledging the roles of the PI and sponsor.

#### *Negotiation of Clinical Trial Agreements*

1. Additional award negotiation procedures beyond those outlined above apply to a sponsored research project designated as a clinical trial.
2. The PI or Study Personnel provide the OSPA RA with a copy of the proposed agreement and a sponsor contact as early in the process as possible.
3. The OSPA RA screens the terms of the CTA for specific provisions related to IRB or Health Insurance Portability and Accountability Act (HIPAA) issues which need coordination with the IRB. Types of issues that may require IRB/OSPA coordination include additional

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #10</b>	<b>TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination</b>	<b>Page 4 of 11</b>

university/sponsor certifications or requirements related to human research protections, applicable federal assurances, and sponsor access to protected health information. Specific examples include, but are not limited to, the following:

- Provisions for study-related reporting and notifications;
  - Coverage of subject injury and medical care;
  - Rights/permissions to subject samples and prior medical records; and
  - Use of participant data in future sponsor reviews.
4. When appropriate, the OSPA RA notifies ORI staff and provides a copy of the contract language in question. ORI staff advise the OSPA RA on pertinent existing regulatory and institutional policy, provide requested documentation or certifications, or refer the request to the IRB for review, as appropriate. ORI staff act as a liaison between the IRB and the OSPA RA and respond to OSPA RA requests on a case-by-case basis. The OSPA RA ensures that the resulting provisions incorporated into the CTA comply with the guidance obtained from the IRB/ORI.
  5. The OSPA RA notifies ORI staff if any provisions in the contract language differ from the IRB informed consent template applicable policies (e.g., provisions for coverage of subject injury and medical care). Also, ORI staff notify the OSPA RA if the IRB makes any changes in the consent form that differ from the IRB informed consent template applicable policies. In these cases, the ORI staff and the OSPA RA review the informed consent document and the contract language for consistency. If the informed consent document needs changes, ORI staff forward required changes to the PI and the IRB for review and approval.
  6. The OSPA RA obtains a copy of the IRB approval letter from the PI or the ORI and places it in the file. The RA maintains a checklist of documents required to complete a clinical trial file, including the following:
    - A copy of the research protocol (becomes a part of the CTA by attachment);
    - The fully signed agreement;
    - The Internal Approval Form; and
    - The IRB approval letter.
  7. When applicable, given the nature of the research, the OSPA RA includes a clear statement in the CTA that addresses medical care for research subjects with a research-related injury.
  8. The OSPA RA includes provisions in the CTA for reporting to the sponsor any deviations from the research protocol necessary to protect the safety, rights, or welfare of patients enrolled in the clinical trial and any serious or adverse reactions resulting from participation in the study.

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #10</b>	<b>TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination</b>	<b>Page 5 of 11</b>

9. Once the OSPA RA has all required documentation, he/she establishes the account.
10. If all other documentation is complete prior to receiving certification of IRB approval, the OSPA RA may establish an account with restrictions preventing research subject enrollment and prospective subject contact. See *Establishing Accounts* below.
11. In studies in which sponsors are responsible for monitoring the progress of the research to be conducted, the OSPA RA includes written provisions in the agreement for the sponsor to promptly report (i.e. within 30 days) any information, during and after the study, that may affect research oversight of a protocol by the IRB, affect the safety of human subjects or their willingness to participate, and/or influence the conduct of the study, as required by the Food and Drug Administration.
12. If UK receives such information from the sponsor, including evidence of serious or continuing noncompliance or evidence of scientific misconduct, OSPA staff report it to the IRB and the ORI.
13. During the study, the OSPA RA notifies ORI staff of applicable post-approval CTA amendments that may affect the informed consent. ORI staff notify the OSPA RA regarding applicable protocol amendments that may affect the CTA.

*OSPA/ORI Coordination: IRB Fees*

1. The OSPA RA screens the industry-sponsored clinical trial budget to ensure the PI has included the IRB review charge. UK policy requires a one-time \$3,000 charge for IRB review unless the OSPA Director waives the requirement.
2. After the OSPA RA acquires a fully signed CTA, he/she forwards to the ORI the information needed to prepare the invoice for this fee. Required information includes the following:
  - Name, address, phone, and fax number of contact person;
  - Sponsor protocol number;
  - IRB protocol number;
  - PI name; and
  - Protocol title.
3. The OSPA RA includes the e-mail sent to the ORI in OSPA's files.
4. ORI staff prepare the invoice and send it to the sponsor. ORI staff include the UK tax number on each invoice with the payee designated as the University of Kentucky Research Foundation.

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #10</b>	<b>TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination</b>	<b>Page 6 of 11</b>

5. If appropriate, ORI staff send a second reminder to the sponsor if the sponsor does not respond.
6. ORI staff immediately deposit any checks received into the established account.
7. ORI staff also forward the original notification email with cover email confirming receipt of the check to the OSPA Director and RA.

#### *Establishing Accounts*

1. Before establishing a new account, the OSPA RA reviews the electronic file for accuracy and completeness and verifies the PI has obtained IRB approval.
2. Many sponsors will not issue an award for sponsored research involving human subjects without IRB approval, and OSPA will not typically establish an account without it. However, if all other documents are complete except the certification of IRB approval, the OSPA RA may forward a form to the PI and his/her chair for signature. Upon receipt of this form and approval from the OSPA Director, OSPA may proceed to establish an E-account with the written understanding that no activity involving human subjects will take place until the PI obtains IRB approval. For clinical trials, an e-account is not established without special circumstances.

If OSPA establishes an account prior to IRB approval, the OSPA staff add the following statement to the first Project Account Data Record (PADR) in the OSPA electronic database: "This account has been established in advance of approval or exemption by the IRB. You may not enroll subjects, initiate any contact with prospective human subjects, collect data on human subjects or use existing data/specimens collected from living human subjects until IRB approval or exemption is obtained.

3. Once the OSPA RA receives the IRB approval letter from the ORI, the PI or study personnel, he/she enters the IRB protocol number in the OSPA electronic database.
4. UK will not disburse sponsored research funds until the PI has completed a financial conflict of interest disclosure and, if appropriate, a management plan is in place for the PI or other investigator on a project.

#### *Negotiation of Subaward Agreements for Off-Site Sponsored Research*

1. The OSPA SA contacts ORI reliance management staff for advice whenever questions arise in subaward agreements for off-site human research.

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #10</b>	<b>TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination</b>	<b>Page 7 of 11</b>

2. The OSPA SA uses Attachment 2 of the FDP template to facilitate communication and exchange of the required information between subrecipients for the involvement of human subjects.
3. The PI completes the eIAF before submitting a proposal to an extramural sponsor, checking *yes* if the project uses subcontracted or outside consultants.
4. The OSPA RA checks the proposal budget and the award documents to identify proposals which include subaward agreements as part of the proposed research and directs the PI to the online Sub-agreement Request Form. The AA sends instructions with PADR1 cover page and the CGOs are provided with a monthly report of the new accounts with subaward G/Ls in the budget. The CGO will then contact the PI and direct them to the subaward database.
5. The PI completes the online Sub-agreement Request Form, checking “*yes*” if the subcontracted portion of the project includes human subjects. The PI attaches a detailed scope of the work to be completed by the subrecipient, a budget, and a description of the plan for both supervising/monitoring the subrecipient’s performance and reporting. The subrecipient shares responsibility for detailing the scope of work and budget.
6. OSPA uses the Federal Demonstration Partnership (FDP) subaward template whenever appropriate and maintains templates for subawards when the FDP template cannot be used. The PI may obtain the template from the SA.
7. The OSPA SA ensures the subaward agreement includes clauses which require the subrecipient to abide by all applicable human research regulations and which specify that the subrecipient bears full responsibility for the proper and safe performance of its work and services involving human subjects.
8. In the subaward agreement, the OSPA SA identifies the subrecipient’s work under the subaward as involving human subjects by checking “*yes*” for that statement. In the FDP subaward template, the standard IRB clause is added to Attachment 4: Reporting and Monitoring Requirements.
9. If the OSPA SA checks “*yes*” indicating that the subrecipient’s scope of work involves human subjects, the subrecipient provides documentation to the OSPA SA that an IRB has reviewed and approved the work.
10. The Federalwide Assurance (FWA) number is captured on the Subcommitment Form or is listed in the entity profile if the subrecipient is part of the FDP expanded clearinghouse.

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #10</b>	<b>TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination</b>	<b>Page 8 of 11</b>

11. The OSPA SA checks the OHRP database for the subrecipient's active approved FWA number before submitting the subaward for full execution.

*Negotiation of Subaward Agreements for Off-Site Research Sponsored by the U.S. Department of Health and Human Services*

1. If research is federally funded by the U.S. Department of Health and Human Services (HHS), each performance site must independently assure HHS of its intent to comply with federal regulations for the protection of human subjects. To do so, each site negotiates approval of its own written assurance with the Office for Human Research Protections (OHRP).
2. OSPA maintains a template for subaward agreements for prime awards funded by an agency of the HHS and uses the FDP template whenever appropriate. The PI may obtain the template from the SA. The subaward agreement for HHS-sponsored research involving human subjects includes clauses that require the subrecipient to abide by all applicable human research regulations and specify that the subrecipient bears full responsibility for the proper and safe performance of its work and services involving human subjects.
3. If the subrecipient's work involves human subjects, the PI checks "yes" for that statement on the online Sub-agreement Request Form. The subaward agreement contains provisions requiring the subrecipient to provide the institution's federally assigned assurance number to the OSPA SA along with documentation that an IRB has reviewed and approved the research described in the sub-agreement scope of work.
4. For HHS-sponsored projects, the subrecipient also provides a letter from an IRB representative indicating the date of review/approval and committing to submit the IRB's federally assigned assurance number to the PI.
5. The SA checks the OHRP database for the subrecipient's active approved Federalwide Assurance number before submitting the subaward for full execution.
6. The PI is responsible for submitting the federalwide assurance numbers for each site to the IRB annually and for maintaining current documentation for the entire project throughout the course of the research in accordance with federal and UK IRB requirements.
7. In the subaward agreement for HHS-sponsored projects, the subrecipient certifies that his/her institution has a human subjects education program that complies with federal requirements if required by the terms and conditions of the prime award.

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #10</b>	<b>TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination</b>	<b>Page 9 of 11</b>

8. The subaward agreement and any subsequent amendments for continued funding also contain a certification statement that the project is under a currently active IRB approval.

*NIH-funded Research that generates large-scale Genomic Data subject to the Genomic Data Sharing (GDS) Policy*

1. A PI who seeks or receives NIH-funding for research that will generate large-scale human genomic data submits to the IRB an initial application or modification request including a protocol for the collection of genomic and/or phenotypic data and genomic data sharing plan.

The IRB reviews and verifies that the protocol and plans for subsequent data sharing for future research:

- meet human subject regulations and GDS policy standards;
  - are consistent with the informed consent of study participants from which the data were obtained;
  - delineate data that is excluded from sharing based on options or conditions in the informed consent (i.e., data use limitation statement);
  - include, if applicable, safeguards (e.g., Certificate of Confidentiality) to minimize potential for individual, family, or group harm (e.g., stigmatizing genetic trait, discrimination based on genetic variant); and,
  - include adequate de-identification of data, consistent with HHS and HIPAA standards.
2. ORI indicates any identified data use limitations in the IRB approval letter.
3. Once approved, the PI submits the IRB approval letter to OSPA.
4. The OSPA Director signs an Institutional Certification verifying that:
- the protocol and data sharing plan has IRB approval based on conditions above;
  - sharing is consistent with applicable national, tribal, and state laws, regulations, as well as relevant institutional policies; and
  - any limitations on the future research use of the data, as expressed in the informed consent documents or IRB review, are delineated.

*Access to NIH-Designated Data Repositories subject to the NIH Genomic Data Sharing (GDS) Policy*

1. A PI who plans to seek data from a controlled-access NIH data repository contacts OSPA to develop a data access request. OSPA consults with the PI and the information technology representative from the PI's department to ensure compliance with data security standards.

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>		
<b>Revision #10</b>	<b>TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination</b>	<b>Page 10 of 11</b>

2. OSPA gathers signed documentation from all individuals who will have access to the data confirming their acknowledgment of data policies.
3. The PI and OSPA co-sign a Data Use Certification (DUC) Agreement to complete the submission of the request for review by an NIH Data Access Committee (DAC).
4. Generally, access to GDS datasets do not stipulate IRB review and approval; however, in the rare occurrence that the NIH DAC requires local IRB review for a specific dataset, the PI submits the appropriate IRB application.

*Terminations or Lapses in IRB Approval for Sponsored Research*

1. PADRs for non-competing years require active IRB approvals to be in place to ensure IRB approval for ongoing sponsored research has not lapsed or been terminated by the IRB. The OSPA RA will not add funds to an existing account for a sponsored project including human subjects research in non-competing years unless an active IRB approval is in place.
2. If the IRB terminates approval of a sponsored project due to noncompliance, the RCO provides the OSPA Director with a copy of the resulting termination letter.
3. OSPA takes the appropriate action in accordance with the sponsor requirements.
4. If IRB approval lapses due to failure of the PI to submit a continuation review application, ORI staff send the PI a lapse of approval letter. The PI is responsible for informing the project sponsor and OSPA that IRB approval has expired.

**REFERENCES**

Not applicable

**ATTACHMENT****University of Kentucky  
IRB Fee Schedule**

**Table 1** below shows the IRB fees for protocols submitted to the UK IRB for review after February 1, 2017. With the exceptions described below, these fees apply to human subjects clinical trial protocols supported by industry funding. Sponsors will be invoiced for industry-sponsored studies reviewed by the UK IRB.

*Table 1*

<b>Type of Submission</b>	<b>Fee Schedule Effective as of February 1, 2017</b>
Initial Review	\$3000
Continuing Review	\$0
Modification review	\$0

**Exceptions:**

- Human subjects research that qualifies for Exempt IRB review.
- Protocols involving the non-research use of a Humanitarian Use Device.
- Protocols for an emergency or one-time use of an investigational drug, biologic, or device.
- Industry support is limited to the provision of a drug or device.

**Table 2** below shows the IRB fees for industry-sponsored protocols submitted to a non-UK IRB for review after February 1, 2017. Protocols submitted to a non-UK IRB must be registered with the UK ORI.

*Table 2*

<b>Type of Submission</b>	<b>Fee Schedule Effective as of February 1, 2017</b>		
			<b>UK IRB Institutional Compliance Review Fee</b>
Initial Review	External IRB fee schedule	<b><u>PLUS</u></b>	\$2000
Continuing Review	External IRB fee schedule	<b><u>PLUS</u></b>	\$0
Modification Review	External IRB fee schedule	<b><u>PLUS</u></b>	\$0
Other reviews/IRB services	External IRB fee schedule	<b><u>PLUS</u></b>	\$0