RUTGERS

Biosafety Requirements for Human Subject Studies

The Rutgers Institutional Biosafety Committee (IBC) works with the Institutional Review Board (IRB) to help ensure that Rutgers' Principal Investigators (PIs) and associated Rutgers study personnel are aware of compliance requirements beyond the need to register with the IRB for the following types of studies:

1. Human clinical studies with recombinant materials (tissues, cells, fluids, etc., FDA Investigational New Drug that are recombinant or genetically modified, and or FDA-approved therapies that are recombinant or genetically modified (e.g. CD19 CAR-T cells Yescarta and Kymriah)
   and/or;
2. Research involving recombinant and non-recombinant materials (tissues, cells, fluids, etc.) from human subjects

Please use the table below to help determine whether your research activities require IBC approval, as well as have other institutional requirements.

Note: if required, IBC approval must be in place **before** an IRB application can be approved!

Questions? Contact biosafety@rutgers.edu!

Activity	Requirements:
Processing[1] of study specimens	○ **If processing will be within a Rutgers laboratory:** ○ An approved IBC protocol is required before commencing the work and must cover the: ▪ Description of the material(s) being collected ▪ Procedures and equipment to be used for the collection and processing ▪ Location(s) of the work ▪ Personnel involved, as applicable ○ After IBC approval, upload the IBC approval letter into the eIRB application ○ **If processing will be done by an outside (non-Rutgers) laboratory:** ○ Check the requirements for Collecting, Transporting and Shipping specimens to help ensure all necessary training and permits are in place, as applicable. ○ Contact biosafety@rutgers.edu for an IBC exemption email that can be uploaded into your eIRB application. ○ **If location of the processing laboratory has yet to be determined:**

	○ Contact biosafety@rutgers.edu for assistance in locating a Rutgers Core for processing/shipping services, as needed (fees are involved for these services). Respective Cores would provide their IBC approval letter for uploading into the eIRB application.
Collecting specimens (or receiving subject-collected specimens)	○ Clinical Health and Safety Training[2] for all Rutgers employees involved.
Transporting specimens using personal vehicle	○ Materials of Trade (MOT) training [4] ◦ MOT training is available as a stand-alone online course, but it is also included as a component of the IATA Shipping Training[5]
Shipping specimens outside of Rutgers	○ **Domestic shipping**: ○ IATA Shipping Training[5] (includes MOT[4] component) ○ **International shipping**: ○ IATA Shipping Training[5] ○ Clearance from Rutgers Export Control[6] is required ○ Confirm with Study Sponsor whether the receipt of the investigational study material requires an Import Permit before sending the material
Administering recombinant/genetically modified study drug to human subjects	○ Contact biosafety@rutgers.edu to assess whether the study drug requires IBC approval.

1. Manipulation of unfixed human materials, including centrifuging, pipetting, aliquoting, transferring from the original receptacle, preparing for fixation, embedding, histology activities such as cryostat, cutting, etc.
2. Clinical Health and Safety training is required for all personnel who have direct patient contact and/or will be handling/transporting human materials as part of their job. The module is located on the REHS Training Calendar tab (scroll down to table headed, 'Online Training Links')
3. Laboratory Safety/Biosafety Training is required if working in a Rutgers research laboratory. In-person training is required initially, and an online refresher is required annually, thereafter. Click here to access *the Rutgers Courses* to register for a session and the *Online Training Links* table to access the online refresher module. ***Note***: choose to include the optional biosafety/BBP content when asked on the online Registration page.
4. Persons requiring MOT training must contact biosafety@rutgers.edu for access to the online module. Personnel must be up to date with either Clinical Health and Safety Training or Laboratory Safety/Biosafety Training, as appropriate.
5. IATA 'Category B' Shipping Training is required to ship specimens via commercial carrier. Instructor-led training (presented virtually) is required initially, and an online refresher module is required every 2 years, thereafter. Click here to access *the Rutgers Courses* to register for an instructor-led session and the *Online Training Links* table to access the online refresher module.
6. RU Export Control must be contacted for approval of any shipments outside of the US.