

UNIVERSITY OF SOUTHERN MAINE  
Office of Research Integrity & Outreach

<b>Procedure #:</b>	HRPP-018; IBC-002
<b>AAHRPP:</b>	Element I.1.C.
<b>Date Adopted:</b>	06/10/2019
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<b>Reviewed By:</b>	IRB; IBC; ORIO
<b>Procedure Title:</b>	IBC Coordination

## **1.0 Objective**

- 1.1. To describe procedures for coordination between the Institutional Review Board (IRB), Office of Research Integrity and Outreach (ORIO) 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.

## **2.0 General Description**

- 2.1. Both the IBC and the IRB are committed to ensuring the protection of human subjects involved in research.
- 2.2. Research that requires review by both the IBC and the IRB cannot commence until both the IBC and the IRB issue approval letters.
  - 2.2.1. If conditional approval is granted, the research cannot commence until all conditions are met.

## **3.0 Responsibility**

- 3.1. It is the responsibility of the ORIO staff, Research Compliance Administrator (RCA), Research Compliance Administrator (RCA), IRB, IBC, and Principal Investigators (PI) to execute this SOP.

## **4.0 Procedure**

### **4.1. Protocol Review**

- 4.1.1. When a PI proposes research that falls under the purview of the IBC, the PI must submit their protocol to the IBC.

- 4.1.2. If ORIO staff receive an IRB application, which in their judgment may require IBC approval, the RCA or designee contacts the RCA for assistance in determining whether IBC review is required.
  - 4.1.2.1. The RCA screens the protocol to determine if prior IBC approval is required or if the study may be submitted directly to the IRB.
  - 4.1.2.2. The RCA notifies the PI and RCA in writing of the outcome of his or her review.
- 4.1.3. If the IBC reviews a protocol which plans to or uses an external IRB, the RCA immediately (i.e. within two (2) days) notifies the RCA.
- 4.1.4. If the RCA determines that the protocol does not need prior IBC approval, the investigator submits an IRB application following IRB standard operating procedures.
  - 4.1.4.1. The IRB conducts the review following standard operating procedures.
- 4.1.5. If the RCA determines that the protocol requires prior IBC approval, the investigator must obtain provisional IBC approval before submitting the IRB initial review application.
  - 4.1.5.1. The IRB will not approve new protocols falling under IBC purview unless the PI has obtained IBC review and provisional approval first and has included the required IBC documentation in the IRB application.

## **4.2. Complaints and Alleged Noncompliance**

- 4.2.1. If the IBC receives a complaint from a subject, community member, staff, or researcher concerning alleged noncompliance or subject rights and welfare, the RCA immediately (i.e., within two days) notifies the RCA and Research Integrity Officer (RIO).
  - 4.2.1.1. The RCA and RCA may confer with the RIO to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, IBC, or both committees.
- 4.2.2. If the complaint/alleged noncompliance falls under IRB purview, the RCA initiates an inquiry following standard operating procedures.
  - 4.2.2.1. After the IRB has completed its review of the complaint/alleged noncompliance, the RCA is responsible for providing the RCA with a copy of the final deliberations.

- 4.2.2.2. If the IRB determines that the incident is reportable to a federal regulatory agency, the RCA is responsible for sending a copy of the federal report to the RCA.
- 4.2.3. If the complaint/alleged noncompliance falls under IBC purview, the RCA initiates an inquiry following standard IBC operating procedures.
  - 4.2.3.1. After the IBC has completed its review of the complaint/alleged noncompliance, the RCA is responsible for providing the RCA with a copy of the final deliberations.
  - 4.2.3.2. If the IBC determines the incident is reportable to a federal regulatory agency, the RCA is responsible for sending a copy of the federal report to RCA.

### **4.3. Quality Assurance**

- 4.3.1. If the RCA or any IRB personnel audits or inspects an IRB protocol under IBC purview, the RCA or the IRB is responsible for providing the IBC with a copy of the report.
  - 4.3.1.1. The RCA is responsible for sending the report to the IBC to determine whether additional IBC action is necessary.
- 4.3.2. If the RCA or any IBC personnel audits or inspects an IBC protocol under IRB purview, the RCA or the IBC is responsible for providing the IRB with a copy of the report.
  - 4.3.2.1. The RCA is responsible for sending the report to the IRB to determine whether additional IRB action is necessary.

### **4.4. Joint Policy/Procedures**

- 4.4.1. The RCA, when appropriate, is responsible for initiating efforts to establish joint IRB/IBC policy, procedures, and submission forms.