TITLE:	**IBC Application and Review Process for Protocols Involving Human Gene Transfer Experiments. [UNMC-IBC10]**
OVERVIEW:	All studies using biohazardous materials must undergo IBC review. This policy was designed to address the special requirements necessary for experiments using human gene transfer applications.
APPLIES TO:	All principal investigators conducting experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants. 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
DEFINITION(S):	*Human gene transfer* is the deliberate transfer into human research participants of either: 1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or 2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria: a. Contain more than 100 nucleotides; or b. Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or c. Have the potential to replicate in a cell; or d. Can be translated or transcribed.
PROCEDURES:	Research cannot be initiated until Institutional Biosafety Committee and all other applicable institutional and regulatory authorization(s) and approvals have been obtained. Refer to the policy, "IBC Application and Review Process for New Protocols" for additional information. 1. Use the RSS program found at https://net.unmc.edu/rss to start an

	application. Select "IBC" from the black bar across the top of the page. Select "New Protocol" under the "IBC Application" heading. 2. Once all appropriate sections have been complete, sign the application and submit for pre-review by the IBC Chair. 3. The full IBC membership will review the application at a convened meeting. 4. Following the review process, the principal investigator may be asked to amend the application. Comments may be communicated via e-mail or letter. Copies of the transmitted comments are appended to the meeting minutes. During this review process, all laboratories using RG-2 and RG-3 biohazardous materials will be requested to have a laboratory inspection by the Biosafety Officer. Refer to the policy entitled, "IBC Laboratory Inspection Process" for additional information. 5. The PI will submit the amended application for expedited member review. Further amendments or clarifications may be requested at this time. 6. If it has been determined that the protocol successfully complies with the requirements of the *NIH Guidelines*, a letter approving the protocol authorizing initiation of the studies upon documentation of all applicable approvals will be sent to the PI.
RECORD KEEPING:	The PI should maintain a record of the approved IBC protocol and the approval letter in RSS. The IBC ORA office will maintain a copy of the protocol and approval letter per sponsor requirements.
OTHER INFORMATION:	The IBC has been charged by Federal law with the planning and implementation of the campus biosafety program with a purpose to ensure the health and safety of all personnel working with biohazardous agents. The IBC makes certain that research conducted at the Institution is in compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and the *Federal Select Agent Program*, reviews campus biosafety policies and procedures, and reviews individual research proposals for biosafety concerns.
REFERENCES:	
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University of Nebraska Medical Center

Biosafety Policies and Procedures

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