wcg IRB

Frequently Asked Questions About IBC Review Requirements

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WCG administers Institutional Biosafety Committees (IBCs) on behalf of over 400 institutions around the world. As partners working with a broad array of sponsors, CROs, and institutions we are frequently asked to help determine whether a clinical trial requires IBC review. Our general advice on this matter is shown in this document. To request specific advice, please address any questions to IBC Services via our contact form and a member of our team will respond as soon as we receive your inquiry.

Definitive interpretations of NIH requirements may be requested by direct query to NIH at NIHGuidelines@od.nih.gov

IBC oversight of certain types of research is mandated by *the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).* In addition, many sponsors and sites elect to request voluntary IBC oversight of certain clinical trials even when such oversight is not required by *NIH Guidelines.* Under the *NIH Guidelines*, IBC approval for clinical research is required when two criteria are met:

1. The research is Human Gene Transfer (HGT) research as defined *in NIH Guidelines* Section III-C[i];

AND

2. The research is subject to *NIH Guidelines* due to relevant funding as defined in Section I-C. Relevant funding includes: i) funding used for investigational product development[ii]; ii) funding to the clinical trial sponsor, and/or iii) funding to the business or institution hosting the clinical trial site.

For a multicenter clinical trial, if research is subject to the *NIH Guidelines* due to funding at the level of the sponsor or of product development, then IBC review is required at ALL domestic clinical trial sites.[iii] If there is no applicable funding at the level of sponsor or of product development, then research is subject to the *NIH Guidelines* at each site that is currently in receipt of applicable NIH funding.[iv]

I represent a clinical trial sponsor. Does my HGT clinical trial require IBC approval at all sites?

Looking at this question from a sponsor perspective, points to consider include the following:

- Does the Sponsor currently receive any direct NIH funding for research involving recombinant or synthetic DNA or RNA (for this or for other projects)? If so, all HGT research conducted by Sponsor company requires IBC approval at each domestic clinical trial site.
- Does the investigational product (IP) contain recombinant or synthetic DNA or RNA materials developed by the Sponsor using current or past NIH funding? If so, any clinical research using this IP requires IBC approval at each domestic clinical trial site.
- Does the investigational product (IP) contain recombinant or synthetic DNA or RNA materials developed using NIH funds by some other business or institution, such as an academic research institution, and does that business or institution currently have contractual arrangements with the Sponsor? If so, any clinical research involving those materials requires IBC approval at each domestic clinical trial site.

I represent a clinical trial site. Does HGT research at my site require IBC approval?

Looking at this question from a site perspective, points to consider include the following:

- Does my site belong to an institution or business that currently receives any direct NIH funding for research involving recombinant or synthetic DNA or RNA? If so, then all HGT clinical trials conducted at this site require IBC approval.
- Does a specific HGT clinical trial involve funding at the product or sponsor level as defined above? If so, then that specific clinical trial requires IBC approval.
- Our subject matter experts are happy to answer questions from Sponsors, CROs, and sites about specific applications of the *NIH Guidelines* and expectations for IBC review. Please address any questions to our online Contact Us form. When we receive your question, a member of our team will personally follow up within the same business day.

[i] Section III-C-1

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. 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 c) Can be translated or transcribed.

Research cannot be initiated until Institutional Biosafety Committee and all other applicable institutional and regulatory authorization(s) and approvals have been obtained.

The deliberate transfer of recombinant or synthetic nucleic acids into one human research participant, conducted under a Food and Drug Administration (FDA) regulated individual patient expanded access Investigational New Drug (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.

[ii] Section I-C-1-a-(2)

Research that involves testing in humans of materials containing recombinant or synthetic nucleic acids developed with NIH funds, if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials.

[iii] For clinical research outside the United States, we recommend consulting NIH to determine whether IBC review is required at some or all sites.

[iv] A history of past NIH funding to the site is not relevant to IBC requirements at the site level. Participation in NIH-funded clinical research, when the site is not the funding recipient, is not relevant to IBC requirements at the site level.