

Human Gene Transfer Institutional Review Process

- 1) Principal Investigator
 - a. Submits to OSURF Office of Sponsored Programs the proposal and “Authorization to Seek Off-Campus Funds” form (PA-005) indicating in PA-005 section 6E that the study involves Human Gene transfer.
 - b. Submits proposed research protocol to Chair for departmental review
- 2) Department Chair - assures that the protocol has undergone scientific review and that the department will support the proposed research with appropriate resources
- 3) Principal Investigator - Notifies the Institutional Biosafety Committee (IBC) of new HGT study and submits IBC application, protocol and curriculum vitae (in NIH biographical sketch format).
- 4) IBC Coordinator initiates database record, assigns IBC protocol number, notifies IBC Chair of protocol receipt and requests that the IBC Chair proceed with required notifications (detailed in step 5). IBC Coordinator also ensures that HGT study is added to HGT Tracking sheet.
- 5) Chair, Institutional Biosafety Committee
 - a. Forwards this process document and provides additional information to the Principal Investigator regarding the Human Gene Transfer Review Process
 - b. Pre-reviews the IBC application
 - c. Determines if all necessary external reviews have been completed (e.g., RAC)
 - d. Determines if any additional information is required (e.g., from RAC, sponsor)
 - e. Notifies the following individuals / offices of the impending HGT:
 - i. AVP, Office of Research Compliance
 - ii. Associate Dean for Clinical Research, College of Medicine (COM)
 - iii. Deputy Executive Director, OSU Research Foundation – In order to flag project as HGT and ensure appropriate contractual terms and conditions
 - iv. Director, Technology, Licensing and Commercialization (TLC) – To review and determine if there are any potential intellectual property issues
 - v. University Conflict of Interest Administrator, Office of Research Compliance – To review and ensure no conflicts of interest
 - vi. Legal Counsel for the College of Medicine and Office of Legal Affairs – To ensure appropriate contractual terms and conditions
 - f. Notifies IBC Coordinator when study is ready for IBC agenda
- 6) Institutional Biosafety Committee (IBC)
 - a. Reviews the research protocol utilizing infectious disease and/or other consultants as required.
 - b. Approves, Disapproves, Requires Modifications, or Defers research protocol
- 7) Principal Investigator
 - a. Attends IBC meeting (when requested)
 - b. Provides additional information as requested
 - c. Responds to any IBC concerns and/or conditions

Human Gene Transfer Institutional Review Process

- 8) Institutional Biosafety Committee (IBC)
 - a. Reviews Principal Investigator responses to any conditions set by the committee
 - b. Approves the research protocol
 - c. Provides copy of IBC minutes to Institutional Review Board
 - d. IBC Chair produces Human Gene Therapy Risk Summary and provides to:
 - i. Institutional Review Board (IRB)
 - ii. AVP, Office of Research Compliance
 - iii. Associate Dean for Clinical Research, COM
- 9) Principal Investigator
 - a. Submits application and protocol to Institutional Review Board (IRB)
 - b. Identifies unbiased independent subject advocate for study
- 10) Institutional Review Board (IRB)
 - a. Reviews IBC minutes
 - b. Reviews the proposed research using the usual approval criteria and with the focus of the review on the human subjects involved
 - c. Utilizes consultants as necessary
 - d. Confirms that an unbiased subject advocate for the study will be provided
 - e. Approves, Disapproves, Requires Modifications, or Defers as appropriate
- 11) Principal Investigator
 - a. Attends IRB meeting (as needed)
 - b. Provides additional information
 - c. Addresses concerns or conditions specified by the IRB (as needed)
- 12) Institutional Review Board (IRB)
 - a. Reviews responses to conditions set by the committee
 - b. Issues final IRB Approval of the study
 - c. Provides a summary of the IRB Minutes to:
 - i. AVP, Office of Research Compliance
 - ii. Associate Dean for Clinical Research, COM
- 13) OSU Research Foundation
 - a. Negotiates sponsored research agreement (if applicable) ensuring that the necessary contract conditions are in place regarding:
 - i. Indemnification - Full indemnification of the Institution for any claims related to or resulting from the performance of the study at OSU
 - ii. Subject Injury – Sponsor covering any costs related to subject injuries that are not covered by subject’s insurance
 - iii. Insurance
 1. Institution as a named beneficiary of sponsor’s clinical trial insurance coverage
 2. Coverage limits appropriate for sponsor’s liability obligations and meeting OSU’s minimum coverage requirements

Human Gene Transfer Institutional Review Process

3. Obtains a certification of sponsor's insurance (i.e., an ACORD) demonstrating coverage and naming OSU as beneficiary of policy
 - iv. Federal Reporting requirements
 1. Define if Sponsor or Institution will be responsible for all NIH Office of Biotechnology Activities (OBA) mandated reporting requirements as outlined in ["NIH Guidelines for Research Involving Recombinant DNA Molecules"- Appendix M](#) ("NIH Guidelines").
 2. Define that in the event the Sponsor is determined to be the responsible reporting party, that the OSU Institutional Biosafety Committee receives copies of all OBA mandated submissions and reports.
 - b. Finalizes sponsored research agreement pending approval of research by Vice President, Office of Research
- 14) AVP, Office of Research Compliance and Associate Dean for Clinical Research, COM - prepare a Human Gene Transfer Summary and provide to the Vice President, Office of Research
- 15) Vice President, Office of Research - reviews Human Gene Transfer Summary and provides it to the following University Executive Leadership (or their designees) for review:
- a. Executive Vice President & Provost
 - b. General Counsel
 - c. Sr. VP for Business and Finance
 - d. Sr. VP for Health Sciences & Dean, COM and Public Health
 - e. Sr. VP for External Relations
 - f. Copy provided to Principal Investigator; PI's Department Chair; AVP, Office of Research Compliance; Associate Dean for Clinical Research, COM; Deputy Executive Director, OSURF; OSU Institutional Official
- 16) University Executive Leadership or their designees - forward any comments or concerns about the proposed research to Vice President, Office of Research
- 17) Vice President, Office of Research
- a. If proposed research is NOT Approved, the VP, Office of Research contacts the following individuals in order to address issues:
 - i. AVP, Research Compliance
 - ii. Associate Dean for Clinical Research, COM
 - b. If proposed research is Approved, VP, Office of Research formally notifies the following individuals that the proposed research has been approved and can proceed and provides a copy of the approved Human Gene Therapy Summary document:
 - i. Principal Investigator

Human Gene Transfer Institutional Review Process

- ii. Principal Investigator's Department Chair
 - iii. Deputy Executive Director, OSURF
 - iv. Director, Office of Responsible Research Practices (ORRP)
 - v. Chair, Institutional Biosafety Committee
 - vi. AVP, Office of Research Compliance
 - vii. Associate Dean for Clinical Research, COM
 - viii. Institutional Official,
- 18) Deputy Executive Director, OSU Research Foundation (or designee)
- a. Executes sponsored research agreement (if applicable)
 - b. Ensures that copies of Approval Notification and Human Gene Therapy Summary is filed in the project files
- 19) Director, Office of Responsible Research Practices (ORRP) (or designee)
- a. Ensures that copies of Approval Notification and Human Gene Therapy Summary is filed in the IRB and IBC files for the study
 - b. Ensures that copies of all Adverse Event (AE) and Serious Adverse Event (SAE) reports as well as IBC and IRB reviews of AE and SAE reports are provided to IBC and Office of Research Compliance (ORC)
- 20) IBC Coordinator
- a. With input from IRB analyst, maintains HGT Tracking Sheet and updates status information and AE/SAE reports as they are received
 - b. Ensures that copies of all AE/SAE reports are filed in IBC files
- 21) In the event that an AE/SAE report is received, the Office of Research Compliance will review and will notify the following individuals and provide copies of AE/SAE reports to:
- a. Chair, Institutional Biosafety Committee
 - b. AVP, Office of Research Compliance
 - c. Associate Dean for Clinical Research
 - d. Institutional Official for Human Subjects Research
- 22) AVP, Office of Research Compliance and Associate Dean for Clinical Research, COM will review reports and as appropriate notify:
- a. VP, Office of Research
 - b. Director, External Relations (as needed in order to prepare external communications regarding the events in conjunction with study Sponsor)
- 23) VP, Office of Research will, as appropriate, inform University Executive Leadership of any significant changes or adverse events encountered with the study and take appropriate steps to ensure the safe and compliant conduct of the study
- 24) Principal Investigator – Principal Investigator (or designee) has the responsibility of providing all mandated documentation to the NIH Office of Biotechnology Activities

Human Gene Transfer Institutional Review Process

with copies to the Institutional Biosafety Committee per [NIH Guidelines, Appendix M-I-C-1](#) as follows:

- a. Within twenty (20) days of consenting the first subject the PI (or designee must forward to NIH OBA and Institutional Biosafety Committee copies of the following documents:
 - i. Institutional Biosafety Committee approval letter
 - ii. Institutional Review Board approval letter
 - iii. IRB approved Informed Consent document
 - iv. IRB approved Human Subjects Protocol
 - v. Brief written report including the following elements:
 1. How the PI responded to each of the RAC's recommendations (if applicable)
 2. Any modifications to the protocol required by the FDA
 - vi. Curriculum vitae of the Principal Investigator(s) (in 2 page biographical sketch format)
 - vii. NIH Grant number(s) (if applicable)
 - viii. FDA IND Number
 - ix. Date of the initiation of the clinical trial
- b. In the event of any AE or SAE, the PI (or designee must forward to NIH OBA and Institutional Biosafety Committee copies of the required documents - see [NIH Guidelines, Appendix M-I-C-4](#) for specific details on reporting requirements.
- c. Annually via a progress report the PI (or designee must forward to NIH OBA and Institutional Biosafety Committee copies of the required documents - see [NIH Guidelines, Appendix M-I-C-3](#) and [NIH Guidelines, Appendix M-I-C-4](#) for specific details on reporting requirements.
- d. In the event of opening additional sites that are conducting the trial the PI (or designee must forward to NIH OBA and Institutional Biosafety Committee copies of the required documents - see [NIH Guidelines, Appendix M-I-C-3](#) and [NIH Guidelines, Appendix M-I-C-4](#) for specific details on reporting requirements.

Note: Per NIH Guidelines, Appendix M-I-C-4, “*Principal Investigators may delegate to another party, such as the corporate Sponsor, the reporting functions set forth in Appendix M, with written notification to NIH OBA of the delegation and of the name(s), address, telephone and fax numbers of the contact. The Principal Investigator is responsible for ensuring that the reporting requirements are fulfilled and will be held accountable for any reporting lapses.*” In the event that Principal Investigator delegates NIH OBA reporting to Sponsor, a copy of delegation letter must be submitted to Institutional Biosafety Committee as well as NIH OBA.