ORA Procedure and Process Template

Title: Institutional Biosafety Committee Review of Clinical Research Studies

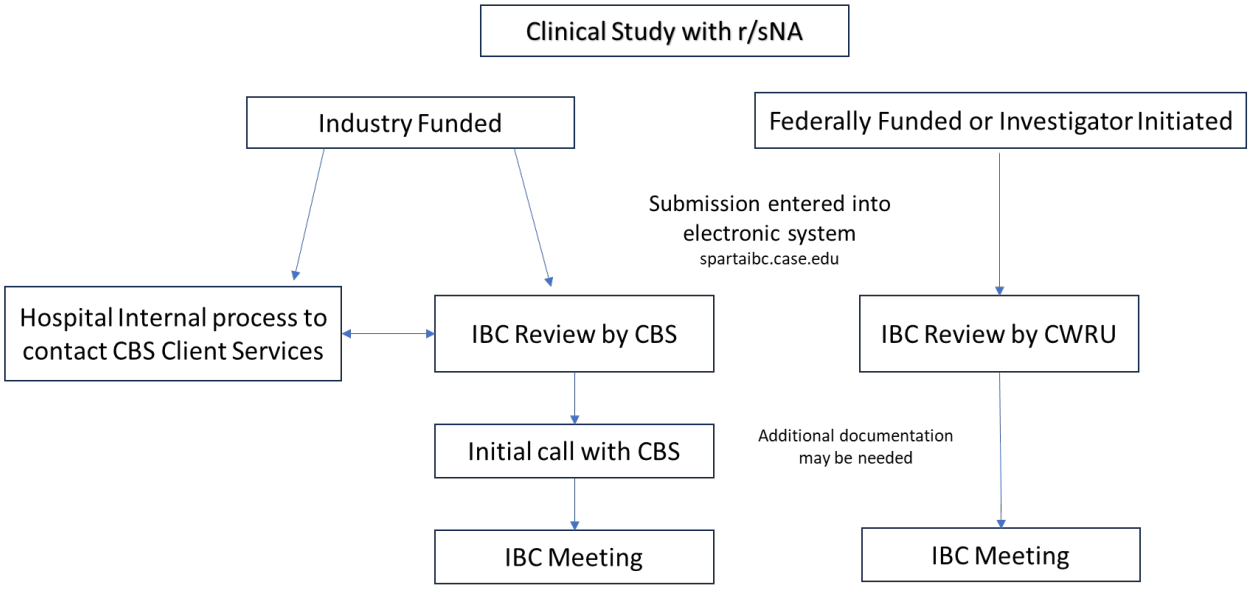
Audience: Affiliate hospital administrators/researchers conducting clinical research with recombinant or synthetic nucleic acid molecules

Summary/Purpose: The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* define regulatory requirements for institutions receiving federal funding. Research that falls under the *NIH Guidelines*, including human gene transfer research, must be reviewed by an Institutional Biosafety Committee (IBC).

Background and Rationale:
A variety of investigational products involve the transfer of recombinant or synthetic nucleic acid molecules (r/sNAs) into human research participants, including but not limited to: vaccines, viral vectors, and cell therapies. These studies will require review and approval by the IBC prior to initiation. Based on the funding for the study, the IBC review will be conducted according to the following:

- Industry-sponsored clinical studies will be reviewed by an external IBC registered with the NIH Office of Science Policy under Case Western Reserve University (CWRU).
- All other clinical studies, including grant-funded and investigator-initiated studies, will be reviewed by the CWRU IBC at a standing monthly meeting.

Procedure/Process:



External IBC Review conducted by Clinical Biosafety Services (CBS) [Industry sponsored]

1. Industry sponsors should be provided information on external IBC fees - this information can be requested by contacting case-ibc@case.edu. Once an industry-sponsored study

has been identified to be conducted at a CWRU affiliated hospital, two steps are needed to initiate IBC review:

a. The hospital team contacts CBS Client Services (clientservices@clinicalbiosafety.com) with the sponsor/study information so that CBS can establish the billing pathway (CBS will bill the sponsor directly).
b. The research team submits an IBC protocol in the CWRU IBC electronic system (spartaibc.case.edu), providing the sponsor documents, PI CV, and locations within the hospital which will be used for the storage, preparation, and administration of the investigational product.

2. Once the billing is established, the review process will consist of:
    a. A meeting between a CBS Associate Partner and the study team to review the hospital locations and the sponsor documents provided.
        i. Provides an opportunity for anyone or any unit involved in the research to discuss the study procedures and the biosafety measures that are typical for the type of investigational product being used in the study.
        ii. Additional information may be collected or requested, including documentation of facilities and training as outlined in the next section.
    b. A date will be set for the IBC meeting to review the study.
        i. The committee includes representatives from CWRU and UH and any individual involved in the study or facilities is welcome to attend.
    c. The committee will approve or disapprove the study. Approvals will be for one year, a continuing review will be needed if the study is still enrolling or participants are still being administered the investigational product.
        i. Approval may include recommendations, or the approval may be contingent upon further actions or information.
    d. CBS will communicate the outcome of the meeting with the PI and study team and follow up as needed. All documentation will be provided by CBS and added to the CWRU IBC electronic system record.

<u>Documentation of Facilities and Training</u>

The IBC will need documentation of facilities within the hospital, and this information will be maintained for all studies at the site and reviewed yearly unless there are any changes implemented at the hospital.

1. Training:
    a. Documentation of Bloodborne Pathogen (BBP) Training by a staff member involved in the clinical study.
    b. Infectious Substance Shipping Training (such as IATA Training) for one staff member responsible for shipping human materials.
    c. PIs, co-investigators, and study staff who are listed on the IBC submission will need to complete CITI training: NIH Recombinant DNA Guidelines and Human Gene Transfer courses every 3 years
2. Facilities - photos of areas where the study agents are stored, prepared, administered and disposed
    a. Administration room

   b. Storage room and storage unit (refrigerator, freezer)
   c. Preparation room
   d. Biological safety cabinet (BSC) or Compounding aseptic containment isolator (CACI)
   e. Waste containers in administration and preparation room (biohazardous waste, pharmaceutical waste, chemo waste) with biohazard label
   f. Biohazard waste storage area (prior to vendor collection)
   g. Sharps containers
   h. Eyewash stations (plumbed, portable bottles)
   i. Transport container
   j. Disinfectant product labels
3. Equipment Certification Reports (BSC, CACI)
4. Hospital Exposure Control Plan
5. Site Maps, indicating sinks, eyewashes, and biohazard storage areas
   a. Preparation room
   b. Storage room
   c. Administration room

IBC Review conducted by Case Western Reserve University (CWRU) [Federally funded]

1. The research team submits an IBC protocol in the CWRU IBC electronic system (spartaibc.case.edu), providing study details including the locations within the hospital which will be used for the handling of the agent, procedures involving the study agent and biosafety measures in place to minimize risk of exposure to staff, the community and the environment (PPE, disinfection, waste disposal, etc).
2. The submission will undergo pre-review by staff in the Office of Research Administration and Technology Management at CWRU. Any clarifications/changes that are needed will be sent back to the PI/study team.
3. The completed IBC submission will be placed on a meeting agenda for review by the CWRU IBC.
   a. The committee meets on the second Thursday of the month
   b. The submission should be received by the IBC office one month prior to the meeting.
4. The committee will approve, approve with modifications, table or disapprove the study. The PI and study contacts will be notified of the committee decision through the electronic system, including any follow up that is needed. Approvals will be for one year, and a continuing review will be needed if the study is still enrolling or participants are still being administered the investigational product.

Definitions:

Biological Safety Cabinet (BSC) - an engineering control designed to protect laboratory personnel, the environment and materials being handled from exposure to infectious aerosols and splashes.

Compounding Aseptic Containment Isolator (CACI) - provides a safe and clean environment for work involving hazardous materials, antineoplastic, or cytotoxic compounding applications.