



National Cancer Institute  
Central IRB Initiative

# NCI CIRB: TOP 5 FAQs

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## **What is the CIRB's independent model?**

The CIRB reviews CTEP-sponsored Phase 3 adult clinical trials and Pilot, Phase 2, and Phase 3 pediatric clinical trials. The CIRB is the IRB of Record responsible for study review and local context considerations for enrolled Signatory Institutions.

## **What is the role of the local IRB in the CIRB's review model?**

There is no CIRB-defined role for the local IRB. However, Signatory Institutions are responsible for monitoring the conduct of the research and may delegate monitoring responsibilities within the institution as they wish, including to the local IRB.

## **How does the CIRB learn about my institution's local context considerations?**

The CIRB is informed of local context considerations via the following three Worksheets:

- Annual Signatory Institution Worksheet About Local Context
- Annual Principal Investigator Worksheet About Local Context
- Study-Specific Worksheet About Local Context

These Worksheets and the instructions to complete them may be found at the following URL:  
[https://www.ncicirb.org/CIRB\\_IndependentModelInfo.asp](https://www.ncicirb.org/CIRB_IndependentModelInfo.asp)

## **Can institutional boilerplate language be added to CIRB-approved consent forms?**

Yes, with prior CIRB approval. It is expected that most institutions will need to add boilerplate language to CIRB-approved model consent forms. The boilerplate language is submitted to the CIRB via the "Annual Signatory Institution Worksheet About Local Context." Once the CIRB reviews and approves the boilerplate language, the Signatory Institution Principal Investigator is required to incorporate the boilerplate language into the NCI CIRB-approved model consent form.

## **How do I notify the CIRB about adverse events and noncompliance?**

Individual adverse events are not reported to the CIRB unless they are determined to be a potential unanticipated problem or potential serious or continuing noncompliance. Locally-occurring potential unanticipated problems or serious or continuing noncompliance are reported to the CIRB using the "Potential Unanticipated Problem or Serious or Continuing Noncompliance Form." The CIRB reviews these reports, makes a determination, and reports to OHRP and FDA, as applicable.

More questions? Call toll free (888) 657-3711 or email [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com)  
for more information

