

Important:

Investigator Confirmation of Board Requirements

DHHS regulation 45 CFR 46.109(d) states “An IRB shall notify investigators and the institution in writing of modifications required to secure IRB approval of the research activity....” Based on this regulation, effective October 1, 2005, investigators approved for new research studies are required by WIRB to confirm their acceptance of the requirements imposed by the Board. No action is required for studies approved prior to October 1, 2005.

Enrollment may not commence until the investigator has accepted the Board’s requirements and sent the form to WIRB.

- If the Board’s requirements are **acceptable**, the investigator should sign the form and send it to WIRB. Enrollment may commence once the form is completed. Sites should retain a signed and dated copy of the form for their records along with confirmation of having sent the form (fax confirmation, copy of e-mail, etc.)
- If one or more of the Board’s requirements are **not acceptable**, mark the applicable box, provide explanatory comments, and return the form to WIRB. Enrollment may not commence.

It is VERY IMPORTANT that sites return the form to WIRB in a timely manner **whether the investigator found the requirements acceptable or not.**

Blank copies of the form may be downloaded at www.wirb.com.

Please contact WIRB Client Services at the phone number above if you have questions.