



Institutional Biosafety Committee
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Quick Guide: Conducting Human Gene Transfer Research at WCMC

Part I: Before the Trial Begins

Step 1

Submit your Investigational New Drug (IND) Application to the FDA in accordance with [21 CFR 312](#).

Tip: Visit the FDA's [website on the IND Application Process](#) for helpful information and FAQs.

Step 2

Submit your protocol to the National Institutes of Health Office of Biotechnology Activities (NIH-OBA) for review by the Recombinant DNA Advisory Committee (RAC), in accordance with [Appendix M-I of the NIH Guidelines](#).

Tip: For insight into the NIH Review process, [see the FAQ provided by NIH-OBA](#).

Step 3

Submit your protocol to the IRB according to IRB submission procedures.

Tip: See the [IRB FAQ](#) and [IRB website](#) for instructions.

Step 4

Resolve all protocol and informed consent issues that the IRB has identified before you submit to the Institutional Biosafety Committee (IBC).

Tip: The only remaining IRB issue should be the missing IBC approval letter and administrative issues (e.g., Study Specific Financial Disclosure Forms, HRBAF form, etc).

Step 5

Submit all ten (10) documents to the IBC for review **as a single bookmarked PDF**:

- (1) Cover letter stating the contents of your submission
- (2) Copy of the latest IRB issue letter indicating that only administrative issues remain before IRB approval is granted.
- (3) Application for Use of Recombinant DNA Molecules in Human Gene Transfer Research, available at the [IBC website](#).
- (4) IRB-reviewed protocol form (with all IRB requested changes reviewed by the IRB)
- (5) IRB-reviewed informed consent form(s) (with all IRB requested changes reviewed by the IRB)
- (6) IRB-reviewed recruitment materials (Flyers, radio ads, etc.)
- (7) Current Clinical Protocol
- (8) Current Investigator's Brochure
- (9) Letter from NIH-OBA's Recombinant DNA Advisory Committee (RAC) demonstrating that your protocol was reviewed by RAC. [Required by the WCMC IBC, even if the protocol is exempt from RAC review.]
- (10) Answers to Appendix M-II through M-V of the NIH Guidelines (as submitted to RAC in Step 2)

Tip: Send your submission to submit2ibc@med.cornell.edu via the website transfer.med.cornell.edu.

Step 6

Submit the IBC approval letter to the IRB.

Tip: For faster processing, send proof of IBC approval directly to your IRB submission contact, who was assigned to you by the IRB when you first sent in your protocol.

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Part II: Post-Approval Reporting Requirements for Human Gene Transfer Trials

Step 7

Within 20 working days of enrolling the first research participant at WCMC, the PI must send a report to NIH-OBA in accordance with [Appendix M-I-C-I of the NIH Guidelines](#).

Step 8

Refer to this chart for federal and institutional reporting requirements after the trial is underway.

Tip: The IBC and IRB share reporting deadlines. The FDA and NIH-OBA share reporting deadlines.

| | Annual Reporting | Amendments | Adverse Events |
|----------------|--|---|---|
| FDA | Submit within 60 days of the anniversary date the IND went into effect, in accordance with 21 CFR 312.33 . | Submit to the FDA in accordance with 21 CFR 312.30 . | Submit in accordance with 21 CFR 312.32 . |
| NIH-OBA | Submit within 60 days of the anniversary date the IND went into effect, in accordance with M-I-C-3 of the NIH Guidelines . | No Submission Required | Submit in accordance with M-I-C-4 of the NIH Guidelines . |
| IRB | Submit your Continuing Review (“annual review”) to the IRB 6 to 8 weeks before your study expires. The expiration date was given in your last Continuing Review approval letter. | IRB approval is required before implementation. See the IRB FAQ for submission instructions. (Once IRB approval is granted, submit to the IBC.) | Submit via submit2irb@med.cornell.edu in accordance with the WCMC Unexpected, Study-Related Adverse Events, Incidents, and Information Reporting Policy |
| IBC | Submit to the IBC a copy of your last NIH-OBA annual report. The due date is the same as your IRB Continuing Review. | IBC approval is required before implementation. Submit to the IBC <u>after</u> IRB approval has been granted. | Submit via submit2ibc@med.cornell.edu in accordance with the WCMC Unexpected, Study-Related Adverse Events, Incidents, and Information Reporting Policy |

If you have any questions about how to comply with these regulations, please contact the IBC at ibc@med.cornell.edu.