OVERVIEW

The Mission of Review Boards
The primary mission of review boards, commonly called Institutional Review Boards (IRBs), is to safeguard the rights and welfare of human test subjects -- both before and during their involvement in a medical research study. These impartial review panels perform the job of risk/benefit assessment -- ensuring that the risks are both minimized and fairly disclosed to study participants when testing drugs, vaccines, or medical devices.

IRBs have the authority to approve, require modifications to, or disapprove the proposed study protocols and consent forms for research that will involve human subjects. In addition, IRBs must review and approve or disapprove the investigator for the research. Once approved, the IRB must monitor the progress of ongoing research. U.S. Food and Drug Administration (FDA) and Health and Human Services (HHS) regulations require that an IRB have at least five members, with varied backgrounds, representing both scientific and non-scientific fields.

WIRB -- A Tradition of Excellence

WIRB is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The Association for the Accreditation of Human Research Protection Programs (AAHRPP) “seeks not only to ensure compliance, but to raise the bar in human research protection by helping institutions reach performance standards that surpass the threshold of state and federal requirements.” On April 28, 2003, WIRB was the first independent IRB to be issued full accreditation by AAHRPP.

WIRB reviews many types of human subject research, including clinical research, behavioral research, and epidemiological research, in the United States and internationally. WIRB reviews research in accordance with three standards:

- the Food and Drug Administration (FDA) Regulations on research with human beings (21 CFR 50 and 56),
- the Health and Human Services (DHHS) Regulations on research with human beings (45 CFR 46 Subparts A, B, C, and D), and
- the International Conference on Harmonization (ICH) "Guidance for Industry-E6 Good Clinical Practice: Consolidated Guideline."
The FDA regulations apply to clinical investigations conducted on medical products under FDA jurisdiction that will be marketed in the United States: principally drugs, devices and biologics.

The DHHS regulations apply to research that is funded by HHS and other agencies that have adopted "the Common Rule," represented at 45 CFR 46, Subpart A. Institutions that receive federal funding for research must obtain an "assurance," a formal agreement with the government in which the institution promises to take prescribed steps for the protection of human subjects. Usually, the assurance will be a FederalWide Assurance (FWA) from the Office for Human Research Protections (OHRP). However, for some research other types of assurances may be used. Please call WIRB's Client Services at 1-800-562-4789 if you have questions about obtaining an assurance, or consult the OHRP web site.

The International Conference on Harmonization (ICH) is an international standard for drug approval that has been adopted as either law or guidance in many countries (EU, Canada, Japan and the United States). In the United States, FDA has adopted it as guidance. It is similar to the FDA drug approval and IRB regulations for the most part, but has a few stricter standards.

WIRB also provides some services under the Privacy Rule (45 CFR Parts 160 and 164) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). WIRB will review requests for waivers and partial waivers of authorization upon the request of a covered entity. WIRB will also review authorization language upon the request of a covered entity. If the authorization language is embedded in the research consent document, then the IRB must review it. If the authorization language is separate from the research consent document, then the covered entity may determine whether or not to submit the language for IRB review. WIRB will review separate authorization documents upon request.

WIRB compliance with government regulations is paramount. Investigators and research sponsors are welcome to visit WIRB facilities and to review our written procedures.

For more information, contact Client Services at (800) 562-4789 or clientservices@wirb.com
The Western Institutional Review Board (WIRB) was established in 1968 to provide human subject protection for endocrinology research conducted by Dr. Angela Bowen, the former president of WIRB. WIRB later reviewed a variety of research for other investigators in the local community, and Dr. Bowen incorporated WIRB in 1977.

With the introduction of the FDA research regulations in 1981 came an increased need for independent IRB review services. In response, WIRB established the current for-profit structure, allowing an expanded clientele to be served throughout the local community and across the United States.

WIRB has developed over the years and added services to meet researcher and subject needs. WIRB strives to respond to the evolving needs of the global research community and has provided services internationally since 1986.

WIRB first offered institutional IRB services in 1996. With the changing regulatory environment of the late nineties, WIRB extended its institutional services to several large university IRBs and other local IRBs. WIRB provides services to a growing number of institutions, while continuing to serve independent researchers around the world.

The Applied Research Ethics National Association established the Council for Certification of IRB Professionals (CCIP) in 1999 to advance the quality of human subject protection programs through a voluntary certification program initiated in 2000. A WIRB staff member was part of the first group to be recognized by CCIP as a Certified IRB Professional (CIP), and more than 40 WIRB employees have since been certified.

In late 2001, WIRB implemented an electronic document storage system, to provide the Board and staff with easy access to IRB records. In early 2003, after several years of development, WIRB implemented a validated electronic workflow and database system, allowing the staff to provide a higher level of support to the Board.

Twice a year, WIRB welcomes a new class of international Fellows to its International Fellows Program. Conducted in partnership with the World Health Organization Research and the Special Programme for Research and Training in Tropical Diseases (WHO/TDR),
the National Institutes of Health (NIH) and the University of Washington, the WIRB International Fellows Program is a six-month long training program for foreign health care professionals who desire to learn how to establish or improve review boards in their regions. It is an intensive program designed to help participants develop the skills necessary to create and/or manage and administer international review boards that will protect the rights and welfare of human research subjects. The World Health Organization (WHO/TDR) chose WIRB to host this program because of WIRB's long history of excellence.

WIRB established a panel to review research conducted in Canada in 2001. The Panel, whose standing membership is composed of Canadian nationals, meets every other week.

In June 2008, Dr. Bowen retired, and Stephen Rosenfeld, M.D., M.B.A., joined WIRB as the new President and Chief Executive Officer.

Today WIRB provides review services for more than 200 institutions (academic centers, hospitals, networks and in-house biotech research), as well as for individual investigators in all 50 states and internationally. WIRB has worked with all major pharmaceutical and device manufacturers, CROs, and the biotech industry. With WIRB's preeminent position in the industry, we are able to provide a broad range of services with the flexibility to meet individual needs and in full regulatory compliance.

As part of its mission to protect the rights and welfare of subjects, WIRB maintains a 24-hour phone line that subjects can use to discuss concerns and ask questions. A WIRB staff physician is always available for these calls.

The Western Institutional Review Board is composed of more than a dozen individual review panels. Each WIRB panel consists of nine standing members and designated alternates.

### Panel Structure and Schedule

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New protocols are assigned to panels based on both the specialty required to review the protocol and the next available panel meeting. New protocols generally go to board the week following their receipt. The upper right corner of the WIRB Certificate of Approval displays the panel assignment of the related protocol.

Once a protocol is assigned to a particular panel, all subsequent reviews for that protocol (new investigators, changes in research and continuing review) will be carried out by that panel. Reviews for investigators at Canadian locations are assigned to the WIRB Canadian panel; therefore, a single protocol can be assigned to both a U.S. panel and the Canadian panel. Complete submission forms and associated review materials must be received by WIRB at least six working days before the panel is scheduled to meet.

WIRB recommends that submissions be sent using the online submission feature of our WIRB.com website. The Online Submission feature will let you upload documents to us through a safe and secure process and receive an immediate confirmation of receipt. To use this feature, click the ‘Online Submission’ button near the middle of the WIRB.com home page and follow the easy directions.

Users who desire detailed tracking information may also establish a WIRBNet account on WIRB’s web site (click on the yellow “WIRBNet LOGIN” button on the home screen to start the process). WIRBNet is an on-line information portal designed to provide expanded submission detail, enhanced tracking features and the secure download of approval documents. WIRBNet liberates users from the limits of time zones, phone calls and e-mails.

To learn more about WIRBNet, WIRB.com, or WIRB’s panel structure, or to determine the panel assignment of a particular protocol, call Client Services at (360) 252-2500 or e-mail clientservices@wirb.com.

For more information, call Client Services at (800) 562-4789
or
clientservices@wirb.com
INSTITUTIONAL REVIEWS

Ethical Review for Federally Funded, Institution Based Research

WIRB has a long history of partnering with academic and non-academic Institutions in their human subject protections programs. We recognize that the review needs of an institution differ from those of a research sponsor or independent clinical investigators. Thus, the range of services WIRB offers can be customized accordingly.

WIRB can serve as an institution’s sole IRB or one of an institution’s IRBs for human subjects research through inclusion on an institution’s Federalwide Assurance. WIRB meets all requirements of the U.S. Department of Health and Human Services (HHS) regulations on human subject protection (45 CFR §46), and is able to provide IRB services for federally funded research that falls under the auspices of the Office for Human Research Protections (OHRP).

WIRB offers a broad range of review services for a variety of institutions, including academic medical centers, hospitals, research groups and biotech companies. WIRB has experience reviewing federally-regulated and industry-sponsored research for both large and small institutions. WIRB can act as the sole review board or support the work of an institution's own institutional review board.

The question of local review may be of concern to an institution when an IRB is based in another state or region or country. WIRB has systems in place to address this issue. In addition to the broad expertise of its Board members and alternate reviewers, WIRB has regional representatives who take the pulse of the local community to determine attitudes and customs that might influence research protocols.

For more information, call Client Services at (800) 562-4789 and ask for the Institutions Department or contact clientservices@wirb.com
MULTICENTER REVIEWS

Multicenter/Multi-Investigator IRB Review

The Western Institutional Review Board (WIRB) has reviewed multicenter studies involving up to several thousand investigators. WIRB staff has substantial experience and expertise in managing document flow and coordinating communications for large studies with multiple parties such as contract research organizations (CROs) and coordinating groups. WIRB provides a primary contact person for each multicenter study to respond to client questions and to quickly address concerns.

The involvement of WIRB staff in the planning stages of a multicenter study helps to ensure program continuity and regulatory compliance. After review and (if appropriate) modification by a WIRB review panel, WIRB staff can prepare a consent form in “approvable” form for use as a template by the sponsor or CRO. WIRB holds daily meetings to review the addition of new investigators and sites to previously approved multi-center protocols.

Changes to research protocols (and to consent forms, if required) are promptly reviewed as received; proposed changes can be pre-reviewed via WIRB’s approvable process, can be reviewed for an entire multicenter group of investigators at one time, or one by one as needed. Reports of unanticipated problems are reviewed by Board physicians, as received. All recruitment materials must be submitted for review. Complimentary review is provided for items included with the initial review submission.

Forms and additional information available at www.wirb.com

For more information, contact Client Services at (800) 562-4789 or clientservices@wirb.com
Phase 1 Mission Statement

The mission of the Western Institutional Review Board is to protect the rights and welfare of the human research subject. In support of the mission, WIRB will review research from dedicated clinical/pharmacological units. Human subject safety is the primary focus with an emphasis on providing an impartial review to meet ethical requirements. These ethical requirements include:

- Scientific or social value
- Scientific validity
- Fair subject selection
- Favorable risk-to-benefit ratio
- Independent Review
- Informed consent
- Respect for enrolled subjects

Phase 1 General Information

Phase 1 research units are dedicated inpatient facilities. The research has a specialized focus with standardized processes in recruitment, consenting and enrolling, specimen collection, and payment. The types of research are pharmacokinetic, pharmacodynamic, first in human healthy volunteers, bioequivalence, and drug-drug interaction and may deal with special populations such as subjects with impaired liver or kidney function.

Prior to the first submission being received, a site assessment visit will be conducted and a template consent form will be established, which plays an integral part in the timeliness of the review process.

Anyone interested in receiving more information on the review of Phase 1 – First in Man Research should contact:

Linda L. Morrison, CIP
Vice President, New Business Development/Institutions
Western Institutional Review Board
3535 Seventh Avenue, SW, Olympia, WA 98502
P: 360-252-2443  F: 360-252-2490
E-mail: lmorrison@wirb.com
INTERNATIONAL ETHICS REVIEW

Ethics Committee for International Research Studies

Western Institutional Review Board has offered international research review services since 1986. WIRB meets all requirements for institutional review boards (IRBs) under regulations of the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), and the guidelines of the International Conference on Harmonisation (ICH). International studies are reviewed to FDA and ICH standards unless otherwise indicated.

The Board’s review of international studies normally is requested under the following circumstances:

- When study data is expected to be submitted to the U.S. FDA;
- When a local ethics review committee is not available;
- When a supplement to local ethics review is desired; or
- When the research is funded by an agency of the U.S. Government.

WIRB advisors abroad, including individuals who have completed WIRB’s International Fellows Program, are available to provide the Board with information on the local culture and attitudes that could affect research. WIRB also works with local ethics committees, whenever possible, to supplement local review and ensure compliance with FDA standards and ICH guidelines.

WIRB Board members have superior credentials, assuring the highest quality review. All reviewers receive a complete copy of the study protocol and proposed consent form.

WIRB’s full-time staff assists human subjects, sponsors, and investigators. WIRB's lengthy experience in reviewing foreign research enables the Board to provide specialized services for international studies. WIRB has multi-lingual, in-house staff to assist callers in several languages. In addition, a language interpreter service is used to assist callers who do not speak English. For written documents that are approved by WIRB and require
translation, WIRB offers translation services. The Translation Services Information Sheet outlines these services.

WIRB-approved consent forms contain an international telephone number and our address for persons with questions about their rights as research subjects. The telephone call is toll-free from several countries.

For more information, contact Client Services at:
(800) 562-4789 (toll-free, USA & Canada)
or
clientservices@wirb.com
INFORMED CONSENT

The Western Institutional Review Board (WIRB) provides a range of consent form services including review of a sponsor’s template consent form, review of individual consent forms, and preparation of written consent forms for investigators or sponsors, when requested.

Consent documents are reviewed to determine whether all required elements of consent are present. Documents are modified, as necessary, by the WIRB Board to meet applicable regulations and WIRB specifications. Clarity, full disclosure, and regulatory compliance are the reasons for the Board changes.

Upon request, WIRB will review template consent forms prior to their distribution to investigators. These are modified to achieve “approvable status” rather than being approved outright. “Approvable” consent forms are subsequently approved by the Board, with requested modifications, in tandem with approval of individual investigators.

WIRB staff can write consent forms if the service is requested when investigators submit their protocol. There is a fee for this service.

After WIRB approval, a “ready-to-use” copy of the form will be provided to the investigator, the sponsor, and/or contract research organizations (CRO) or coordinating group. A “redlined” copy of the submitted consent form that clearly notes Board changes and the reasons for those changes also is provided. The WIRB-approved consent form is identified by an approval stamp in the upper right corner of each page. If requested, WIRB can prepare the final version using investigator letterhead.

A toll-free telephone number is listed in each consent form for study subjects to contact WIRB with questions about their rights or the conduct of the study. Complaint resolution is provided as a service to subjects. When a subject complaint is received by WIRB, both the investigator and sponsor are notified; however, the identity of the subject may be withheld, depending on the subject’s preferences. Board involvement continues until resolution is achieved.

*For more information, contact Client Services at (800) 562-4789 or clientservices@wirb.com*
Consent Form
Elements

Required Elements for Informed Consent for Human Subjects

Consent forms should be written in simple, non-technical language, generally aiming for a
seventh-grade reading level. Avoid language that suggests any subject waiver of rights or
investigator/sponsor release from liability. Avoid general use of "I understand" or "You
understand" language, and write all but the consent section in the second person. Avoid
wording that may seem coercive or overly reassuring to a potential subject.

Please include the following when writing a consent form:

1. Explain the purpose of the research study, the expected duration of subject
participation, and the approximate number of subjects involved in the study. (The
number of study centers or subjects at any one center is not needed.)

2. Describe visits and procedures to be followed, including any that are experimental
(investigational).

3. Describe any reasonably foreseeable risks and discomforts to the subject. This must
be in non-technical, lay language.

4. Include a statement that unknown risks and discomforts are possible; if appropriate,
include unknown risks to an embryo or fetus if a subject is or becomes pregnant. Also
include, when appropriate, a statement that study medication should be kept out of the
reach of children or persons of limited understanding.

5. Describe possible benefits to the subject or others; indicate that benefits are not
guaranteed.

6. Describe proposed payment for participation, if any, including per-visit amounts or
other planned payments.

7. Describe any known or anticipated costs to the subject as a result of research
participation. Include any planned third-party billing.
8. Describe appropriate alternative treatments or procedures, if available.

9. List any parties, such as a contract research organization (CRO), site management organization (SMO) or coordinating group, that may inspect the subject's medical records (in addition to the sponsor, FDA, HHS agencies, governmental agencies in other countries, and WIRB). WIRB has standard language for this confidentiality section and will incorporate the listed parties.

10. State whether compensation and/or medical treatment is available if a research-related injury or illness occurs, who will be responsible for costs, and where further information may be obtained.

11. List a contact person for information on research-related questions or research-related injury; WIRB will be included as a contact for subjects' rights.

12. Include a statement of voluntary participation and withdrawal, including that the subject may refuse to participate, that the subject may end participation at any time without penalty, and that the subject's participation may be ended by the investigator or sponsor, for any reason, without the subject's consent.

13. Include a statement that significant new findings developed during the research, which may affect the subject's willingness to continue participation, will be provided to the subject.

14. Include a statement that the subject will receive a copy of the signed and dated consent form.

15. Include a statement of consent to participate.

16. Include an authorization to release medical records to all the parties listed in the confidentiality section.

17. Include a statement that the consent form does not waive subject rights.

18. Include appropriate signature and date lines (include subject, person conducting the informed consent discussion, and investigator, at minimum). Also include a line for a "legally authorized representative" if surrogate consent is allowed or required by the protocol.

19. Include assent for minor subjects, if appropriate.
Continuing Oversight of Ongoing Research Studies

During the initial review of a protocol, the Board makes a determination on the required frequency for reporting information related to the studies. FDA and DHHS regulations regarding continuing review require an IRB to conduct continuing review of the research at intervals appropriate to the degree of risk, but not less than once per year [21 CFR § 56.108 (a)(1), § 56.109(f) and 45 CFR § 46.109(e)]. The Board normally requires full board re-review annually, but for some categories of high-risk research, full board review is conducted more frequently than once a year.

Throughout the year, WIRB also requires sites to complete one or more Continuing Review Report Forms (CRRFs). These reports provide WIRB with the study-related data necessary to monitor the progress of the research at sites. WIRB sends sites a CRRF approximately three weeks prior to the due date, which is printed on the form. Identifying information including investigator name, sponsor name, protocol number and CRRF "sequence" number is listed at the top of each form. Over the course of a year, studies assigned to a "semi-annual" reporting cycle will receive one "Interim" CRRF and one "Study Renewal" CRRF (approximately 45 days before the study's expiration date).

CRRFs must be filled out completely and returned to WIRB in a timely manner. Even if the site has not started enrolling subjects, this must be indicated on the CRRF and returned to WIRB to inform the Board of the study's status at the site.

Forms and additional information available at www.wirb.com
STUDY AMENDMENTS / REVISED INFORMED CONSENT

Changes to Approved Research, Protocol Amendments and Revised Informed Consent

Investigators must submit the exact text of an amendment or other revision to the protocol and any proposed changes to the consent document. A summary of the changes is also required. If the amendment requires a change to the approved consent form, each specific change must be listed. Submitters should include a copy of the most recently WIRB-approved consent form, with changes to that form indicated throughout, or provide a detailed document specifying the requested changes to the approved consent (WIRB cannot process changes illustrated on the sponsor template consent form alone). The changes cannot be implemented until approved by Western Institutional Review Board (WIRB).

All changes to subject materials must be submitted for Board review and approval.

Forms and additional information available at www.wirb.com
REPORTING UNANTICIPATED PROBLEMS

Federal Regulation 21 CFR 56.108(b)(1) and 45 CFR 46.103(b)(5) require the IRB to “follow written procedures for ensuring prompt reporting to the IRB...any unanticipated problems involving risks to human subjects or others.”

An unanticipated problem is defined as any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices or procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

All reports to the IRB of unanticipated problems should clearly explain why the event is "unanticipated" and clearly explain why the event represents a “problem involving risks to human subjects or others.”

WIRB expects reports to the IRB of unanticipated problems to include a corrective action plan to address the issue, or written justification for why none is provided.

The reviewing physician determines -- based on the information in the report and the current subject consent form -- if subjects should be notified verbally of the new information and if consent form modifications may be necessary. Recommended changes will then be submitted to the Board for consideration. Both the sponsor and investigator(s) are notified of any Board action or consent form change resulting from an unanticipated problem report.
Whenever an unanticipated problem occurs at a WIRB approved investigator site, it should be reported to WIRB using the appropriate WIRB forms. Unnecessarily reporting events or problems that do not potentially affect the rights, welfare or safety of subjects in the study may impair the Board's ability to review and respond in a timely manner to actual situations where subject rights, welfare or safety are threatened.

Forms and additional information available at www.wirb.com
TRANSLATION SERVICES

Translating Consent Forms and Other Documents Into Other Languages

There are two options available for obtaining a Western Institutional Review Board (WIRB)-approved translation of a study document:

Option 1: When requested in writing, WIRB will provide a translated version of a Board approved document in the required language(s). Translators will provide a signed certification statement attesting that the document is a true and accurate translation of the WIRB-approved document. There is a translation fee and an administrative fee for this service.

Option 2: The investigator or research sponsor may arrange to have a WIRB-approved document translated. The translator must provide a certification statement that the translation is a true and accurate translation of the WIRB approved version. The certification statement must identify the specific document that was translated (e.g., sponsor and protocol number, name of document), and must provide the form in an electronic form that is editable. Copies with the Board’s approval stamp will then be issued to the site(s). There is an administrative fee for this service.

For information about translations, call Client Services at (800) 562-4789 and ask for the Translation Department or contact clientservices@wirb.com
TRAINING

WIRB On-Site Personalized Training

Learn from the Best

We can deliver trainings right to your door with WIRB On-Site Personalized Training. Customized to fit your organization’s needs and expectations – On-Site Training courses can save you time and money by bringing the training to you. Choose from an existing training, customize one to fit your specific needs, or create your own.

Training for Researchers and Staff:

Consent Writers Workshop is designed to give everyone writing or editing consent forms hands-on training.

Investigator Training for Medical Research is designed to give investigators, potential investigators, and their staff basic information concerning research trials and the responsibilities of investigators. The need for training is based on NIH requirements and the growing trend for pharmaceutical sponsors to require their investigators to be trained. The duration of the course is approximately 7.5 hours.

Canadian Investigator Training for Medical Research is designed to give investigators, potential investigators, and their staff basic information concerning research trials and the responsibilities of investigators when performing trials in Canada. The duration of the course is approximately 7.5 hours.

Site Operations and SOPs Training is designed to give investigators and study coordinators training in optimizing the organization and operation of their research sites. The duration of the course is approximately 7.5 hours.

Good Clinical Practice (GCP) is designed to give investigators and staff basic information concerning good clinical practice. The duration of this course is approximately 5 hours.

Informed Consent and the History of Research is designed to give investigators and staff basic information concerning the history of research and the importance of the consent process. The duration of the course is approximately 4 hours.
Human Subject Recruitment Training is designed to give instruction on WIRB requirements on recruitment practices in regards to medical research. The duration of the course is approximately 5 hours.

On-Site Live Training in Olympia, WA, USA: Any of these courses can be conducted at WIRB’s facilities as well.

Training for Institutions:

Customize your institution training using the following topics:

- Research
  - Non-clinical research
  - Clinical
- Utilization of Study Coordinators
- Finding Studies
- Assessing Protocol Feasibility
- Budgeting for Studies
- Study Files
- SOPs (lecture and exercise)
- Devices
- HIPAA and Other Privacy Issues
- Gene Therapy
- Human Subject Protection
  - IRBs
  - Informed consent
- Investigator Roles and Responsibilities
  - GCPs
  - Regulations and 1572
  - Recruitment
  - Study conduct
  - Conflict of interest
- Investigator/Sponsor Interactions
  - Monitoring
  - Financial disclosure
  - Grants
  - Publications
- Audits & Avoiding Problems
  - Sponsor audits
  - IRB audits
  - Regulatory audits
  - FDA audit findings
- Working with your IRB
CIP Training

Coming Soon!

Training for IRB Staff:

Board Secretary Training is designed to train secretaries to take accurate meeting minutes and to capture the necessary information for regulatory compliance. The student will receive direction and support from a mentor, as well as having opportunity to attend board meetings with a trained board secretary. The course is approximately 7 hours per day over a period of 3 consecutive days.

IRB Administration is designed to give IRB members basic knowledge of IRB functions.

1 Day On-Site Live Training: Development of Compliant IRB Standard Operating Procedures (SOPs) is a one-day course designed to provide IRB staff and members the necessary tools to evaluate and further develop compliant SOPs.

2 Day On-Site Live Training: Development of Compliant IRB Standard Operating Procedures (SOPs) is a 2 half-day course designed to provide IRB staff and members the necessary tools to evaluate and further develop compliant SOPs.

SOP Development Services are available for those wishing to have their existing SOPs audited, edited, and written by qualified WIRB staff. Conducted by WIRB staff in the United States, with communication being by e-mail, fax and phone.

On-Site Service: SOP Development Services are available for those wishing to have their existing SOPs audited, edited, and written by qualified WIRB staff on site.

On-Site Live Training in Olympia, WA, USA: Visitors come to WIRB to learn about IRB functions and processes. Includes observation of a board meeting and time with WIRB staff from regulatory, medical affairs, operations, and Quality Assurance.

Training for IBC:
IBC Administration
IBC Member

Training for DSM:
DSMB Administration
DSMB Members

To request a proposal for training, contact
WIRB Education and Training
at 360-252-2478
CONSULTATIONS

Experienced staff members of WIRB are available to provide consulting services to sponsors and investigators regarding many aspects of human subject research. Regulatory or ethical advice regarding protocols being developed for which IRB approval will be sought is a frequently-requested service. Although an opinion from WIRB staff does not represent an official action by the Board and is not meant to represent any actions the Board may take upon its review of this research, consultation may be helpful to identify issues likely to result in disapproval or in required modifications. Consultation fees are calculated on an hourly basis. To request this service, please contact:

Vice President, Business Development
Phone: (360) 252-2443
Fax: (360) 252-2490
E-mail: Lmorrison@wirb.com

Additional consultation services include auditing, SOP review, consent form writing and specific training requests.
HOW TO CONTACT WIRB

Street Address: 3535 Seventh Avenue SW
Olympia, Washington, USA 98502-5010

Mailing Address: P.O. Box 12029
Olympia, Washington, USA 98508-2029

Telephone: 360-252-2500 (direct)
800-562-4789 (toll-free, USA, Canada & Puerto Rico)

FAX: 360-252-2498

E-Mail: clientservices@wirb.com

Forms and additional information available at www.wirb.com
Site Visits

Federal Regulations grant IRBs the authority to observe the consent process and the research (21 CFR 56.109(f); 45 CFR 46.109(e)).

During any type of site visit, the WIRB representative will focus on subject safety as well as regulatory compliance. The visits also offer an opportunity to the site to address research-related issues and ask questions of the WIRB visitor.

In preparation for the visit, WIRB asks the sites to set out the following review materials in a suitable work area, to allow for the visit to be conducted efficiently and with minimal disruption to the site's work:

- The site's organization's informed consent policies, and the process by which consent is routinely obtained.
- The site's document files for WIRB-approved studies, including:
  - Protocol and amendments,
  - FDA form 1572 (if applicable),
  - IRB correspondence and approved consent form(s),
  - Participant charts or source documents and the consent form(s) for each study,
  - Investigator Brochure(s),
  - Curriculum Vitae (CV) for all research staff, and
  - The Principal investigator's CV and medical license.

WIRB may also ask to see the site's drug storage areas and emergency equipment.

WIRB conducts the following types of site visits:

- **Routine (Site Assessment)** - Routine site visits are generally brief and simple. However, some "routine" visits to sites at institutions with which WIRB has a contract are dictated by the terms of the contract, and those visits' length and depth will vary depending on the terms.
- **For-Cause** - WIRB staff initiate "for-cause" site visits in response to concerns raised about the site or investigator. These visits are usually carried out by WIRB Regional Representatives, Board Members or WIRB management.
- **Board-Directed** - The Board directs site visits in response to concerns raised about the site or investigator. These visits are usually carried out by WIRB Regional Representatives, Board Members or WIRB management.

Sites receive a site visit confirmation notice soon after the site visit has been scheduled. The notice provides the time of the visit, the basis for the visit, the name of the visitor and the agenda for the visit.

The Board reviews all site visit reports. If any follow-up is required, the investigator will be informed about the Board's decision. WIRB does not release copies of site visit reports to sites or sponsors.
WIRB MISSION

The mission of the Western Institutional Review Board is to Protect the Rights and Welfare of the Human Research Subject.

To accomplish our mission, we strive to:

- Ensure that the risks of scientific advancement shall never outweigh the value of human life
- Follow our traditions while embracing new technologies and practices
- Maintain appropriate ethical conduct and regulatory compliance
- Honor our hallmark of respect for all persons
- Engage in a continuing quest for excellence

Quick Links: Download Forms | Track a Submission | Search the Site
Submit New Study Submission | Submit Change in Research | Submit Adverse Events | Submit Protocol Variances | Notify WIRB Study Complete

3535 SEVENTH AVE SW • OLYMPIA, WA 98502-5010
P.O. BOX 12029 • OLYMPIA, WA 98508-2029
(360) 252-2500 • 1-800-562-4789 • FAX (360) 252-2498
www.wirb.com • clientservices@wirb.com

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New Online Submission Feature

WIRB is pleased to announce a new Online Submission feature of our WIRB.com website. Many of our customers have asked for a better way to transmit documents to us. The Online Submission feature will let you upload documents to us through a safe and secure process.

To use this feature, simply click the ‘Online Submission’ button on the WIRB.com webpage and follow the easy directions. You can access the site at www.wirb.com

The general steps are:

1. Select the type of submission you wish to make
2. Upload your individual documents to the site
3. Complete the ‘Submitter Information’ page.
4. Click the ‘Finalize Submission’ button
5. Receive your confirmation page (and email) that includes your Submission Number.

The confirmation means that WIRB has received and can begin processing your submission. You can reference your Submission Number in any communication with our Client Services team. Note that your confirmation email can serve as an official “Acknowledgement of Receipt.” You will still receive a separate tracking number once we create the work order to review your submission.

We are pleased to provide this new service to you, and we hope that this – and other initiatives we are working on – help reduce the time needed for IRB review.

Please let us know if you have any questions, comments or suggestions.
Institution
WIRB New Review Cover Letter/Checklist

Date: ____________________________________

To: Western Institutional Review Board
3535 Seventh Avenue SW
Olympia, WA 98502-5010

From: _________________________________, Principal Investigator

Re: Protocol No.: ____________________________
Title: ______________________________________

As indicated by the boxes checked below, the enclosed documents are submitted for Initial Review:

☐ WIRB Initial Review Submission Form
☐ Protocol (date: ________________________)
☐ Amendments (dates for those included: ________________________)
☐ Investigator’s Brochure, if applicable (dates for those included: ________________________)
☐ Signed FDA Form 1572, if applicable, with WIRB listed as the IRB
☐ FDA letter granting an IDE for the proposed use, sponsor letter stating that the study is a non-significant risk device study, or letter explaining why the investigation is exempt from the IDE requirements under 21CFR 812.2(c) or otherwise exempt.
☐ Complete grant application, if submitted to a Federal agency.
☐ Informed consent form (hard copy)
   OR
☐ Informed consent form (MS Word, 3.5” DISKETTE)
☐ Advertisements (How many? _________)
☐ Curriculum Vitae for Principal Investigator and all Sub-Investigators
☐ Professional License for Principal Investigator
☐ Professional Licenses for all Sub-Investigators (if applicable)
☐ Radiation Safety Committee Approval (if applicable)
☐ Other documents (______________________________________)

Signature of Principal Investigator or Designee ________________________ Date ___________

Prepared and sent to WIRB by:

Printed Name/Title ________________________ Signature ________________________ Date ___________
WIRB INITIAL REVIEW SUBMISSION REQUIREMENTS

The following is a general list of items needed by WIRB to begin the review process for your research study. You will need to submit a submission form with each protocol you submit for review. If you have questions, call 1-800-562-4789 or e-mail clientservices@wirb.com for assistance.

ALL INITIAL REVIEW REQUESTS must include one copy of the following:

- Current version of WIRB initial review submission form (posted at www.wirb.com)
- Protocol* (WIRB can assist during the planning stages of a multi-center study by pre-reviewing the protocol and subject materials, including the consent form. Please use the WIRB form “Initial Review Submission Form for Sponsors and CROs” available on the download forms page of www.wirb.com.)
- Current professional license for Principal Investigator, showing the expiration date*
- Curriculum Vitae (CV) for Principal Investigator and each Sub-Investigator*
- Consent form*
- Other materials to be provided to the subjects which are not included in the protocol, such as advertisements, questionnaires, subject diaries, etc.* (Any commercially available validated instruments cited in the protocol that are used without modification are not listed individually on the Certificate of Approval; however, approval of the protocol does extend to the uses of such industry standard forms as described in the approved protocol.)

If a DRUG/BIOLOGIC study, a copy of the following:

- Investigator’s Drug Brochure*
- Background Information for Food Supplements*
- FDA Form 1572 (if applicable)
- Qualified Investigator Undertaking Form (Canadian sites)
- Documentation from sponsor or FDA verifying the IND (Investigational New Drug) number, if one is required for the research.* If an IND is not required, provide the reason why in writing.
- For gene transfer studies subject to RAC review, please submit the RAC correspondence, Appendix M responses, and IBC approval and minutes (if available). If the IBC review has yet to occur, please provide a date for the intended review and contact information for your NIH-OBA registered IBC. WIRB can provide IBC oversight; see the WIRB Services tab at www.wirb.com.

If a DEVICE study, provide device manual and ONE of the following:

- FDA Letter granting the Investigational Device Exemption (IDE)*; OR
- Letter from sponsor stating that the study is a non-significant risk device study;* OR
- Letter explaining why the investigation is exempt from the IDE requirements under 21CFR 812.2(c) or otherwise exempt.*

*Material may be omitted if WIRB is already in receipt of a current version.


### Initial Review Submission Form

**Instructions:**
- Handwritten copies of this form are accepted, but WIRB encourages submitters to submit a typed version to prevent errors and delays due to legibility problems.
- All questions must be answered. "N/A" is only an option where indicated.
- Please check the WIRB website to ensure you are completing the most current version of this form – form is updated at least once per year.

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Sponsor Protocol No.</th>
</tr>
</thead>
</table>

### I. PRINCIPAL INVESTIGATOR (PI) INFORMATION

Please provide information about the person legally responsible for the conduct of the research. WIRB must be assured that the investigator can personally oversee the conduct of the research and the protection of human subjects. [21 CFR 56.102 (h); for Canadian investigators: Part C Division 5 of the *Food and Drug Regulations*, Part 4 of the *Natural Health Products Regulations* (if applicable), *Medical Devices Regulations* (if applicable)]

<table>
<thead>
<tr>
<th>1. PI Name:</th>
<th>Gender: ☐ M ☐ F</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. PI Company Name:</td>
<td></td>
</tr>
<tr>
<td>1b. PI Mailing Address: (street, city, state/province, postal code, country)</td>
<td></td>
</tr>
<tr>
<td>1c. PI Phone: ( )</td>
<td>PI Fax: ( )</td>
</tr>
<tr>
<td>1d. How would the PI prefer to receive study documents? (check one)</td>
<td>☐ Fax ☐ E-mail ☐ Regular Mail</td>
</tr>
<tr>
<td>1e. PI Degree(s):</td>
<td>PI Specialty(ies):</td>
</tr>
<tr>
<td>1f. If this research will be conducted through an organization which has a contract to use WIRB for IRB services, please provide the name of the organization:</td>
<td>N/A ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Study Coordinator Name:</th>
<th>Gender: ☐ M ☐ F</th>
</tr>
</thead>
<tbody>
<tr>
<td>2a. Study Coordinator Phone: ( )</td>
<td>Study Coordinator Fax: ( )</td>
</tr>
<tr>
<td>2b. Does the study coordinator need to receive a copy of the regulatory documents in addition to the copy sent to the PI?</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>*If Yes, How would the coordinator prefer to receive study documents? (check one)</td>
<td>☐ Fax ☐ E-mail</td>
</tr>
</tbody>
</table>
Investigator
Submission Form for Multi-Center Protocols
(Use ONLY for multi-center protocols already reviewed by WIRB.)

The following is a general list of items needed by WIRB to begin the review process for your research study. You will need to submit a submission form with each protocol you submit for review. If the protocol you are submitting has NOT been previously reviewed by WIRB, you cannot use this form; you must use the full length Initial Review Submission Form (posted at www.wirb.com). If you have questions, call 1-800-562-4789 or e-mail clientservices@wirb.com for assistance.

INITIAL REVIEW REQUESTS must include one copy of the following:

- Current version of WIRB initial review submission form (posted at www.wirb.com)
- Current professional license for Principal Investigator, showing the expiration date*
- Curriculum Vitae (CV) for Principal Investigator and each Sub-Investigator*
- Any site-specific materials to be provided to the subjects that were not previously submitted by the sponsor or CRO. (Any commercially available validated instruments cited in the protocol that are used without modification are not listed individually on the Certificate of Approval; however, approval of the protocol does extend to the uses of such industry standard forms as described in the approved protocol.)

For DRUG or BIOLOGIC research, provide each of the following:

- FDA Form 1572 (if applicable)
- Canadian Qualified Investigator Undertaking Form (Canadian sites)
- For gene transfer studies subject to RAC review, please submit the RAC correspondence, Appendix M responses, and IBC approval and minutes (if available). If the IBC review has yet to occur, please provide a date for the intended review and contact information for your NIH-OBA registered IBC. WIRB can provide IBC oversight; see the WIRB Services tab at www.wirb.com.

*Material may be omitted if WIRB is already in receipt of a current version.
Investigator Submission Form for Multi-Center Protocols

Instructions:
- Handwritten copies of this form are accepted, but WIRB encourages submitters to submit a typed version to prevent errors and delays due to legibility problems.
- All questions must be answered. "N/A" is only an option where indicated.
- Please check the WIRB web site to ensure you are completing the most current version of this form – form is updated at least once per year.
- Use this form only for multi-center protocols already reviewed by WIRB.

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| 1. PRINCIPAL INVESTIGATOR (PI) INFORMATION: Please provide information about the person legally responsible for the conduct of the research. WIRB must be assured that the investigator can personally oversee the conduct of the research and the protection of human subjects. [21 CFR 56.102 (h); for Canadian investigators: Part C Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Products Regulations (if applicable), Medical Devices Regulations (if applicable)] |
|---|---|---|
| 1a. PI Company Name: | Gender: | M | F |
| 1b. PI Mailing Address: (street, city, state/province, postal code, country) | | | |
| 1c. PI Phone: | PI Fax: | PI E-mail: |
| | | |
| 1d. How would the PI prefer to receive study documents? (check one) | Fax | E-mail | Regular Mail |
| | | | |
| 1e. PI Degree(s): | PI Specialty(ies): |
| | |
| 1f. If this research will be conducted through an organization which has a contract to use WIRB for IRB services, please provide the name of the organization: | N/A |
| | |

| 2. Study Coordinator Name: |
|---|---|---|
| 2a. Study Coordinator Phone: | Study Coordinator Fax: | Study Coordinator E-mail: |
| | | |
| 2b. Does the study coordinator need to receive a copy of the regulatory documents in addition to the copy sent to the PI? *If Yes, How would the coordinator prefer to receive study documents? (check one) | Fax | E-mail | *Yes | No | |
RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:

PROTOCOL NO.:

SPONSOR:

INVESTIGATOR:

SITE(S):

STUDY-RELATED PHONE NUMBER(S):

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

[Add the following statement only if the study protocol expressly allows the enrollment of subjects not capable of consenting for themselves:] A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research subject. If you are a legally authorized representative, please remember that "you" means the research (study) subject.

SUMMARY
[The summary section should summarize for the subject what the informed consent process will tell them, including:
• How research differs from regular health care.
• The rights and responsibilities of research subjects.
• Information subjects should have before joining a research study.]
You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form,
- Having the study doctor or staff explain the research study to you,
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study: [remove any that do not apply]

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- Other parts of this study may involve experimental (investigational) drugs or procedures, that are being tested for a certain condition or illness. An investigational [drug, device, vaccine] is one that has not been approved by the U.S. Food & Drug Administration (FDA).
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study. Taking part in a research study could affect your current or future insurance coverage.

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- What drug or device or procedures will be used;
Any possible benefits to you;
The possible risks to you;
The other medical procedures, drugs or devices that could be used instead of being in this research study; and
How problems will be treated during the study and after the study is over.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY
[In simple language, explain the following:
• Why the research is being done
• What the experimental components are]

PROCEDURES
[In simple language and in a simple bullet format, explain the following:
• The tests and procedures that will be done
• Which procedures/drugs are standard care and which are for research purposes only
• Whether a placebo or sham procedure will be involved
• The chances of being assigned to various study arms
• The method of assignment (random, etc.)]

RISKS AND DISCOMFORTS
[In simple language and in a simple bullet format (whenever possible), explain the possible risks and discomforts:
Start with the side effects for the experimental drugs, devices or procedures. List, for example:
• most common
• less common
• rare]
[Follow with risks and side effects for all drugs, devices or procedures used in the study.]

There may be side effects that are not known at this time.

[Include any risks relative to pregnancy for both men and women. For example:]
Women who are pregnant or nursing a child may not take part in this study. Before entering the study, you and your study doctor must agree on the method of birth control you will use during the entire study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study.

Men who are in this research study should not get a sexual partner pregnant while taking the study drug [If applicable also add the following:] and for [specify amount of time] after the last dose of study drug. The effect of the study drug on sperm is not known.
[Or other pregnancy language supplied by sponsor—rewrite, if necessary, to simplify]

Your condition may not get better or may get worse during this study.
NEW INFORMATION
You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS
[In simple language indicate the possible benefit for both the subject and future patients.]
Your [name of condition] may improve while you are in this study; however, this cannot be promised. The results of this study may help people with [insert name of condition] in the future.
[or]
It cannot be promised that you will receive any medical benefits from being in this study.

COSTS
[In simple language state:]
• What will be billed to the subject or to their insurance
• Who pays if insurance does not (do not use exclamatory language).]

[For example:] [Sponsor Name] will provide the study [drug/device] free of charge during this study. Procedures that are done only for the study, such as extra lab tests will not be billed to you or your insurance company.

You or your insurance company may be billed for:
• Any standard medical care given during this research study.
• [list other costs as necessary]

Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include the costs of treating side effects. Otherwise, you might have unexpected expenses from being in this study.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

PAYMENT FOR PARTICIPATION
[Include this section only if subjects will be paid or if the sponsor requires subjects to be told that they will not be paid.]
You will be paid $____ for each completed study visit. If you do not finish the study, you will be paid only for the visits you have completed.
TEMPLATE
WIRB Consent Form HIPAA

ALTERNATIVE TREATMENT
If you decide not to enter this study, there is other care available to you, such as [List the major ones such as drugs / devices / procedures / supportive]. The study doctor will discuss these with you. You do not have to be in this study to be treated for [disease, condition, symptoms].

[Or]
This is not a treatment study. Your alternative is not to participate in this study.

[Use the following authorization format if the site is collecting health information, is a covered entity under HIPAA and is not using a separate HIPAA authorization form.

If the site is not collecting health information, is not a covered entity under HIPAA or is using a separate HIPAA authorization form, use the "Confidentiality" text that follows, rather than the authorization text below.

California sites: This entire HIPAA section plus authorization statement should be placed at the end of the consent form following a page break and must include its own set of signature lines.]

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

[Select additional from below, as appropriate.]

- Information gathered for this research about:
  - HIV / AIDS
  - Hepatitis infection
  - Sexually transmitted diseases
  - Other reportable infectious diseases
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
  - The diagnosis and treatment of a mental health condition

- Records about any study drug you received
- Records about the study device.

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with [enter SMO name], an agent for the study doctor [if no SMO, delete this sentence].

Who might get this information?

- The sponsor of this research. “Sponsor” means any persons or companies that are:
  - working for or with the sponsor, or
Your information may be given to:
- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Western Institutional Review Board® (WIRB®)
[Add any institutional names above WIRB.]

Why will this information be used and/or given to others?
- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
- Yes, but this permission will not stop automatically.
[or]
- This permission will be good until [date] [required in CA, IN, WA, and WI].

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Confidentiality [Use the following confidentiality text if the site is not collecting health information, is not a covered entity under HIPAA or is using a separate HIPAA authorization form.]
Study information collected about you will be given to the sponsor. “Sponsor” means any persons or companies that are working for or with the sponsor, or owned by the sponsor.
TEMPLATE
WIRB Consent Form HIPAA

It will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study [drug or device] may be considered for approval. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor;
  delete the following if no CRO or SMO
- [CRO name], an agent for the sponsor;
- [SMO name], an agent for the study doctor;
[Add any institutional names above WIRB.]

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA,
- Department of Health and Human Services (DHHS) agencies,
- governmental agencies in other countries, and
- Western Institutional Review Board® (WIRB®).

Total confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be given out during those presentations.

COMPENSATION FOR INJURY
[Example:]
If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.
[or other language supplied by sponsor, simplified.]

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Taking part in this study is voluntary. You may decide not to take part or you may leave the study at any time. Your decision will not cause any penalty or loss of benefits to which you are entitled.

The study doctor or the sponsor may stop your participation in this study at any time without your consent for any of the following reasons:
- it is in your best interest;
- you do not later consent to any future changes that may be made in the study plan;
- [if the protocol lists specific reasons, insert them here];
- or for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.
SOURCE OF FUNDING FOR THE STUDY
The sponsor [name] will pay for this research study. [Or other wording, as appropriate].

QUESTIONS
Contact _____ [name] at _____ [number(s)] _____ for any of the following reasons:
- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some types of questions, such as questions about appointment times. You may contact WIRB if you cannot reach the research team or if you want to talk to someone else.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

CONSENT
I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above [remove if you used a Confidentiality section rather than an Authorization section above].

By signing this consent form, I have not given up any of my legal rights.

[Example signature block for research involving adults able to consent, minors, and adults who lack the capacity to consent:]

Consent and Assent Instructions:
Consent: Subjects 18 years and older and able to provide consent must sign on the subject line below.
Subject Name

CONSENT SIGNATURE:

Signature of Subject (18 years and older)  
Date

Signature of Legally Authorized Representative (when applicable)  
Date

Authority of Subject’s Legally Authorized Representative or Relationship to Subject (when applicable)

Signature of Person Conducting Informed Consent Discussion  
Date

ASSENT SIGNATURES, For Adult Subjects with a Legally Authorized Representative:

Assent:

For subjects who have a legally authorized representative, I confirm that:

☐ I have explained the study to the extent compatible with the subject’s understanding, and the subject has agreed to be in the study.

OR

☐ The subject is not able to assent due to lack of mental capacity.
ASSENT SECTION For Subjects Under 18 Years Old:
Statement of person conducting assent discussion:

1. I have explained all aspects of the research to the subject to the best of his or her ability to understand.
2. I have answered all the questions of the subject relating to this research.
3. The subject agrees to be in the research.
4. I believe the subject’s decision to enroll is voluntary.
5. The study doctor and study staff agree to respect the subject’s physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

______________________________  Date
Signature of Person Conducting
Assent Discussion

Statement of Parent/Legally Authorized Representative:

My child appears to understand the research to the best of his or her ability and has agreed to participate.

______________________________  Date
Signature of Parent/Legally Authorized Representative

Ver. 01-07-2008
NOTICE: CONSENT FORM CHANGES

Two copies of your consent form are enclosed. One copy shows the changes made by the Western Institutional Review Board® (WIRB®). Items shown with a line through them have been deleted. Items shown with a double underline have been added by WIRB®. THIS COPY IS FOR YOUR REFERENCE ONLY.

The second copy is your “clean” copy. The “clean” copy with the WIRB® stamp is the official approved version. ONLY THE CONSENT FORM WITH THE APPROVAL STAMP MAY BE USED TO CONSENT YOUR SUBJECTS.

The following list (legend) of reasons for changes is provided. A superscript number (small number slightly above the printed line) that matches the list will appear on your redlined copy where appropriate to help you understand the reason(s) for a change.

<table>
<thead>
<tr>
<th>Number</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Conform to federal regulations, ICH guidelines, or state or local laws</td>
</tr>
<tr>
<td>02</td>
<td>Accuracy (to agree with protocol)</td>
</tr>
<tr>
<td>03</td>
<td>Coercive/reassuring language</td>
</tr>
<tr>
<td>04</td>
<td>Board-required words, phrases, paragraphs or changes</td>
</tr>
<tr>
<td>05</td>
<td>Sponsor-required words, phrases, paragraphs or changes</td>
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<tr>
<td>06</td>
<td>Duplication of information</td>
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<tr>
<td>07</td>
<td>Improve subject protection/safety</td>
</tr>
<tr>
<td>08</td>
<td>Clarity/Correction/Consistency</td>
</tr>
<tr>
<td>09</td>
<td>Created new paragraph</td>
</tr>
<tr>
<td>10</td>
<td>Moved from another area of consent form</td>
</tr>
<tr>
<td>11</td>
<td>Form changed from first to second person except consent section in first person, as required by Board.</td>
</tr>
<tr>
<td>12</td>
<td>Required for investigator, institution, or country (investigator’s location)</td>
</tr>
<tr>
<td>13</td>
<td>Submitted changes</td>
</tr>
<tr>
<td>14</td>
<td>Modifications previously approved by Board for this protocol</td>
</tr>
</tbody>
</table>
Consent and Assent Instructions:
Consent: Subjects 18 years and older must sign on the subject line below
For subjects under 18, consent is provided by the Legally Authorized Representative
Assent: Is not required for subjects 6 years and younger
Is required for subjects ages 7 through 17 years using the Assent section below.

Subject Name (printed)

CONSENT SIGNATURE:

Signature of Subject (18 years and older) Date

Signature of Legally Authorized Representative
(when applicable) Date

Authority of Subject’s Legally Authorized Representative or Relationship to Subject

Signature of Person Conducting Informed Consent Discussion Date

ASSENT SECTION:
Statement of person conducting assent discussion:

1. I have explained all aspects of the research to the subject to the best of his or her ability to understand.
2. I have answered all the questions of the subject relating to this research.
3. The subject agrees to be in the research.
4. I believe the subject’s decision to enroll is voluntary.
5. The study doctor and study staff agree to respect the subject’s physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Signature of Person Conducting Assent Discussion Date

Statement of Parent/Guardian:

My child appears to understand the research to the best of his or her ability and has agreed to participate.

Signature of Parent/Guardian Date
THE FOLLOWING WERE APPROVED:

INVESTIGATOR:

BOARD ACTION DATED:

PANEL:

STUDY APPROVAL EXPIRES:

STUDY NUM:

WIRB PRO NUM:

INVEST NUM:

WO NUM:

CONTINUING REVIEW:

SITE STATUS REPORTING:

SPONSOR:

PROTOCOL NUM:

AMD. PRO. NUM:

TITLE:

SAMPLE

APPROVAL INCLUDES:

WIRB APPROVAL IS GRANTED SUBJECT TO:

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789

This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB). WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Theodore D. Schultz, J.D., Chairman

(Date)

This document electronically reviewed and approved by Orive, Otto on 8/3/2007 6:48:04 AM PST. For more information call Client Services at 1-360-252-2500

Page 1 of 2
ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.
   a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.
   b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB.
   c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

3. Obtain pre-approval from WIRB for any planned deviations that could adversely affect the safety or welfare of subjects, or the integrity of the research data and any changes in the research activity. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects. Immediately report to WIRB any such emergency changes implemented.

4. Promptly report to WIRB any new information that may adversely affect the safety of the subjects or the conduct of the trial.
   a. Report to WIRB all adverse events that are unanticipated and possibly related, within 10 days of the investigator becoming aware of them.
   b. Promptly report to WIRB other unanticipated problems involving risks to human subjects or others. These events do not readily fit the formal definition of Adverse Event, but could impact human subject safety and/or rights. Examples include theft of a computer containing private identifiable subject information, or study staff getting ill from inhaling a study agent.
   c. Provide reports to WIRB concerning the progress of the research, when requested.

5. Report to WIRB any unplanned protocol variance that could adversely affect the safety or welfare of subjects, or the integrity of the research data, within 10 days of becoming aware of the variance. Other unplanned variances may be recorded on a log and submitted with continuing review reports.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

Contact

Company Name

SITES: If the PI has an obligation to use another IRB for any site listed below and has not submitted a written statement from the other IRB acknowledging WIRB’s review of this research, please contact WIRB’s Client Services department.

Address
1. NAME AND ADDRESS OF INVESTIGATOR

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFIES THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS ATTACHED.
   - CURRICULUM VITAE
   - OTHER STATEMENT OF QUALIFICATIONS

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED.

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY.

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES).
   - Western Institutional Review Board
   - 3535 Seventh Avenue SW
   - Olympia, WA 98502-5010

6. NAMES OF THE SUBINVESTIGATORS (e.g., research fellows, residents, associates) WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR.
8. ATTACH THE FOLLOWING CLINICAL PROTOCOL INFORMATION:

☐ FOR PHASE 1 INVESTIGATIONS, A GENERAL OUTLINE OF THE PLANNED INVESTIGATION INCLUDING THE ESTIMATED DURATION OF THE STUDY AND THE MAXIMUM NUMBER OF SUBJECTS THAT WILL BE INVOLVED.

☐ FOR PHASE 2 OR 3 INVESTIGATIONS, AN OUTLINE OF THE STUDY PROTOCOL INCLUDING AN APPROXIMATION OF THE NUMBER OF SUBJECTS TO BE TREATED WITH THE DRUG AND THE NUMBER TO BE EMPLOYED AS CONTROLS, IF ANY; THE CLINICAL USES TO BE INVESTIGATED; CHARACTERISTICS OF SUBJECTS BY AGE, SEX, AND CONDITION; THE KIND OF CLINICAL OBSERVATIONS AND LABORATORY TESTS TO BE CONDUCTED; THE ESTIMATED DURATION OF THE STUDY; AND COPIES OR A DESCRIPTION OF CASE REPORT FORMS TO BE USED.

9. COMMITMENTS:

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

I have read and understand the information in the investigator’s brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR:

1. Complete all sections. Attach a separate page if additional space is needed.

2. Attach curriculum vitae or other statement of qualifications as described in Section 2.

3. Attach protocol outline as described in Section 8.

4. Sign and date below.

5. FORWARD THE COMPLETED FORM AND ATTACHMENTS TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND).

10. SIGNATURE OF INVESTIGATOR

11. DATE

(WARNING: A willfully false statement is a criminal offense, U.S.C. Title 18, Sec. 1001.)

Public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDER (HFD-94)
12229 Wilkins Avenue
Rockville, MD 20852

Food and Drug Administration
CBER (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.”

Please DO NOT RETURN this application to this address.
WIRB Reporting System for
Unanticipated Problems that are Adverse Events

Federal Regulation 21 CFR 56.108(b)(1) and 45 CFR 46.103(b)(5) require the IRB to “follow written procedures for ensuring prompt reporting to the IRB...any unanticipated problems involving risks to human subjects or others...”

An unanticipated problem is defined as any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices or procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

All reports to the IRB of unanticipated problems should explain clearly why the event is "unanticipated" and clearly explain why the event represents a “problem involving risks to human subjects or others.”

WIRB expects reports to the IRB of unanticipated problems to include a corrective action plan to address the issue, or written justification for why none is provided.

Please note that unnecessarily reporting problems that do not meet the criteria outlined above may impair the Board’s ability to review and respond in a timely manner to actual situations where subject rights, welfare or safety are threatened.

Adverse events are any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.
FDA guidance documents recognize that:

1. "individual adverse event reports generally require an evaluation of their relevance and significance to the study, including an evaluation of other adverse events, before they can be considered to be an unanticipated problem," and

2. "All reports to the IRB of unanticipated problems should explain clearly why the event described represents a ‘problem’ for the study and why it is ‘unanticipated.’"

FDA believes that reports that lack such evaluation should not be provided to the IRB.

The reporting requirements for WIRB may differ from the reporting requirements for the sponsor. Report to WIRB only adverse events that in the opinion of the investigator may represent unanticipated problems involving risks to the other subjects in the research.

A. For adverse events that are determined to be unanticipated problems occurring at your site:
Use the Report Form for Unanticipated Problems that are Adverse Events to report an unanticipated adverse event that occurred at your site.

Investigators are required to report adverse events that fit the following criteria within 10 working days of the time the investigator becomes aware of them:

- Event is Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the subject population being studied,

- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

If the adverse event is clearly not related to the study drug, device, procedures, or washout process, it would not represent a risk to other subjects in the research or a “problem” for the study and, therefore, does not have to be reported to WIRB.

B. For adverse events that are determined to be unanticipated problems that did not occur at your site (non-site adverse reports such as IND safety reports, SUSAR reports, and so forth):

WIRB will accept non-site adverse event reports submitted by investigators and from sponsors on behalf of investigators, if, in accord with 21 CFR 312.32,

- the event described is both serious and unexpected,
- the report identifies all previous safety reports concerning similar adverse experiences,
- the report analyzes the significance of the current adverse experience in light of the previous reports, and
- the report outlines a corrective action plan.
WIRB will not accept non-site adverse events that do not identify all previous safety reports concerning similar adverse experiences, analyze the significance of the current adverse experience in light of the previous reports and outline a proposed correction action plan. These submitted reports will generally be returned to the submitter with a description of the WIRB reporting requirements and guidance encouraging the submitter to resubmit with the required analysis.

If you have arranged for the sponsor to report the unanticipated problem directly to WIRB, we do not expect you to provide us with a duplicate copy of the report received from the sponsor.

If the sponsor, CRO or SMO does not submit non-site adverse events that are determined to be unanticipated problems to WIRB on behalf of your site, you are required to submit them, along with the required explanation outlined above, within 10 days of the date you receive them.

WIRB recognizes that for multicenter studies, the sponsor is in a better position to process and analyze adverse event information for the entire study, and to assess whether an occurrence is both "unanticipated" and a "problem" for the study. Accordingly, you may rely on the sponsor's assessment and provide to WIRB a report of the unanticipated problem prepared by the sponsor.
Report Form for Unanticipated Problems that are Adverse Events
(due within 10 days of identifying an unanticipated problem that is an adverse event)

Principal Investigator Name: 
WIRB Protocol No.: 
Sponsor Protocol No.: 
  Sponsor: 
  Study Drug/Device: 
  Date of this Report: 

AE Description / Treatment / Outcome (including relevant dates):

Pertinent subject history:

Why do you consider the event “unanticipated”?

Why do you consider the event a “problem involving risks to human subjects or others”? 
Report Form for Unanticipated Problems that are Adverse Events (continued)

What changes do you propose to the consent form and/or the protocol in order to protect the rights, welfare and safety of the research subjects?

If none are proposed, provide the rationale for why changes are not needed.

Printed or Typed Name of Person Completing This Form

Company/Title

Phone number

Fax number

E-mail
WIRB Reporting System for Unanticipated Problems that are Not Adverse Events

Federal Regulation 21 CFR 56.108(b)(1) and 45 CFR 46.103(b)(5) require the IRB to “follow written procedures for ensuring prompt reporting to the IRB...any unanticipated problems involving risks to human subjects or others...”

An unanticipated problem is defined as any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the subject population being studied;

- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices or procedures involved in the research); and

- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

All reports to the IRB of unanticipated problems should explain clearly why the event is "unanticipated" and clearly explain why the event represents a “problem involving risks to human subjects or others.”

WIRB expects reports to the IRB of unanticipated problems to include a corrective action plan to address the issue, or written justification for why none is provided.

Please note that unnecessarily reporting problems that do not meet the criteria outlined above may impair the Board’s ability to review and respond in a timely manner to actual situations where subject rights, welfare or safety are threatened.
Instructions for reporting unanticipated problems that are not adverse events.

Use the Report Form for Unanticipated Problems that are Not Adverse Events to report the following unanticipated problems:

- Unanticipated problems that do not fit the definition of an adverse event, but which may, in the opinion of the investigator, involve risk to the subject, affect others in the research study, or significantly impact the integrity of research data. For example, report occurrences of breaches of confidentiality, accidental destruction of study records, or unaccounted-for study drug.

- Unplanned protocol deviations/violations that have already occurred, that may adversely affect the rights, safety or welfare of subjects or the integrity of the research data, AND for which you did not seek WIRB pre-approval.

Report occurrences within 10 days of becoming aware of them.

Note: Planned protocol deviations that may adversely affect the rights, safety or welfare of subjects or the integrity of the research data should be submitted to WIRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR § 46.103(b)(4); FDA 21 CFR § 56.108(a)(4); ICH 3.3.7]. Use the WIRB CIR/Subject Recruitment (Ads) Submission Form to request approval of a planned protocol deviation prior to implementation. (Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days on the attached Report Form for Unanticipated Problems that are Not Adverse Events.)
Report Form for Unanticipated Problems that are Not Adverse Events
(due within 10 days of determining that a problem is an unanticipated problem that is
NOT an adverse event)

Principal Investigator Name: ____________________________________________

WIRB Protocol No.: ____________________________________________________

Sponsor Protocol No.: ___________________________________________________

Sponsor: ________________________________________________________________________________________________

Study Drug/Device: _______________________________________________________

Date of this report: _______________ □ Initial □ Follow-up

Date of occurrence: _______________

Describe the problem:

______________________________________________________________________________________________

Why do you consider the event “unanticipated”?  

______________________________________________________________________________________________

Why do you consider the event a “problem involving risks to human subjects or others”?  
Were there adverse effects to those involved?  If so, please describe.

______________________________________________________________________________________________

______________________________________________________________________________________________
Report Form for Unanticipated Problems that are Not Adverse Events (continued)

Describe what action you have taken or will take to prevent recurrence:

Printed or Typed Name of Person Completing This Form

Phone number  Fax number

Company/Title

E-mail
NOTICE
Continuing Review Report is Due

Enclosed is a Continuing Review Report Form. WIRB uses the data from these questionnaires to monitor the progress of the research at your site for the protocol listed on the report form. Complete and return the enclosed report before the specified due date listed on the form.

The Board may take action to suspend or terminate approval of this research at your location if reports are not accurately completed and returned promptly.

If your study has closed, please complete a study closure form available at www.wirb.com.

So we can ensure prompt and accurate service, please notify WIRB of any changes to contact or location information. We can be contacted via one of the numbers listed above or e-mailed at clientservices@wirb.com.
**CRRF Work Sheet**

*(An abbreviated* guide to completing the WIRB Interim CRRF for study coordinators and PIs)*

The following instructions are provided for a select set of CRRF items that sites frequently misinterpret or about which WIRB receives inquiries.

* **A full set of instructions is available at** [www.wirb.com](http://www.wirb.com).

If this is the first report submitted since a subject has consented to participate, attach a signed WIRB-approved consent document. *(You should mark “NA” if you have already submitted a signed consent form or if WIRB approved a waiver of consent or waiver of documentation of consent for all subjects.)*

Subjects should be signing the clean version of the most current WIRB-approved consent form (redlined consent forms are provided for reference purposes only).

If the study at your site is under the oversight of another IRB in addition to WIRB, send only a signed copy of the WIRB-approved consent form.

**AT YOUR SITE:** Have there been any unanticipated adverse events at your site which have not previously been reported to WIRB? If yes, attach a report to this form.

* **Detailed instructions and forms for reporting adverse events are available at** [www.wirb.com](http://www.wirb.com) as a single packet.*

**AT YOUR SITE:** Have there been any other unanticipated study-related problems at your site which have not been previously reported to WIRB? If yes, attach appropriate information.

Unanticipated problems are issues outside the Adverse Event reporting system which may involve risk to the subject, or affect others in the research study. They include, but are not be limited to:

- Breach of confidentiality
- Destruction of study records
- Study drug unaccounted for

**Is there new risk or benefit information related to the research not previously reported to WIRB? If yes, attach a copy.**

*These might be IND safety reports not previously reported to WIRB or other updates to risk or benefit information related to the study.*

Have the hospital privileges of the PI or the subinvestigators at the hospital where subjects are treated or seen in case of emergency been reduced since your last report?

* **If yes, explain how the change will affect the plan for treatment and/or emergency care of subjects:** (attach additional sheet if necessary)

WIRB must be assured that there is an appropriate system in place in the event that a subject is hospitalized. If neither the PI nor the sub-investigators have privileges at the designated emergency facility, please describe how subjects would be referred for hospitalization, what physician(s) would assume the role of the attending, and how communication between the attending physician and the investigator would be assured. It is not sufficient to state, “They will be referred to the emergency room.”
1. AT YOUR SITE: Has the study begun? Yes__ *No__
   *If no, proceed to #7.

2. AT YOUR SITE: Have you consented subjects? Yes___ No____

3. AT YOUR SITE: If this is the first report submitted since a subject has consented to participate, attach a signed WIRB-approved consent document.
   (You may mark "NA" if you have already submitted a signed consent form or if WIRB approved a waiver of consent or waiver of documentation of consent for all subjects.) Attached___ NA___

4. AT YOUR SITE: Are you still enrolling subjects? Yes___ No____

5. AT YOUR SITE: Are subjects still receiving active treatment? Yes___ No____

6. AT YOUR SITE: Have there been any unanticipated study-related problems that involve risks to subjects or others which have not been previously reported to WIRB? Yes___ No____
   *If yes, complete and attach the appropriate WIRB reporting form.

7. Is there new risk or benefit information related to the research not previously reported to WIRB? Yes___ No____
   *If yes, attach a copy.

8. Are there changes to the protocol or consent form not previously reported to WIRB? Yes___ No____
   *If yes, attach a copy.

9. Have you received any subject complaints since your last report? Yes___ No____
   *If yes, summarize the complaint(s): (attach additional sheet if necessary)

10. Is the PI aware of any changes in state or local laws related to research? Yes___ No____
    *If yes, attach appropriate information.
11. What is the PI's perception of the community's attitude toward research? ...................................... *Neg___ Pos___
   *If negative, please explain: (attach additional sheet if necessary)

12. Is the PI aware of any recent events in his/her community (such as deaths or serious injuries) related to research? .......................................................................................................... *Yes___ No___
   *If yes, please attach any information you may have about the event.

13. Have you been audited for any study by the FDA or OHRP since your last report? ....................... *Yes___ No___
   *If yes, date of audit: ___________. Please submit a copy of the FDA report as soon as available (or indicate if the report has been previously provided to WIRB).
   Comments:

14. Investigators must ensure each member of the research study team/staff has had training in the protection of human subjects. Have you added new study staff since your last report? ......................... *Yes___ No___
   *If yes, has each new member of the team completed human subject protection training?
   Yes___ **No___
   **If no, the team member must discontinue participation in the research until they have received training. Comments:

Note: HIPAA training alone is not sufficient. WIRB's expectation is that training include topics such as ethical principles related to human subject protections, federal regulations for protection of human subjects, and Good Clinical Practice. A list of potential sources, including web-based tutorials and books, is available at www.wirb.com or by contacting WIRB's Client Services.

15. Are there any current investigations or charges involving the Principal or Sub-Investigator(s)? .... *Yes___ No___
   *If yes, attach appropriate information.

16. Has the PI's medical license been renewed during this reporting period? ...................................... *Yes___ No___
   *If yes, please attach a copy.

17. Have the hospital privileges of the PI or the sub-investigators at the hospital where subjects are treated or seen in case of emergency been reduced since your last report? ........................................ *Yes___ No___
   *If yes, please explain how the change will affect the plan for treatment and/or emergency care of subjects: (attach additional sheet if necessary)

18. Signed: ___________________________________________ Date: ____________________

   Investigator or Designee

   Please retain copy(ies) of the completed form for your study records.
**INTERIM CONTINUING REVIEW REPORT**

(21 CFR § 56.108 & 56.109; 45 CFR § 46.103 & 46.109)

**DUE:**

- PANEL:
- WIRB.PRO.NO.:
- INV.NO.:
- STUDY NO.:
- SEQ.:
- INST.TRACKING:

**REMEMINDER NOTICE**

COMPLETION AND RETURN OF THIS REPORT IS NECESSARY TO COMPLY WITH FEDERAL REGULATIONS (21 CFR §56.108 & 56.109; 45 CFR §46.103 & 46.109). ANSWER ALL QUESTIONS. IF NOT APPLICABLE, INDICATE "NA".

**WIRB WILL CONSIDER THE STUDY OPEN AT YOUR SITE UNTIL A STUDY CLOSURE REPORT IS RECEIVED.** (Closure forms are available at www.wirb.com.)

| 1. AT YOUR SITE: Has the study begun? | Yes___ No___ |
| *If no, proceed to #7. |

| 2. AT YOUR SITE: Have you consented subjects? | Yes___ No___ |

| 3. AT YOUR SITE: If this is the first report submitted since a subject has consented to participate, attach a signed WIRB-approved consent document. (You may mark "NA" if you have already submitted a signed consent form or if WIRB approved a waiver of consent or waiver of documentation of consent for all subjects.) | *Attached___ NA___ |

| 4. AT YOUR SITE: Are you still enrolling subjects? | Yes___ No___ |

| 5. AT YOUR SITE: Are subjects still receiving active treatment? | Yes___ No___ |

| 6. AT YOUR SITE: Have there been any unanticipated study-related problems that involve risks to subjects or others which have not been previously reported to WIRB? | *Yes___ No___ |
| *If yes, complete and attach the appropriate WIRB reporting form. |

| 7. Is there new risk or benefit information related to the research not previously reported to WIRB? | *Yes___ No___ |
| *If yes, attach a copy. |

| 8. Are there changes to the protocol or consent form not previously reported to WIRB? | *Yes___ No___ |
| *If yes, attach a copy. |

| 9. Have you received any subject complaints since your last report? | *Yes___ No___ |
| *If yes, summarize the complaint(s): (attach additional sheet if necessary) |

| 10. Is the PI aware of any changes in state or local laws related to research? | *Yes___ No___ |
| *If yes, attach appropriate information. |
11. What is the PI's perception of the community's attitude toward research? ......................................................... *Neg____ Pos____
   *If negative, please explain: (attach additional sheet if necessary)

12. Is the PI aware of any recent events in his/her community (such as deaths or serious injuries) related to research? ................................................................. *Yes____ No____
   *If yes, please attach any information you may have about the event.

13. Have you been audited for any study by the FDA or OHRP since your last report? ........................................ *Yes____ No____
   *If yes, date of audit: ______________. Please submit a copy of the FDA report as soon as available (or indicate if the report has been previously provided to WIRB).
   Comments:

14. Investigators must ensure each member of the research study team/staff has had training in the protection of human subjects. Have you added new study staff since your last report? ................................. *Yes____ No____
   *If yes, has each new member of the team completed human subject protection training?
   Yes ______ **No_____
   **If no, the team member must discontinue participation in the research until they have received training. Comments:

Note: HIPAA training alone is not sufficient. WIRB's expectation is that training include topics such as ethical principles related to human subject protections, federal regulations for protection of human subjects, and Good Clinical Practice. A list of potential sources, including web-based tutorials and books, is available at www.wirb.com or by contacting WIRB's Client Services.

15. Are there any current investigations or charges involving the Principal or Sub-Investigator(s)? .... *Yes____ No____
   *If yes, attach appropriate information.

16. Has the PI's medical license been renewed during this reporting period? ......................................................... *Yes____ No____
   *If yes, please attach a copy.

17. Have the hospital privileges of the PI or the sub-investigators at the hospital where subjects are treated or seen in case of emergency been reduced since your last report? ......................................................... *Yes____ No____
   *If yes, please explain how the change will affect the plan for treatment and/or emergency care of subjects: (attach additional sheet if necessary)

18. Signed: ________________________________ Date: ________________________________

Investigator or Designee

Please retain copy(ies) of the completed form for your study records.

Page 2 of 2
Your IRB Approval is About to Expire
Study Renewal Review Report is Due

Enclosed is a Continuing Review Report Form. WIRB uses the data from these questionnaires to monitor the progress of the research at your site for the protocol listed on the report form. Complete and return the enclosed report before the specified due date listed on it.

The enclosed report indicates ‘Study Renewal’ in the upper right corner. The Study Renewal form includes additional questions and requests additional summary materials be attached to the report.

- Sites will receive one ‘Study Renewal’ Continuing Review Report per protocol per calendar year. Please verify that the reported data (specifically, enrollment numbers) do not conflict with the previous report (if any) before forwarding this Continuing Review Report form to WIRB.

- Reports indicating ‘Study Renewal’ also provide notice to sites that WIRB will conduct a Continuing Review of the research in the near future because the study approval period is about to elapse.

- Board may conduct continuing review up to 30 days prior to the study expiration date listed on the certificate of approval. Review fees apply for the Continuing Review service.

- If your study has closed please complete a study closure form available at www.wirb.com. For continuing studies, no further action is required; simply complete and return the enclosed report.

The Board may take action to suspend or terminate approval of this research at your location if reports are not accurately completed and returned promptly.

So we can ensure prompt and accurate service, please notify WIRB of any changes to contact or location information. We can be contacted via one of the numbers listed above or e-mailed at clientservices@wirb.com.
CRRF Work Sheet
(An abbreviated* guide to completing the WIRB Study Renewal CRRF for study coordinators and PIs)

The following instructions are provided for a select set of CRRF items that sites frequently misinterpret or about which WIRB receives inquiries.
*A full set of instructions is available at www.wirb.com.

--Provide the following enrollment numbers:

\[
\begin{align*}
\text{Subjects active} & + \quad \text{Subjects in follow-up} & + \quad \text{Withdrawals*} & \quad \text{(include any deaths)} & + \quad \text{Screen failures*} & + \quad \text{Subjects completed*} & = \quad \text{Total Subjects consented*}
\end{align*}
\]

The reported number of total subjects consented cannot decrease over time.

"Withdrawals" signed the consent form, but later withdrew from the study, either before or after receiving study drug, device or intervention.

"Screen failures" signed the consent form, but later proved not to qualify for the study during screening procedures.

--Number of females consented
--Number of ethnic minorities consented

Check your numbers:
- Total women consented ≤ Total subjects consented.
- Total of ethnic minorities consented ≤ Total subjects consented.

--Approximate ethnic makeup of consented subjects: (must add up to exactly 100%)

<table>
<thead>
<tr>
<th>Ethnic Group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black or African American</td>
<td>_____%</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>_____%</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>_____%</td>
</tr>
<tr>
<td>White</td>
<td>_____%</td>
</tr>
<tr>
<td>Asian</td>
<td>_____%</td>
</tr>
<tr>
<td>Other: (specify)</td>
<td>_____%</td>
</tr>
</tbody>
</table>

--AT YOUR SITE: Have there been any other unanticipated study-related problems at your site which have not been previously reported to WIRB? If yes, attach appropriate information.

Unanticipated problems are issues outside the Adverse Event reporting system which may involve risk to the subject, or affect others in the research study. They include, but are not be limited to:
- Breach of confidentiality
- Destruction of study records
- Study drug unaccounted for

--Does the scientific literature indicate changes in knowledge relevant to the conduct of the study? If yes, attach a brief summary of the information

The summary should include a brief description of any changes in the currently accepted therapy or practices utilized in the protocol. Study coordinators should request a response from the Principal Investigator, who should be aware of relevant changes in the standard of care.
STUDY RENEWAL
CONTINUING REVIEW REPORT
(21 CFR § 56.108 & 56.109; 45 CFR § 46.103 & 46.109)

DUE:

PANEL:
WIRB.PRO.NO.:
INV.NO.:
STUDY NO.:
SEQ.:
INST.TRACKING:

SPONSOR:

INVESTIGATOR:

TITLE:

PROTOCOL:

DRUG:

COMPLETION AND RETURN OF THIS REPORT IS NECESSARY TO COMPLY WITH FEDERAL REGULATIONS (21 CFR § 56.108 & 56.109; 45 CFR § 46.103 & 46.109). ANSWER ALL QUESTIONS; IF NOT APPLICABLE, INDICATE "NA".

YOUR IRB APPROVAL IS ABOUT TO EXPIRE. CONTINUING REVIEW WILL BE CONDUCTED UNLESS A CLOSURE REPORT IS RECEIVED. (Closure forms are available at www.wirb.com.)

1. AT YOUR SITE: Has the study begun? ................................................................. Yes ___ *No ___
   *If no, proceed to #10.

2. If this is the first report submitted since a subject has consented to participate, attach a signed WIRB-approved consent document. (You may mark "NA" if you have already submitted *Attached ___ NA ___ a signed consent form, or if WIRB approved a waiver of consent or waiver of documentation of consent for all subjects.)

3. Are you still enrolling subjects? ................................................................. Yes ___ No ___

4. Provide the following enrollment numbers:

   Subjects in screening + Subjects in follow-up + Withdrawals* + Screen failures* + Subjects completed* = Total subjects consented*

   (consented, not yet active) (include any deaths) (Consented)

5. Number of females consented .................................................................

6. Number of racial minorities consented ....................................................

7. Approximate racial makeup of consented subjects: (must add up to exactly 100%)

   White: _____ %
   Asian: _____ %
   Other: (specify) _____ %
   Black or African American: _____ %
   Native Hawaiian or other Pacific Islander: _____ %
   American Indian or Alaska Native: _____ %

8. AT YOUR SITE: Have there been any unanticipated study-related problems that involve risks to subjects or others which have not been previously reported to WIRB? ................................................................. *Yes ___ No ___
   *If yes, complete and attach the appropriate WIRB reporting form.

9. AT YOUR SITE: Have there been any subject withdrawals which have not been previously reported to WIRB? ................................................................. *Yes ___ No ___
   *If yes, indicate the reasons for the withdrawals. (Attach additional sheet if necessary.)

10. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study? ................................................................. *Yes ___ No ___
    *If yes, attach a brief summary of the information.

Page 1 of 2

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11. Is there new risk or benefit information related to the research not previously reported to WIRB?  *Yes___ No__  
   *If yes, attach a copy.

12. Are there changes to the protocol or consent form or other material seen by subjects not previously reported to WIRB?  *Yes___ No__  
   *If yes, attach a copy.

13. Have you received any subject complaints since your last report?  *Yes___ No__  
   *If yes, summarize the complaint(s): (attach additional sheet if necessary)

14. Is the PI aware of any changes in state or local laws related to research?  *Yes___ No__  
   *If yes, attach appropriate information.

15. What is the PI’s perception of the community’s attitude toward research?  *Neg___ Pos__  
   *If negative, please attach an explanation.

16. Is the PI aware of any recent events in his/her community (outside of this study) (such as deaths or serious injuries) related to research?  *Yes___ No__  
   *If yes, please attach any information you may have about the event.

17. Investigators must ensure each member of the research study team/staff has had training in the protection of human subjects. Have you added new study staff since your last report?  *Yes___ No__  
   *If yes, has each new member of the team completed human subject protection training?  
      Yes___ **No__
   **If no, the team member must discontinue participation in the research until they have received training. Comments:

Note: HIPAA training alone is not sufficient. WIRB’s expectation is that training include topics such as ethical principles related to human subject protections, federal regulations for protection of human subjects, and Good Clinical Practice. A list of potential sources, including web-based tutorials and books, is available at www.wirb.com or by contacting WIRB’s Client Services.

18. Have you been audited for any study by the FDA or OHRP since your last report?  *Yes___ No__  
   *If yes, date of audit: . Please submit a copy of the FDA report as soon as available (or indicate if the report has been previously provided to WIRB).

19. Has the research team conflict of interest information provided to the Board since the last review changed?  *Yes___ No__  
   *If yes, please attach a summary of the changes (you may fill out and attach a copy of the WIRB Financial Disclosure Form available at www.wirb.com).

20. Are there any current investigations or charges involving the Principal or Sub-Investigator(s)?  *Yes___ No__  
   *If yes, attach appropriate information.

21. Has the PI’s license been renewed during this reporting period?  *Yes___ No__  
   *If yes, please attach a copy.

22. Have the hospital privileges of the PI or the sub-investigators at the hospital where subjects are treated or seen in case of emergency been reduced since your last report?  *Yes___ No__  
   *If yes, please explain how the change will affect the plan for treatment and/or emergency care of subjects: (attach additional sheet if necessary)

23. Is there any information you have not otherwise reported that summarizes study activity to date?  *Yes___ No__  
   *If yes, please explain or attach appropriate information.

24. Signed: ___________________________  Date: ___________________________

   Investigator or Designee

Please retain copy(ies) of the completed form for your study records.
**STUDY RENEWAL**
**CONTINUING REVIEW REPORT**
(21 CFR § 56.108 & 56.109; 45 CFR §46.103 & 46.109)

**DUE:**

**SPONSOR:**
**INVESTIGATOR:**
**TITLE:**

**protocol:**
**DRUG:**

**REMINDER NOTICE**

COMPLETION AND RETURN OF THIS REPORT IS NECESSARY TO COMPLY WITH FEDERAL REGULATIONS (21 CFR §56.108 & 56.109; 45 CFR §46.103 & 46.109).
ANSWER ALL QUESTIONS; IF NOT APPLICABLE, INDICATE "NA".

YOUR IRB APPROVAL IS ABOUT TO EXPIRE. CONTINUING REVIEW WILL BE CONDUCTED UNLESS A CLOSURE REPORT IS RECEIVED. (Closure forms are available at www.wirb.com.)

1. **AT YOUR SITE:** Has the study begun? ................................................................. Yes___ *No___
   *If no, proceed to #10.

2. **If this is the first report submitted since a subject has consented to participate, attach a signed WIRB-approved consent document.** (You may mark "NA" if you have already submitted a signed consent form, or if WIRB approved a waiver of consent or waiver of documentation of consent for all subjects.)
   *Attached___ NA___

3. Are you still enrolling subjects? ................................................................. Yes___ No___

4. Provide the following enrollment numbers:
   - Subjects in screening (consented, not yet active)
   - Subjects active
   - Subjects in follow-up
   - Withdrawals* (include any deaths)
   - Screen failures* (Consented)
   - Subjects completed*
   = Total subjects consented*

   *Cumulative total from start of study

5. **Number of females consented** .................................................................

6. **Number of racial minorities consented** ..................................................

7. **Approximate racial makeup of consented subjects:** (must add up to exactly 100%)
   - White: ______ %
   - Asian: ______ %
   - Black or African American: ______ %
   - Native Hawaiian or other Pacific Islander: ______ %
   - Other: (specify) ______ %
   - American Indian or Alaska Native: ______ %

8. **AT YOUR SITE:** Have there been any unanticipated study-related problems that involve risks to subjects or others which have not been previously reported to WIRB? ........................................... *Yes___ No___
   *If yes, complete and attach the appropriate WIRB reporting form.

9. **AT YOUR SITE:** Have there been any subject withdrawals which have not been previously reported to WIRB? .................................................... *Yes___ No___
   *If yes, indicate the reasons for the withdrawals. (Attach additional sheet if necessary.)

10. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?... *Yes___ No___
    *If yes, attach a brief summary of the information.

---

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11. Is there new risk or benefit information related to the research not previously reported to WIRB? *Yes___ No___
   *If yes, attach a copy.

12. Are there changes to the protocol or consent form or other material seen by subjects not previously reported to WIRB? *Yes___ No___
   *If yes, attach a copy.

13. Have you received any subject complaints since your last report? *Yes___ No___
   *If yes, summarize the complaint(s): (attach additional sheet if necessary)

14. Is the PI aware of any changes in state or local laws related to research? *Yes___ No___
   *If yes, attach appropriate information.

15. What is the PI’s perception of the community’s attitude toward research? *Neg___ Pos___
   *If negative, please attach an explanation.

16. Is the PI aware of any recent events in his/her community (outside of this study) (such as deaths or serious injuries) related to research? *Yes___ No___
   *If yes, please attach any information you may have about the event.

17. Investigators must ensure each member of the research study team/staff has had training in the protection of human subjects. Have you added new study staff since your last report? *Yes___ No___
   *If yes, has each new member of the team completed human subject protection training?
   Yes___ **No___
   **If no, the team member must discontinue participation in the research until they have received training. Comments:

Note: HIPAA training alone is not sufficient. WIRB’s expectation is that training include topics such as ethical principles related to human subject protections, federal regulations for protection of human subjects, and Good Clinical Practice. A list of potential sources, including web-based tutorials and books, is available at www.wirb.com or by contacting WIRB’s Client Services.

18. Have you been audited for any study by the FDA or OHRP since your last report? *Yes___ No___
   *If yes, date of audit: . Please submit a copy of the FDA report as soon as available (or indicate if the report has been previously provided to WIRB). Comments:

19. Has the research team conflict of interest information provided to the Board since the last review changed? *Yes___ No___
   *If yes, please attach a summary of the changes (you may fill out and attach a copy of the WIRB Financial Disclosure Form available at www.wirb.com).

20. Are there any current investigations or charges involving the Principal or Sub-Investigator(s)? *Yes___ No___
   *If yes, attach appropriate information.

21. Has the PI’s license been renewed during this reporting period? *Yes___ No___
   *If yes, please attach a copy.

22. Have the hospital privileges of the PI or the sub-investigators at the hospital where subjects are treated or seen in case of emergency been reduced since your last report? *Yes___ No___
   *If yes, please explain how the change will affect the plan for treatment and/or emergency care of subjects: (attach additional sheet if necessary)

23. Is there any information you have not otherwise reported that summarizes study activity to date? *Yes___ No___
   *If yes, please explain or attach appropriate information.

24. Signed: ____________________________ Date: ____________________________

Investigator or Designee

Please retain copy(ies) of the completed form for your study records.
Instructions for Sites Using Humanitarian Use Devices (HUDs)

WIRB understands that some of the questions on its Continuing Review Report Form are not pertinent to the use of HUDs, but you must complete the applicable questions and mark the rest “NA”. See the next page for a sample form indicating which questions can routinely be marked “NA”.


WIRB requires all approved, active sites provide progress reports at least annually (21 CFR § 56.109(f)). Continuing Review Report Forms are sent to sites approximately two weeks before their due date.

In situations where progress reports are not returned with accurate information in a timely manner, Federal Regulations grant the Board authority to suspend or terminate approval of the use of the device at the site (21 CFR § 56.113).

If the Board takes action to suspend approval for use of a HUD at your site, you would not be allowed to use the HUD on any new patients until the Board receives the information it requires and votes to lift the suspension.

Therefore, it is imperative that you submit the enclosed continuing review report as soon as possible.
SAMPLE CRRF for Sites Using HUDs

You may mark some questions “NA” as shown below, all the other questions must be completed and returned to WIRB in a timely manner.

YOUR IRB APPROVAL IS ABOUT TO EXPIRE. CONTINUING REVIEW WILL BE CONDUCTED UNLESS A CLOSURE REPORT IS RECEIVED. (Closure forms are available at www.wirb.com.)

1. AT YOUR SITE: Has the study begun? ......... Yes___ *No___
   *If no, proceed to #12.

2. If this is the first report submitted since a subject has consented to participate, attach a signed WIRB-approved consent document. (You may mark “NA” if you have already submitted a signed consent form or if WIRB has approved another copy.)
   Attached ___ NA _

3. Are you still enrolling subjects? ......... Yes ___ NA No ___

4. Are subjects still receiving active treatment? ......... Yes ___ NA No ___

5. Provide the following enrollment numbers:

   Subjects in screening (consented, not yet active) + Subjects active + Subjects in follow-up + Withdrawals* (include any deaths) + Screen failures* (Consented) + Subjects completed* = Total Subjects consented*

   *Cumulative total from start of study

6. Number of females consented.......

7. Number of racial minorities consented ....... NA

8. Approximate racial makeup of consented subjects: (must add up to exactly 100%)

<table>
<thead>
<tr>
<th>Race</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>NA %</td>
</tr>
<tr>
<td>Black or African American</td>
<td>NA %</td>
</tr>
<tr>
<td>Asian</td>
<td>NA %</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>NA %</td>
</tr>
<tr>
<td>Other: (specify)</td>
<td>NA %</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>NA %</td>
</tr>
</tbody>
</table>

9. AT YOUR SITE: Have there been any unanticipated study-related problems that involve risks to subjects or others which have not been previously reported to WIRB? .......... *Yes___ No___
   *If yes, complete and attach the appropriate WIRB reporting form.

10. AT YOUR SITE: Have there been any subject withdrawals which have not been previously reported to WIRB? .......... *Yes___ No___
    *If yes, indicate the reasons for the withdrawals: (attach additional sheet if necessary)

11. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study? ................. *Yes___ No___
    *If yes, attach a brief summary of the information.

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STUDY CLOSURE REPORT

Investigator Name: ____________________________

Sponsor Pro. Nr.: ______________________________

WIRB Pro. Nr.: _________________________________

WIRB Study Nr: ________________________________

Please complete this closure form when:
1. All subjects at your site have finished their final visits and any follow-up activities (such as phone calls, post-card contacts, or long-term follow up required by the protocol) are completed,
2. The sponsor or the sponsor representative has indicated the study is closed at your site, and
3. If the study was conducted under a Federalwide Assurance, all data analysis at the site is completed.

Do not submit this form until all of the above has been accomplished.

Until a closure form is received, WIRB oversight of the research at your site will remain active, including Continuing Study review as appropriate. (If you already have a designated closure form, you may submit it to WIRB in place of this one.)

Please send your sponsor or CRO contact a copy of this form for their records.

1. Date study closed: __________
   (mm/dd/yy)

2. Total subjects who signed the consent form: _________

3. Were there any unanticipated problems involving risks to subjects or others at your site that have not been previously reported to WIRB?
   □ No    □ Yes (If Yes, complete the appropriate WIRB reporting form and attach it)

4. Comments about the study: (Use reverse side or additional pages, if needed)

5. ____________________________  ____________________________
   Investigator Signature (or designee)  Date (mm/dd/yy)
Western Institutional Review Board® (WIRB)®
3535 Seventh Avenue, SW – P.O. Box 12029
Olympia, Washington 98502
1-360-252-2500

**IRB FEE SCHEDULE (Payable in U.S. Dollars)**
*Effective April 1, 2008*

*Amounts past due 60 days subject to 1% monthly interest*
*(For locations outside the 50 United States, add 10% – For Canadian locations, add 10% plus GST)*

<table>
<thead>
<tr>
<th>Service Description</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Review</td>
<td>$1,750.00</td>
</tr>
<tr>
<td>Protocol/Grant</td>
<td></td>
</tr>
<tr>
<td>Principal Investigator</td>
<td></td>
</tr>
<tr>
<td>Consent Forms</td>
<td></td>
</tr>
<tr>
<td>Recruitment Materials</td>
<td></td>
</tr>
<tr>
<td>Multicenter Studies, Additional Investigators (each)</td>
<td>$825.00</td>
</tr>
<tr>
<td>Site Specific Consent Forms</td>
<td></td>
</tr>
<tr>
<td>Site Specific Recruitment Materials</td>
<td></td>
</tr>
<tr>
<td>Study Renewal Review (each site, at least annually)</td>
<td>$825.00</td>
</tr>
<tr>
<td>Changes to Research (each site)</td>
<td>$285.00</td>
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<td>Protocol Amendments/Revisions</td>
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<td>Consent Form Modifications</td>
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<td>New or Updated Recruitment/Retention Materials</td>
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<td>Change to Research Locations</td>
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<td>Increased Subject Enrollment Level</td>
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<tr>
<td>Site Prepared Translations</td>
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</tr>
<tr>
<td>Other Changes to Research</td>
<td></td>
</tr>
<tr>
<td>Co-Investigator or Change of Investigator</td>
<td>$825.00</td>
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<tr>
<td>Videoconference</td>
<td>$350.00</td>
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<tr>
<td>Teleconference</td>
<td>$150.00</td>
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<tr>
<td>IRB Study Transfer</td>
<td>$550.00</td>
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<tr>
<td>For review of IRB and study records for research in progress, Initial Review fees also apply.</td>
<td></td>
</tr>
<tr>
<td>Generic Non-Protocol Related Material</td>
<td>$550.00</td>
</tr>
<tr>
<td><em>e.g.: Regulatory exempt determination, site pre-screening consent forms, generic advertising, centralized call screening or recruitment scripts</em></td>
<td></td>
</tr>
<tr>
<td>WIRB Translations Services</td>
<td>Variable (per English word)</td>
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<tr>
<td>Minimum translator charge $150 + Changes to Research Fee.</td>
<td></td>
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<tr>
<td>WIRB Written Consent Form</td>
<td>Variable ($150 per hour)</td>
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<td>Minimum charge $450.</td>
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</table>

*Protecting the Rights and Welfare of the Human Research Subject*
Initial Review

• Initial Review of Protocol and Investigator ................................................................. $1,750.00
  Protocol/grant, principal investigator, first consent form, recruitment materials

• Additional Investigators, Multi-Center studies ............................................................. $825.00
  Per investigator. Includes previously approved consent form(s), site-specific recruitment
  materials. For multi-center studies with over 25 sites, please call for pricing.

• Additional Consent Forms (each) .................................................................................. $300.00

Continuing Review

• Study Renewal Review (each site, at least annually) ....................................................... $825.00

• Annual Review of Generic or Non-Protocol Related Material ..................................... $550.00

Changes in Research

Protocol amendments/revisions, change to research locations, increased subject enrollment level, site prepared translations, new or updated recruitment/retention materials, other changes to research

• Changes to Research Involving Consent Form Review* .............................................. $350.00

• Changes to Research not Involving Consent Form Review* ....................................... $250.00

• Same Change, Each Additional Site ............................................................................. $150.00

• Co-Principal Investigator or Change of Investigator .................................................... $825.00

Other Services

• Videoconference .............................................................................................................. $350.00

• Teleconference .............................................................................................................. $150.00

• Generic or Non-Protocol Related Material ..................................................................... $550.00
  e.g. regulatory exempt determination, site pre-screening consent forms, generic advertising, centralized call screening or recruitment scripts

* Charges will be per submission unless the items require multiple and substantively independent review (e.g. consistent changes across several documents will receive a single charge; substantively different changes to different documents submitted at the same time but requiring independent review by the Board may receive more than one charge).

Protecting the Rights and Welfare of the Human Research Subject
Other Services (continued)

- WIRB Translations Services................................................................. Variable
  Cost based on number of words, minimum translation fee of $150 plus $300
  administrative fee
- WIRB Written Consent Form............................................................. Variable
  $250 per hour, minimum of 3 hours
- Consulting......................................................................................... call for estimate
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