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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. [Required by the WCMC IBC, even if the protocol is exempt from RAC review.]
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. Submit to NIH using GeMCRIS http://oba.od.nih.gov/rdna/adverse_event_oba.html
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.	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. **If you are conducting a vaccine trial, contact the IBC at ibc@med.cornell.edu about what your annual report must contain.**	IBC approval is required for **all** amendments before implementation. Submit to the IBC at submit2ibc@med.cornell.edu after IRB review has been conducted.	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.

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