

2 Application Submission

The *Application to Conduct Human Research forms* (Please see *Chapter 11, "Application Forms"* for more information) is available on the internet at www.sunrisehealthorc.com. The professional Sunrise Health Office of Research Compliance (SHORC) staff is happy to answer any questions you may have regarding human subjects taking part in research or the review of applications by the Sunrise Health Institutional Review Board (SHIRB). Any questions regarding SHIRB review or the content of the manual should be directed to the Sunrise Health Office of Research Compliance.

To contact the Sunrise Health Office of Research Compliance please use the following telephone number and address:

Sunrise Health Office of Research Compliance
Sunrise Health Institutional Review Board
3131 La Canada Street, Suite 107
Las Vegas, NV 89169
Telephone number: 702-731-8559
Email address: sunrise.orc@hcahealthcare.com
Web Address: <http://www.sunrisehealthorc.com>

THE BASIC APPLICATION

http://www.sunrisehealthorc.com/Application_to_Conduct_Human_Research.doc

The most common form of SHIRB application consists of five core documents: 1) the form [Application to Conduct Human Research](#); 2) the [Protocol Summary](#); 3) the informed consent form; 4) a complete detailed protocol; and 5) a grant proposal. Other documents may be required as part of the submission depending on the type of research. The following will help investigators identify the documents required to complete a submission to the SHIRB.

All investigators should carefully review the requirements for submission of applications to the SHIRB. Submission of incomplete proposals may result in the delay of the review and approval process. The review process will not be initiated if the proposal is incomplete and/or does not fulfill the SHIRB guidelines. Investigators should carefully review *Chapter 3, the SHIRB Review Process* of this manual and the summary guidelines of the application forms for each type of submission in order to ensure that the appropriate forms are submitted for SHIRB consideration. Application forms are found on the web site.

The IRB Application Form:

The Form, [Application to Conduct Human Research](#) is the legal document requesting SHIRB review of your proposal. Please complete each section as applicable to your submission. The information you provide in the application must include sufficient detail to facilitate an effective review by all members of the SHIRB.

Protocol Summary

This is a summary document describing the protocol and the investigator's plan for recruitment and enrollment of subjects. It includes important regulatory information needed for IRB review. The SHIRB is required by the federal regulations to include members from various

backgrounds, at least one member from the community-at-large, and at least one non-scientific member. The Protocol Summary should explain your research for the lay reader.

The Informed Consent Form/Assent Form:

Sample consent and assent forms can be found on the web site. All consent/assent forms are required to reflect the SHIRB format and style. (Please refer to *Chapter 4, "Informed Consent Requirements"*, for information regarding the requirements for informed consent.) Only Sunrise Health IRB reviewed, approved, stamped, and dated consent and/or assent forms can be used to consent subjects.

The Research Proposal

A detailed research protocol is required for the complete SHIRB review of your research. All submissions should include a scientific protocol that includes a complete explanation of the following information:

- a. Background
- b. Objectives of the research
- c. Significance
- d. Thorough description of how human subjects will participate in the research
- e. Eligibility requirements for subjects
- f. Design/methodology
- g. Treatment regimen(s) (*for medically invasive research*)
- h. Clinical information (when applicable) (*for medically invasive research*)
- i. Analysis of the collected data
- j. References

Grant Proposal

In order to perform a complete review the SHIRB is required to examine the grant proposal. Investigators need not include the funding section or the breakdown of dispersal of funds unless requested by the SHIRB.

Pilot Studies

The participation of human subjects in research requires review by the SHIRB or, in the case of Claims of Exemption, by the SHORC in consultation with the SHIRB. The Committee is required to assess the risks and benefits resulting from human subjects participating in all research. Pilot studies and feasibility studies, even if they include only one subject, require the same consideration by the SHIRB/SHORC as a project that requests the participation of 100 or more subjects.

Investigators interested in conducting feasibility of pilot work should consider contacting the SHORC prior to submitting an application. The SHORC can advise the investigator on how to appropriately address issues related to the risks and benefits of participating. (Please see *Chapter 4, "Informed Consent Requirements"* for additional information.)

If the Research is conducted at non Sunrise Health facilities or Recruitment is performed at non Sunrise Health facilities**Letters of Compliance/IRB Approval:**

The application should include any necessary letters of compliance or IRB approvals from non-Sunrise Health facilities or agencies proposed as a research site or source of potential subjects. For example, letters of compliance are required from facilities such as nursing homes that do not have a DHHS approved Multiple Project Assurance and IRB. Letters of compliance are required on the facility's letterhead and must contain a statement that the agency will, "review, abide by and comply with the procedures approved by the SHIRB." Facilities that do have a DHHS approved MPA and IRB, such as the Veteran's Administration, must review and approve the project before the SHIRB will approve the project.

NOTE: Do not wait for the approval of non-Sunrise Health sites before submitting your proposal to the SHIRB. If the SHIRB approves the project prior to your obtaining the letter of compliance or non-Sunrise Health IRB approval the SHIRB approval notice will carry the following codicil: "This Approval Notice is issued for administrative purposes only. No subjects may be contacted, recruited, or enrolled. All related SHIRB-approved consent forms will be held on file with the SHORC until the approval notice from the IRB of [the name of the facility] is received by the SHIRB."

When Research Requires the Review of Other Institutional Committees:**Review and Approval of Other Sunrise Health Committees:**

Please submit other required institutional review committee approvals to the SHIRB. Though other institutional committees share the responsibility for following guidelines in our collective effort to protect human subjects, ultimately the final authority for participation of human subjects in research falls on the SHIRB. Other institutional review committees include but are not limited to the Radiation Safety Committee and Bioethics Committee.

If the Research Involves Advertisements, Posters, Flyers, Press Releases, etc., to Recruit Subjects:

Contact Documents: The SHIRB is required to review any advertisements, flyers, internet postings (with the internet address), etc., for subject recruitment, correspondence to subjects or other cooperating individuals such as referring physicians or facilities. In addition, the SHIRB reviews all press releases intended to facilitate recruitment of subjects. Contact documents are not approved or valid without an SHIRB approval stamp, date, and number. Only SHIRB approved documents may be used in the conduct of research.

Please include recruitment materials with your initial and continuing review applications. If the material is not ready at the time of initial application, investigators may submit the material as an amendment to an already approved project. Requests for approval of recruitment materials following initial SHIRB review of the protocol should allow sufficient time for any necessary revisions prior to publication. Advertisements, press releases, etc., may qualify for expedited review (Please see *Chapter 3, "The SHIRB Review Process"*, for more information).

Contact documents should not make any claims, either explicitly or implicitly that the research is superior to any current practice. Please limit advertisements to:

1. The name of the investigator and contact information;
2. A simple and concise description of the purpose of the research;
3. General eligibility criteria for participating;
4. A truthful description of the possible benefits which may result from participation in the research. If there are no benefits, please indicate whether subjects are paid for their participation or receive free treatment.

If the Research Includes Surveys, Questionnaires, etc.

Instruments: The SHIRB is required to review all research instruments such as surveys, questionnaires, etc. Please include the instruments, if available, with your initial application. Investigators may submit draft versions of study instruments for SHIRB review. The SHIRB is required to review any modifications to research instruments. Please submit an amendment form to the SHIRB when requesting changes to previously approved instruments. If the SHIRB approves the project prior to the review of the finalized instruments the investigator will receive a codiciled approval notice indicating that the instruments cannot be used until they are reviewed and approved by the SHIRB.

Drug and Device Brochures

The SHIRB is required to examine the Investigator's Drug Brochure and/or device manual in order to adequately assess the risk/benefit ratio for subjects taking part in the research. In addition, please complete [Appendix C of the Application to Conduct Human Research](#), for research conducted with non-Food and Drug Administration (FDA) approved drugs or drugs used for indications other than those approved by the FDA. (Please see *Chapter 9, "FDA Requirements"*, for more information.)

There are special considerations for emergency care and compensation for injury to subjects participating in privately sponsored drug and device studies. (Please see *Chapter 4, "Informed Consent Requirements: Description of Informed Consent Forms, Emergency Care and Compensation for Injury"*, for more information.)

Claim of Exemption

A claim of exemption means that a research activity does not require SHIRB review and approval. The institution, however, is still obligated to review all such activities, whether funded or not, and certify that the research meets the federal requirements for a "Claim of Exemption". In order to fulfill federal requirements for the proper review of research, investigators cannot "self-exempt" from SHIRB review. Sunrise Health has determined that evaluation and certification of exempt status is performed by the SHORC in consultation with the SHIRB. If the activity does not qualify for a Claim of Exemption, the investigator is notified by the SHORC within three working days of submitting the

application. **The Claim of exemption does not necessarily mean that the investigator is exempted from the informed consent requirements.** (Please see *Chapter 3, "The IRB Review Process"* and *Chapter 4, "Informed Consent Requirements"* for more details.)

The following materials are required when submitting a Claim of Exemption:

1. Application for Claim of Exemption
2. An abstract of the research, purpose and objectives of the study;
3. Consent forms or a statement indicating the activity qualifies for a waiver of informed consent under the guidelines outlined in *Chapter 4, "Informed Consent Requirements"*;
4. Recruitment materials, i.e., advertisements, flyers, phone scripts, etc.;
5. Approval from participating institutions, i.e., schools or agencies, if applicable.

Investigators are strongly urged to consult with the SHORC before applying for exemption from SHIRB review. (Please see *Chapter 3, "The SHIRB Review Process"* and *"Exempt fro SHIRB Review" Guidelines*).

Modifications to Currently Approved Research (Amendments):

All changes to an existing, ongoing, approved protocol are required to have SHIRB review and approval prior to implementation. Minor changes that do not increase the risk to research subjects may receive an expedited review. Modifications to approved protocols that may affect the risk to subjects are forwarded to the full Committee for review. (Please see *Chapter 3, "The SHIRB Review Process"* for information regarding expedited review.) Please request all changes to previously approved research on the current SHIRB Form. Amendments include study staff changes, protocol revisions, and enrollment.

An amendment may require full SHIRB review if the change is significant and impacts the risks and benefits to subjects in the research. Changes in the risks or benefits to subjects may require modifications to the consent form and re-consenting of subjects.

The SHIRB may only approve modifications submitted during a current approval year to the end of that period. For example, if the new, or renewal approval is issued on January 1, 2006 it will have an expiration date of December 31, 2006. If an amendment is approved during this time, the approval still lasts only until December 31, 2006. Please incorporate all changes into the [Continuing Review Application Form](#), protocol, and when applicable, the informed consent forms for SHIRB consideration during the renewal review. **All changes must be approved by the SHIRB prior to implementation.**

Changing Investigators: When changing investigators please complete and submit:

1. an [Amendment Form](#);
2. Page 1 of the [Application to Conduct Human Research](#) (completed and signed by the new investigator);
3. A letter from the principal investigator indicating the change in responsibility and a letter from the new investigator accepting responsibility for the research. Changes in Investigators usually qualify for expedited review.

Renewal

The federal regulations do not allow the SHIRB to approve a study for more than one year. The principal investigator is responsible for submitting a renewal application prior to the expiration of the current SHIRB approval.

Ninety days prior to expiration of the SHIRB approval, the Principal Investigator is notified in writing that continuing review of their research protocol is coming due. The forms required for continuing review are available on our website: <http://www.sunrisehealthorc.com> Once the completed forms and required documents are received, the protocol is reviewed either at a convened meeting of the SHIRB or through the expedited review procedure as described previously.

When SHIRB approval expires, the Principal Investigator is notified that all research activities must stop. Research activities include, but are not limited to, recruitment and enrollment of subjects, collection of specimens, research on previously collected specimens, review of medical records or other health information, data analysis, and performance of research tests/procedures, treatment or follow-up on previously enrolled subjects.

If treatment and/or follow-up of subjects are necessary for subject safety and welfare, the Principal Investigator must inform the SHIRB in writing immediately to request permission to continue previously enrolled subjects on study. The SHIRB Chair is responsible for considering these requests on a case-by-case basis and providing written documentation of permission, when granted.

Completion / Termination

In order to formally complete a study file, the SHIRB requires that investigators officially notify the SHIRB when a study is terminated or completed or after data analysis is complete by submitting a *Study Closure Form* when closing out a study.

Training Grants, Program Projects / Multiple Project Grants, Center Grants:

The federal regulations require that the Committee or its designee certify that human subject related research funded by an "overall" grant such as a training grant, program project, multiple project grant or center grant have current SHIRB approval. Please submit the following:

1. *Sponsor / Funding Information* form;

2. The grant application;
3. A cover letter indicating that no funds will be transmitted to the individually supported sub-projects proposing to conduct research with human subjects until the sub-projects have received current approval from the IRB; and
4. A list of all of the human subject related projects supported by the grant. The list should include the following:
 - a. The name of the principal investigator(s);
 - b. The IRB numbers of the project(s)';
 - c. The title of the project(s)';
 - d. The current approval periods for the project(s).

The SHIRB has delegated certification authority to the SHORC. As a result, the SHORC will certify whether the human subject related projects under the "overall" grant have current approval and perform an administrative approval of the funding submission. ***Because the "overall" grant is intended to fund the sub-projects, no human subjects can be enrolled in the "overall" grant.*** (Please see *Chapter 12, "Application to Conduct Human Research*, for the appropriate application materials.)

Instructions for Facilitated Review of Research Approved by the Central Institutional Review Board of the National Cancer Institute

Sunrise Health is a member of the Central Institutional Review Board (CIRB), a project sponsored by the National Cancer Institute (NCI) in consultation with the DHHS Office of Human Research Protection (OHRP) to streamline the process for local IRB review of multi-center cancer treatment trials.

Local investigators who wish to enroll subjects onto CIRB-approved protocols are encouraged to utilize this service. However, the Sunrise Health Institutional Review Board (SHIRB) must review each protocol on an individual, expedited basis to determine if CIRB oversight is appropriate. What follows are instructions for submitting these protocols to the SHIRB for review.

NCI CIRB Website: (<http://www.ncicirb.org>) – general information and access to downloadable protocol versions and consent forms.

INITIAL SUBMISSION

Submit **one hard copy** of the following to the Sunrise Health Office of Research Compliance:

1. Completed *Application Form for SHIRB Facilitated Review of NCI Central IRB (CIRB) Approved Studies*

From www.ncicirb.org:

“As part of this “facilitated review”...local boilerplate additions or deletions to the informed consent, dealing with state and local law, institutional requirements, or IRB policies, may be considered...as long as the proposed changes do not alter the meaning of the CIRB approved consents. Per current OHRP/NCI guidance, any informed consent changes must be justified in the IRB minutes and sent to the Cooperative Group administering that protocol.”

2. CIRB application, protocol, notification letters, SAE reports and amendments **from the CIRB website.**

Note: The consent form should be revised to conform to the current Sunrise Health format and standard statements.

3. Submit the revised consent form electronically (by e-mail) to sunrise.orc@hcahealthcare.com, as well as in hard copy.

SHIRB staff will download the remaining CIRB documentation – primary reviews, and minutes.

Sunrise Health IRB Review

The SHIRB chair or a designated SHIRB member will conduct a facilitated review of the downloaded documents. There are three possible outcomes:

- **Not Accepted:** Local IRB oversight is required. You must prepare an *Application to Conduct Human Research* and submit materials to the SHIRB office by the deadline date for full board review. The CIRB will not be involved in overseeing the protocol.
- **Minor Modifications Required:** Specific stipulations must be addressed before the CIRB can be designated as the IRB of record.

From www.ncicirb.org:

"...the local IRB may add stipulations or local requirements to protocols, particularly to increase subjects' safety, to clarify procedures, etc., but may not delete or contradict any protocol contents...Local IRB's may also make minor word substitutions or additions in the informed consent document, particularly to facilitate better comprehension by the local population, as long as the proposed changes do not alter the meaning of the CIRB approved contents. Per current OHRP/NCI guidance, any informed consent changes must be justified in the IRB minutes and sent to the Cooperative Group administering that protocol."

- **Approved (Protocol Accepted):** The CIRB will be designated as the IRB of record. You will receive an acceptance letter, and a hard copy of the local consent document(s). A confirmation e-mail will come from the CIRB.

Post-Approval Responsibilities

Once the CIRB is designated as the IRB of record, your interaction with the SHIRB will be minimal, but very important.

- **Consent Form Revisions:** Consent forms must always be the most current CIRB approved version. The CIRB will notify the PI and coordinator (by e-mail) when changes to the consent have been made and posted on the CIRB website. Make all changes on the local consent, update the header to match the CIRB-approved consent and submit one hard copy to the SHIRB office. An approval letter will be issued along with a SHIRB approved consent form.
- **Continuing Reviews:** Continuing review will be conducted by the CIRB. The PI and the coordinator will receive e-mail notification of these reviews. Please submit these reviews along with a completed SHIRB *Progress Report Form for CIRB Studies* and the updated local consent form. An approval letter will be issued, along with a SHIRB approved consent form.
- **Adverse Events:** Submit **only** local SAEs to the SHIRB, using the current SHIRB *Adverse Event Reporting Form*. The SHIRB will correspond with the Principal Investigator regarding any action needed, as applicable.

From www.ncicirb.org:

“Your local IRB is still responsible for reviewing SAEs that occur at your site; for all others, the CIRB does the review. Investigators continue using their routine reporting procedures. There is no need for the investigators to report SAEs to the CIRB. SAEs are reported using the customary mechanisms on CTEP-sponsored phase III protocols (Cooperative Group and others); the CIRB will be able to access SAE reports directly from NCI, to review SAEs and to report back to participating local IRB's via a confidential web site.”

- **Study Staff Changes:** Submit any local study staff changes to the SHIRB, as they arise. Use the current SHIRB *Co-Investigator/Study Staff Amendment Form*. If approved, an approval letter will be returned to the local contact person.
- **Other Local Alterations and Updates:** Any locally initiated alterations/updates (e.g., advertisements) should be submitted to the SHIRB for review. If approved, an approval letter will be returned to the local contact person.
- **Study Closure:** To close a CIRB study at this site, submit a SHIRB *Study Closure Report* to the SHIRB. The SHIRB office will send a termination letter to the local contact person and will notify the CIRB.
- **Protocol Amendments (Do not send to the SHIRB):** When the Cooperative Group makes protocol amendments, you must use only the CIRB approved version. These can be downloaded from the CIRB website through the investigator log-in access. These should not be submitted to the SHIRB.

The SHIRB will maintain hard copy files of locally approved CIRB protocols, all subsequent reviews, and other CIRB documentation.

CONTACT INFORMATION - NCIRB – Toll free help line: 888-657-3711