

INFORMATION ABOUT YOUR WCG IRB DOCUMENTS

The initial approval packet contains WCG IRB 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 WCG IRB at 855-818-2289 immediately for assistance. Please refer to the WCG IRB protocol number or WCG IRB study number that is referenced on the documents.

All documents must be retained for future reference.

1. The Certificate of Action is the Investigator's documentation of WCG IRB approval to conduct this research. PLEASE READ ALL PAGES OF THE CERTIFICATE OF APPROVAL CAREFULLY for important information about WCG IRB reporting requirements and consenting instructions.
2. The CONSENT FORM approved by WCG IRB 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.**
3. A list of the WCG IRB Board Members and Alternate Members is included for future reference and should be kept in your study files.
4. WCG IRB will consider the study OPEN at your site until written notification is received that the study is closed. If WCG IRB does not receive a completed study closure report form, continuing review will be conducted. Review fees apply for the continuing review. Provide a completed WCG IRB 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 WCG IRB closure report form is available at wcgirb.com.

5. WCG IRB is registered with OHRP/FDA; our IRB registration number is IRB00000533, parent organization number is IORG0000432.
6. If you have questions about these documents or information in this packet, please contact Client Services at 855-818-2289 or clientservices@wcgirb.com.
7. For more information, please visit our website at wcgirb.com. You will have access to our forms, and can review the requirements for submitting unanticipated problems and changes to the research.