

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
SOP #6-7 Revision #4	TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination		Page 1 of 8
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: 08-21-09

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

Both OSPA and the IRB/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 (CTA); subaward agreements for off-site research; establishing accounts; and suspensions, terminations, and lapses of approval.

Definitions

Sponsors are the agencies, institutions, companies, organizations, foundations, or individual 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 is considered *sponsored research*.

RESPONSIBILITY

Execution of SOP: OSPA Research Administrators (RA), OSPA Director, Clinical Trial Agreement Administrator (CTAA), OSPA Staff, ORI Staff, ORI Director, ORI Research

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #6-7 Revision #4	TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination	Page 2 of 8

Compliance Officer (RCO); ORI Off-Site Research Coordinator, Principal Investigator (PI)/Study Personnel, Associate Deans for Research, Vice President for Research (VPR)

PROCEDURES

Proposal Submission

1. Before OSPA submits a proposal to an extramural sponsor, the PI completes the UK Internal Approval Form, clearly indicating the involvement of human subjects, if applicable, and submits it to OSPA. If the PI does not obtain the necessary project approvals prior to proposal submission, he/she submits the Internal Approval Form as soon after submission as possible.
2. The Internal Approval Form includes questions designed to verify whether the project involves human subjects and whether the PI has obtained IRB approval.
3. The RA screens each proposal and the associated Internal Approval Form. When appropriate, the RA advises the PI of sponsor requirements for submission of the certification of IRB approval and/or completion of mandatory human research training. The RA refers the PI to the ORI in cases where the PI requires additional clarification or assistance with human research protections.
4. The PI 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.
5. When the RA receives the IRB protocol number, OSPA staff enter it into the OSPA electronic database. OSPA identifies all proposals involving human subjects 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 applications require the PI to provide information on the sponsor and, if funded, the OSPA account number. ORI staff enter this information into the ORI database and physical files.
7. The OSPA RA ensures that PIs and research personnel responsible for the design, conduct, or reporting of sponsored research complete financial disclosure statements and certify that they have read the Conflict of Interest Policy prior to proposal submission. (See Investigator Conflict of Interest/OSPA/IRB/ORI Coordination SOP for details.)

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #6-7 Revision #4	TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination	Page 3 of 8

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 RA reviews the proposed research agreement and negotiates acceptable terms between the sponsor and the institution. 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 RA will not accept a research agreement without the administrative approvals contained in the Internal Approval Form.
4. The OSPA RA includes provisions in the research agreement outlining the plans for disseminating research findings in alignment with UK policies and the roles of the PI and the sponsor in publication or disclosure of research results.

Negotiation of Clinical Trial Agreements

1. Additional award negotiation procedures beyond those outlined above apply to sponsored research designated as a clinical trial.
2. The PI provides the CTAA with a copy of the proposed agreement and a sponsor contact as early in the process as possible.
3. The CTAA screens the terms of 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 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 CTAA notifies ORI staff and provides a copy of the contract language in question. ORI staff advise the CTAA on pertinent existing regulatory and institutional

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #6-7 Revision #4	TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination	Page 4 of 8

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 CTAA and respond to the CTAA requests on a case-by-case basis. The CTAA ensures that the resulting provisions incorporated into the CTA comply with the guidance obtained from the IRB/ORI.

5. The CTAA notifies ORI staff if any provisions in the contract language differ from the IRB informed consent template and applicable policies (e.g., provisions for coverage of subject injury and medical care). Also, ORI staff notify the CTAA if the IRB makes any changes in the consent form that differ from the IRB informed consent template and applicable policies. The ORI staff and the CTAA 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 CTAA also obtains a copy of the IRB approval letter from the PI or the ORI and places it in the physical file. The CTAA 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;
 - Financial disclosure forms;
 - The IRB approval letter.
7. When applicable, given the nature of the research, the CTAA includes a clear statement in the CTA that addresses medical care for research subjects with a research-related injury.
8. The CTAA 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.
9. Once the CTAA has all required documentation, he/she forwards the file to the OSPA RA to establish the account.
10. If, prior to receiving certification of IRB approval, all other documentation is complete, the CTAA may forward the file to the RA for account establishment with restrictions preventing research subject enrollment and prospective subject contact. See *Establishing Accounts* below.
11. In studies in which sponsors are responsible for overseeing the progress of the research to be conducted, the CTAA includes written provisions in the agreement for timely communication from the sponsor of any information that may affect research oversight of a protocol by the IRB, affect the safety of human subjects or their willingness to participate, or influence the conduct of the study, as required by the Food and Drug Administration.

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #6-7 Revision #4	TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination	Page 5 of 8

12. If UK receives such information from the sponsor, including evidence of serious or continuing non-compliance or evidence of scientific misconduct, OSPA staff report it to the IRB and the ORI.

OSPA/ORI Coordination: IRB Fees

1. The OSPA CTAA screens the industry-sponsored clinical trial budget to ensure that the PI has included the IRB review charge. UK policy requires a one-time \$2,000 charge for IRB review unless the OSPA Director waives the requirement.
2. After the CTAA 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;
 - Protocol title.
3. The CTAA prints out the e-mail sent to the ORI for 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.
5. If appropriate, ORI staff send a second reminder to the sponsor if the sponsor does not respond.
6. ORI staff deposit any checks received immediately 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 OSPA CTAA. .

Establishing Accounts

1. Before establishing a new account, the RA reviews the physical and data file for accuracy and completeness and verifies that the PI has obtained IRB approval.
2. Most sponsors will not issue an award for sponsored research involving human subjects without IRB approval, and OSPA will not typically establish a clinical trial account without it. If, however, all other documents are complete except the certification of IRB approval, the CTAA will forward a form letter to the PI for signature. This letter indicates that OSPA will

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #6-7 Revision #4	TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination	Page 6 of 8

proceed to establish an account with the written understanding that no activity involving human subjects will take place until the PI obtains IRB approval.

3. If OSPA establishes an account prior to IRB approval, the OSPA staff add a statement to the Project Account Data Record (PADR) in the OSPA electronic database: "This account has been established in advance of approval by the IRB. You may not enroll subjects or initiate contact with prospective subjects, prior to obtaining IRB approval."
4. Once the RA receives the IRB approval letter from the ORI or the PI, the RA enters the IRB protocol number in the OSPA electronic database.
5. UK will not disburse sponsored research funds in the event of an unresolved financial conflict of interest on the part of a PI or other investigator on a project.

Negotiation of Subaward Agreements for Off-Site Sponsored Research

1. OSPA staff contact the ORI off-site research coordinator for advice whenever questions arise in subaward agreements for off-site human research.
2. OSPA makes available to the PI specific forms and standard content/clauses of subaward agreements in the form of templates to facilitate communication and exchange of required information between subrecipients, their non-UK IRBs, and the UK IRB when subcontracted research involves human subjects.
3. Before submitting a proposal to an extramural sponsor, the PI completes the UK Internal Approval Form, checking *yes* if the project uses subcontracted or outside consultants.
4. The RA checks the proposal budget and the award documents to identify proposals which include subaward agreements as part of the proposed research and provides the PI with a copy of the Subagreement Request Form. Alternately, the PI downloads a copy of the form from the OSPA web site.
5. The PI completes the Subagreement Request Form, checks *yes* if the subcontracted portion of the project includes human subjects, attaches a detailed scope of the work to be completed by the subrecipient, and describes the plan for supervising and monitoring the subrecipient's performance and reporting. The subrecipient shares responsibility for detailing the scope of work.
6. OSPA maintains templates for the standard subaward agreement for research involving human subjects on its web site. The PI may obtain the template from the OSPA web site or from the OSPA RA.

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #6-7 Revision #4	TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination	Page 7 of 8

7. The RA ensures that 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 RA identifies the subrecipient's work under the subaward as involving human subjects by checking *yes* in the blank for that statement.
9. If the RA checks *yes* indicating that the subrecipient's scope of work involves human subjects, the subrecipient provides documentation to the RA that an IRB has reviewed and approved the work.

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

1. If research is federally funded by the Department of Health and Human Services (DHHS), each performance site must independently assure DHHS 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 DHHS. The PI may obtain the template from the OSPA web site or from the RA. The subaward agreement for DHHS-sponsored research involving human subjects 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.
3. If the subrecipient's work involves human subjects, the PI checks *yes* for that statement on the Subagreement Request Form. The subaward agreement contains provisions requiring the subrecipient to provide the institution's federally assigned assurance number to the RA along with documentation that an IRB has reviewed and approved the research described in the subagreement scope of work.
4. For DHHS-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 PI is responsible for submitting the 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.

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #6-7 Revision #4	TITLE: Office of Sponsored Projects Administration/IRB/ORI Coordination	Page 8 of 8

6. In the subaward agreement for DHHS-sponsored projects, the subrecipient certifies that his/her institution has a human subjects education program that complies with federal requirements.
7. The subaward agreement and any subsequent amendments for continued funding also contain a certification statement that the project is under a currently active approval.

Terminations or Lapses in IRB Approval

1. To ensure that IRB approval for ongoing sponsored research has not lapsed or that the IRB has not terminated approval, the PADR for non-competing years requires an active IRB approval to be in place.
2. If the IRB terminates IRB approval of a sponsored project due to noncompliance, the ORI 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 an 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 sponsor of the project and OSPA that IRB approval has expired.

REFERENCES

Not applicable