Standard Operating Procedure (SOP)
For Submitting Clinical Gene Transfer Research Protocols

Purpose:

This SOP establishes the procedure for submitting a clinical gene transfer protocol to the IBC-CGT for review. This SOP applies to all clinical trials involving the transfer of recombinant or synthetic nucleic acids into humans. Research cannot be initiated until Institutional Biosafety Committee and all other applicable institutional and regulatory authorization(s) and approvals have been obtained.

The deliberate transfer of recombinant or synthetic nucleic acids into one human research participant, conducted under an FDA-regulated individual patient expanded access IND or protocol, including for emergency use, is not research subject to the NIH Guidelines and thus does not need to be submitted to an IBC for review and approval.

Please refer to the NIH Guidelines for more information: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Procedure:

1) The Dartmouth College Biosafety Officer is the point of contact for IBC-CGT submissions. Please contact the Biosafety Officer, at biosafety@dartmouth.edu to submit a protocol or with any inquiries regarding the submission process.

2) The following materials must be included in the protocol submission. Please email the following materials to the Biosafety Officer at biosafety@dartmouth.edu:

   a. Correspondence Info:
   - i. Letter of scientific review/merit (e.g., Department Approval Letter, CCRC Approval Letter)
   - ii. Letter of IRB approval or date of expected IRB review
   - iii. Letter of assurance from the investigational/site pharmacy of ability to receive, house, and dispense study agent

   b. Protocols/Procedures/Manuals
   - i. Completed Local Safety Standard Operating Procedure (SOP) template.
   - ii. Clinical Protocol
   - iii. Signed Investigator Protocol Signature Page
   - iv. Investigator's Brochure (IB)
   - v. Pharmacy and/or Laboratory Manual for study agent

   c. Documentation of **completion of appropriate training requirements** (e.g. BSL2, blood borne pathogen training) for all study personnel and pharmacy personnel who will come into contact with study agent

Dartmouth College, Institutional Biosafety Committee for Clinical Gene Transfer (IBC-CGT)
37 Dewey Field Road, HB 6216 Hanover, NH 03755
P: 603.646.1762 | ehs@dartmouth.edu

3) The Biosafety Officer and IBC-CGT Chair will perform a pre-review and inform the PI if any additional information is needed. Then, the protocol materials will be sent to the full committee for review.

4) A meeting will be scheduled within a reasonable amount of time. The PI may attend to answer questions posed by the committee.

5) The committee will privately discuss and vote on the protocol. The protocol may be "approved", "conditionally approved", or "not approved". A letter cosigned by the Chair and Biosafety Officer will be sent to the PI stating the committee's decision. If further information is necessary for the committee to reach a decision this will be requested. A copy of this letter kept on file with Environmental Health & Safety.

6) A copy of each protocol and all information pertaining to that protocol is filed in the EHS office IBC-CGT files. The IBC-CGT correspondence with the PI and the approved Local Safety SOP are uploaded into Clinical Trials Management System (CTMS) by the PI.

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