



WESTERN INSTITUTIONAL REVIEW BOARD®
WESTERN INTERNATIONAL REVIEW BOARD®
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INFORMATION ABOUT YOUR WIRB DOCUMENTS

The initial approval packet contains WIRB documents for the referenced research study at your site. Please examine all documents in this packet carefully. If any information is unclear or inaccurate, call WIRB at 1-800-562-4789 immediately for assistance. Please refer to the WIRB protocol number or WIRB study number that is referenced on the documents.

All documents must be retained for future reference.

1. The enclosed **Board Requirements Confirmation** form must be completed and sent to WIRB (via e-mail, fax or postal mail) before enrollment can begin. You may address the Board in person or in writing regarding its requirements. If you wish to address the Board in person or if you have questions, please contact WIRB Client Services at (800) 562-4789 or clientservices@wirb.com.
2. The Certificate of Approval is the Investigator's documentation of WIRB approval to conduct this research. PLEASE READ BOTH SIDES OF THE CERTIFICATE OF APPROVAL CAREFULLY for important information about WIRB reporting requirements and consenting instructions.
3. The CONSENT FORM approved by WIRB has a dated approval stamp in the upper right corner of each page of the form. **This consent form must be used to consent each subject at your site.**
4. A list of the WIRB Board Members and Alternate Members is included for future reference and should be kept in your study files.
5. WIRB will consider the study OPEN at your site until written notification is received that the study is closed. Provide a completed WIRB study closure form when:
 - a. All subjects have finished their final visits and follow-up,
 - b. The sponsor or the sponsor representative has indicated the study is closed at your site, **and**
 - c. If the study was conducted under a Federalwide Assurance, all data analysis at the site is completed.

The WIRB closure report form is available at www.wirb.com.

6. If you have questions about these documents or information in this packet, please contact Client Services at 1-800-562-4789 or clientservices@wirb.com.
7. For more information, please visit our website at www.wirb.com. You will have access to our forms, and can review the requirements for submitting adverse events, protocol variances and changes to the research.

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