

# Human Gene Transfer Institutional Review Process



## 1. Principal Investigator (PI)

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- a. Submits to Office of Sponsored Programs (OSP) 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 (HGT).
- b. Submits proposed research protocol to chair for departmental review.

## 2. Department Chair

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Assures that the protocol has undergone scientific review and that the department will support the proposed research with appropriate resources.

## 3. Principal Investigator

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Notifies the Institutional Biosafety Committee (IBC) of new HGT study by submitting the protocol and supporting documents through e-Protocol.

## 4. IBC Coordinator

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IBC coordinator receives notification of HGT from e-Protocol and forwards protocol to IBC chair and requests that the IBC chair proceed with required notifications (detailed in step 5). IBC coordinator ensures that HGT study is added to HGT Tracking Sheet and forwards this HGT Process Document and additional information regarding the Ohio State Human Gene Transfer Review Process document to the PI.

## 5. Chair, Institutional Biosafety Committee

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- a. Pre-reviews the IBC application.
- b. Determines if all necessary external reviews have been completed (e.g., RAC).
- c. Determines if any additional information is required (e.g., from RAC, sponsor).
- d. Notifies the following individuals/offices of the impending HGT:
  - i. Director, ORC
  - ii. Associate Dean for Clinical Research, College of Medicine (COM).
  - iii. Deputy Executive Director, Ohio State Office of Sponsored Programs – In order to flag project as HGT and ensure appropriate contractual terms and conditions
  - iv. Director, Technology Commercialization Office (TCO) – 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
- e. Assigns the HGT to the IBC agenda.

## 6. Institutional Biosafety Committee

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- 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

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- a. Attends IBC meeting (when requested).
- b. Provides additional information as requested.
- c. Responds to any IBC concerns and/or conditions.

## 8. Institutional Biosafety Committee

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- a. Reviews principal investigator responses to any conditions set by the committee.
- b. Approves the research protocol.
- c. Provides copy of IBC minutes to IRB.
- d. IBC chair produces Human Gene Therapy Risk Summary and provides to:
  - i. Institutional Review Board.
  - ii. Director, Office of Research Compliance.
  - iii. Associate Dean for Clinical Research, COM (or designee).
- e. Assigns the HGT to the IBC agents.

## 9. Principal Investigator

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- a. Submits application and protocol to IRB
- b. Identifies unbiased independent subject advocate for study.

## 10. Institutional Review Board

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- a. Reviews IBC minutes.
- b. Reviews the proposed research using the usual approval criteria with the focus of the review on the human subjects involved.
- c. Utilizes consultants as necessary.
- d. Confirms that an unbiased advocate for the study will be provided.
- e. Approves, Disapproves, Requires Modifications or Defers as appropriate.

## 11. Principal Investigator

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- 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

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- 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. Director, Office of Research Compliance
  - ii. Associate Dean for Clinical Research, College of Medicine, COM (or designee).

## 13. Ohio State OSP

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- 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 Ohio State.
  - 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 Ohio State’s minimum coverage requirements.
    - 3. Obtains a certification of sponsor’s insurance (i.e., an ACORD) demonstrating coverage and naming Ohio State as beneficiary of policy.
  - iv. Federal Reporting Requirements

Define if sponsor or institution will be responsible for all NIH Office of Biotechnology Activities (OBA) mandated reporting requirements as outlined in the [“NIH Guidelines for Research Involving Recombinant DNA Molecules”](#) - Appendix M (NIH Guidelines).

- 5. Define that in the event the sponsor is determined to be the responsible reporting party, that the Ohio State IBC receives copies of all OBA mandated submissions and reports.

- b. Finalizes sponsored research agreement pending approval of research by vice president, Office of Research or provost in cases where a potential conflict of interest may exist.

#### **14. Director, Office of Research Compliance and Associate Dean for Clinical Research, College of Medicine (or Designee)**

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Prepare a Human Gene Transfer Summary and provides to the vice president, Office of Research, or the Provost (in cases where potential conflict may exist) for review and approval.

#### **15. Vice President, Office of Research (or the Provost in Cases where Potential Conflict May Exist)**

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Reviews HGT Summary and IF APPROVED, forwards the HGT Summary to the dean, College of Medicine, copying the following university officials to inform them of the impending HGT:

- a. Office of the Provost or Office of Research (if approved by the Provost).
- b. Office of the General Counsel.
- c. Office of Business and Finance.
- d. Senior Vice President for Health Sciences and Dean, COM and Public Health
- e. Office of External Relations
- f. Additional copy is provided to PI; PI's department chair; Director, Office of Research Compliance; associate dean for clinical research, COM; director, OSP; Ohio State Institutional Official, IBC chair, Director of the Office of Responsible Research Practices (ORRP), IBC coordinator.

#### **16. If the proposed HGT research is NOT APPROVED**

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Then the vice president, Office of Research contacts the director, Research Compliance, and associate dean for clinical research, COM to address issues as needed.

#### **17. Director, Office of Sponsored Programs (or designee)**

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- a. Executes sponsored research agreement (if applicable).
- b. Ensures that copies of Approval Notification and HGT Summary are filed in the project files.

#### **18. Director, Office of Responsible Research Practices (or designee)**

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- a. Ensures that copies of Approval Notification and HGT Summary are 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).

#### **19. IBC Coordinator**

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- 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.

#### **20. In the event that an AE/SAE report is received**

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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. Director, Office of Research Compliance.
- c. Associate Dean for Clinical Research (or designee).
- d. Institutional Official for Human Subjects Research.

## **21. Director, Office of Research Compliance and Associate Dean for Clinical Research, College of Medicine (or designee) will review reports and as appropriate notify:**

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- a. Vice President, Office of Research.
- b. Ohio State Assistant Vice President, University Media Relations (as needed) in order to prepare external communications regarding the events in conjunction with study sponsor.

## **22. Vice President, Office of Research**

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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.

## **23. Principal Investigator**

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PI (or designee) has the responsibility of providing all mandated documentation to the NIH Office of Biotechnology Activities with copies to the IBC per [NIH Guidelines, Appendix M-IC-1](#) as follows:

- a. Within twenty (20) days of consenting the first subject the PI, (or designee must forward to NIH OBA and IBC copies of the following documents:
  - i. IBC approval letter.
  - ii. IRB 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.
    3. Curriculum vitae of the PI(s) (in a 2 page biographical sketch format).
  - iv. NIH Grant number(s) (if applicable).
  - v. FDA IND Number.
  - vi. 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 IBC 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 IBC as well as NIH OBA.*