University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
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Approved By: ORI Director	Signature	Date	Date First Effective: 03-01-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	
Approved By: IBC Biological Safety Officer	Signature	Date	Revision Date: 02/15/2017

OBJECTIVE

To describe procedures for coordination between the Institutional Review Board (IRB)/Office of Research Integrity (ORI) and the Institutional Biosafety Committee (IBC) on protocols involving recombinant and/or synthetic nucleic acid molecules, infectious agents, and/or human gene transfer/therapy products, selected vaccine trials involving Investigational New Drugs (IND), and immunotherapies.

GENERAL DESCRIPTION

Both the IBC and the IRB are committed to ensuring the protection of human subjects involved in research. They have enacted a number of coordination activities in significant areas including: joint committee membership; protocol review; training for IBC/IRB personnel; complaints and alleged noncompliance; quality assurance/improvement findings; and joint policy/procedures.

RESPONSIBILITY

Execution of SOP: Institutional Biosafety Committee (IBC) Staff, IBC Biological Safety Officer (BSO) or designee, IRB Members, ORI Staff, ORI Quality Improvement Program (QIP) Coordinator, ORI Research Compliance Officer (RCO), ORI Research Privacy Specialist (RPS), Principal Investigator (PI)/Study Personnel

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PROCEDURES

Joint Committee Membership

1. The Biological Safety Officer serves as an ex-officio non-voting member of the Medical IRBs. The BSO also serves as an ex-officio voting member of the IBC. The BSO is the primary liaison for ensuring coordination between the IBC and the IRB with respect to protocol review.

2. The ORI Director or his/her designee serves as an ex officio non-voting member of the Medical IRBs and is an ex officio member of the Committee on Safety and Environmental Health, of which the IBC is a subcommittee. The ORI Director or his/her designee serves as primary liaison in the development of joint IBC/IRB policies and procedures.

3. The ORI staff, with input from the BSO, selects IRB members based upon appropriate expertise to serve as IRB primary reviewers for recombinant and/or synthetic nucleic acid molecules, infectious agents, and/or human gene transfer protocols and select vaccine initial review IRB applications. The BSO is responsible for training the designated IRB member(s) on biosafety issues to consider in relation to human research protections, including training on risk assessment.

Protocol Review

1. When a PI proposes research which falls under the purview of the IBC, the PI must submit his/her protocol to the BSO. If ORI staff receive an IRB application, which in their judgment may require IBC approval, ORI staff contact the BSO for assistance in determining whether IBC review is required.

2. The BSO screens the protocol to determine if prior IBC approval is required. The BSO notifies the PI and the ORI in writing of the outcome of his/her review.

3. If the BSO reviews a protocol which plans to or uses an external IRB, the BSO immediately (i.e. within two days) notifies the appropriate ORI staff.

4. If the BSO determines that the protocol does not need IBC review and approval, the IRB conducts the review using IRB/ORI standard operating procedures.

5. If the BSO determines that the protocol requires IBC review and approval, the investigator must obtain IBC approval before the IRB approves the initial review application.

6. The IRB will not approve new protocols falling under IBC purview unless the PI has obtained IBC review and provisional approval and has included the required IBC documentation in the IRB application.

7. ORI staff are responsible for providing the BSO, the IRB's primary IBC reviewer, and the IRB members with protocol review materials, following standard operating procedures for disseminating information prior to the IRB meeting.

8. The BSO or his/her designee provides the IRB with safety expertise, especially with respect to risk assessment. The BSO or his/her designee may attend the convened IRB meeting or send comments in writing. The designated primary reviewer is responsible for conducting primary review following procedures outlined in the Initial Full Review SOP.

Complaints and Alleged Noncompliance

1. If the IBC receives a complaint from a subject, subject family member, staff, or researcher concerning alleged noncompliance or subject rights and welfare, the BSO immediately (i.e., within 2 days) notifies the ORI Research Compliance Officer. The BSO may confer with the ORI RCO to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, IBC, or both committees.

2. If the ORI RCO receives a complaint or alleged noncompliance involving an IBC protocol or issue pertinent to biosafety, the ORI RCO immediately (i.e., within 2 days) notifies the BSO. The ORI RCO may confer with the BSO to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, IBC, or both committees.

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3. If the complaint/alleged noncompliance falls under IRB purview, the ORI initiates an inquiry following standard ORI/IRB operating procedures. The IRB is also responsible for determining whether the incident meets requirements for reporting to the federal regulatory agencies. In making the determination, the IRB follows standard ORI/IRB operating procedures for reporting. (See the Mandated Reporting to External Agencies SOP.)

4. After the IRB has completed its review of the complaint/alleged noncompliance, the ORI RCO is responsible for providing the BSO with a copy of the final deliberations. If the IRB determines that the incident is reportable to a federal regulatory agency, the RCO is responsible for sending a copy of the federal report to the BSO.

5. If the complaint/alleged noncompliance falls under IBC purview, the BSO initiates an inquiry following standard IBC operating procedures. After the IBC has completed its review of the complaint/alleged noncompliance, the BSO is responsible for providing the ORI with a copy of the final deliberations. If the IBC determines the incident is reportable to a federal regulatory agency, the BSO is responsible for sending a copy of the federal report to ORI.

Quality Assurance/Improvement Findings

1. If the ORI Quality Assurance/Improvement Program conducts a directed or routine Quality Improvement Review (QIR) of an IBC protocol, the Quality Assurance/Improvement Program team is responsible for providing the BSO with a copy of the findings of the directed or routine QIR.

2. If the BSO or any IBC personnel audits or inspects an IBC protocol, the BSO is responsible for providing the ORI Quality Assurance/Improvement Program with a copy of the report. The ORI Quality Assurance/Improvement Program team is responsible for sending the report to the IRB to determine whether additional IRB action is necessary.

Joint Policy/Procedures

1. The ORI Director or his/her designee, when appropriate, is responsible for initiating efforts to establish joint IRB/IBC policy, procedures, and submission forms.

2. The IBC, ORI staff, the IRB, or University of Kentucky researchers or administrators may submit suggestions or recommendations for the joint policy/procedure/form initiatives to the ORI Director.

3. The ORI Director and the BSO must approve any revision to existing joint policies or forms.

REFERENCES
Not applicable