

| <b>University of Kentucky Office of Research Integrity and Institutional Review Board<br/>Standard Operating Procedures</b> |  |      |                                   |
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| <b>SOP #4-2<br/>Revision #4</b>   | <b>TITLE: Inspections by Regulatory<br/>Agencies</b> |      | <b>Page 1 of 3</b>                |
| Approved By:<br>ORI Director  | Signature  | Date | Date First Effective:<br>06-28-05 |
| Approved By:<br>Nonmedical IRB<br>Chair   | Signature  | Date |                                   |
| Approved By:<br>Medical IRB Chair   | Signature  | Date | Revision Date:<br>07/29/2011      |

### **OBJECTIVE**

To describe the policies and procedures for the Office of Research Integrity (ORI)/Institutional Review Board (IRB) with respect to inspections by external regulatory agencies

### **GENERAL DESCRIPTION**

IRB and ORI records are subject to regulation and inspection by governmental agencies [e.g., Food and Drug Administration (FDA) or the Office for Human Research Protections (OHRP)].

### **RESPONSIBILITY**

Execution of SOP: Office of Research Integrity (ORI) Staff, IRB Chair, Vice President for Research (VPR), ORI Director, ORI Quality Improvement Program (QIP) Coordinator

### **PROCEDURES**

#### *Upon Notice of Inspection*

1. ORI staff/IRB Chair(s) ask all inspectors to identify themselves by name and title and show appropriate identification. Inspectors must inform ORI staff/IRB Chair(s) what agency they represent and state the reason for the inspection. If an inspector is unable to provide identification, IRB Chair(s)/ORI staff will request that he/she return with the appropriate identification. Inspectors with the FDA must present a Form 482 upon arrival.
2. After the inspector has identified her/himself, UK personnel notify the ORI Director of the inspection. In instances when the ORI Director is not available, ORI staff offer to assist but inform the inspector that the supervisor is not present in the office. ORI staff then suggest that, while they will do their best to help him/her, rescheduling the inspection for a time when the ORI Director is available, as the ORI Director might be better equipped to answer

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questions. If the ORI Director is not present and the federal inspector decides to stay and conduct the inspection, ORI staff must contact the IRB Chair(s), ORI Quality Improvement Program Coordinator, and the VPR immediately.

#### *During Inspection*

1. The ORI Director or designee and a designated ORI staff member are available to the inspector throughout the inspection.
2. The ORI Director or designee, the designated ORI staff member, the Chair of the appropriate IRB (Medical or Nonmedical), if available, and the VPR, if available, may meet with the inspector at the beginning of the inspection.
3. ORI staff and the IRB Chair answer all inspector questions or concerns accurately, honestly, and succinctly and answer only the questions asked.
4. The federal inspector has the right to visually observe and inspect all facilities and records of the IRB.
5. If the inspector requests duplicate copies of IRB records, ORI staff comply with the requests and keep a list of the records the inspector has received for duplication. The inspector may ask to duplicate these records at a UK facility or ask office personnel to duplicate the records. ORI staff members are available to duplicate these records. If the inspector decides to use duplicating equipment outside the ORI offices, an ORI employee must travel with the inspector to the duplication office to verify the documents copied.
6. At the conclusion of the inspection, the ORI Director or designee, designated ORI staff member, the appropriate IRB Chair, if available, and the VPR, if available, may attend the exit interview. If an inspector identifies deficiencies, he/she may leave a copy of the findings with ORI staff, documenting the results of the inspection. If the inspector does not identify any problems during the inspection, the ORI Director/IRB Chair receives a letter following the inspection from agency headquarters confirming the outcome.

#### *Following the Inspection*

1. The ORI QIP Coordinator or designee maintains a record of everything reviewed by the inspector following the inspection, along with copies of any correspondence provided at the conclusion of the inspection or received after the inspection.
2. The QIP Coordinator or designee forwards copies of correspondence received from the inspector to the ORI Director, IRB, and the VPR. The VPR, IRB, and ORI staff discuss any corrective action and prepare and implement a response plan as appropriate.

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3. The IRB/ORI submits a written response regarding the inspection to the appropriate authority, if required. The ORI Director and, if appropriate, the VPR and/or IRB Chair approve any written response. ORI staff send copies to the IRB Chair and the VPR.

### **REFERENCES**

Not applicable