

## 11 Forms

The *Application to Conduct Human Research, Appendices (as applicable), and the Protocol Summary* should be submitted by email to [sunrise.orc@hcahealthcare.com](mailto:sunrise.orc@hcahealthcare.com). The Sunrise Health Institutional Board (SHIRB) Staff will review the submission to be sure it is complete. The staff will then email you as to whether or not the application can be expedited or will need full board review, as well as any requested changes.

If the submission meets determination for expedited review, the staff will notify you within 2-3 working days. In that case, you will need to print your submission, obtain necessary signatures, and submit the original to the SHIRB.

If the submission needs full board review, the staff will notify you within 2-3 working days. In this case, you will need to print your submission, obtain necessary signatures, and submit the original to the SHIRB.

In either case, a copy of the consent document you wish to have approved by the SHIRB **must be sent electronically to** [sunrise.orc@hcahealthcare.com](mailto:sunrise.orc@hcahealthcare.com).

### NEW SUBMISSIONS

1. [Application to Conduct Human Research](#) (including Appendices as applicable)  
For use in preparing submissions for studies where intervention or interaction with subjects is planned. In some cases an Expedited Application Form may be used. *See below.*

#### [Application Appendix A: Co-Investigators/Study Staff](#)

This form should be completed for each study staff member. We recommend that one individual in addition to the PI be designated to receive copies of SHIRB correspondence.

#### [Application Appendix B: Additional Protections for Children Involved as Subjects in Research](#)

Federal regulations require the SHIRB to provide additional protections for children involved as subjects in research. Complete this form if you plan to enroll children.

#### [Application Appendix C: Drugs and Biologics](#)

Complete a separate form for each investigational or FDA-approved drug or biologic being studied.

#### [Application Appendix D: Request for Waiver of Informed Consent/Authorization](#)

Investigators seeking a waiver of subjects' informed consent to the research and a waiver of subjects' written authorization to use and disclose individually identifiable health information for research must request such waivers from the SHIRB.

#### [Application Appendix E: Research Related Use of Excess Human Material/Tissue and Related Health Information](#)

Complete this form for research that is limited to the use of human material/tissue derived from patients and health information related to the material/tissue.

[Application Appendix F: Nursing Implementation and Planning](#)

Complete this form for protocols that will be conducted in the Emergency Department or Inpatient Care Units or protocol that involves the collection of data from Patient Care Services nurses. For studies of inpatients to coordinate care with the clinical nursing staff. Must be approved by a nursing director/manager.

[Application Appendix G: Research Use of FDA-Approved or Investigational Devices](#)

Complete this form for (a) devices being investigated (i.e., devices tested for safety and/or efficacy, or used as comparator); (b) FDA-approved devices that will be used in a non-standard fashion for research purposes (not for the clinical care of the patient); and (c) non-hospital devices being used for research purposes.

[Application Appendix H: Research Related Exposure to Non-ionizing Radiation](#)

Complete this form for research that involves exposure of subjects to non-ionizing radiation

[Application Appendix I – Radiation Exposure Form](#)

Complete this form for research that involves exposure of subjects to ionizing radiation

[Application Appendix J: Additional Protections for Neonates Involved as Subjects in Research](#)

Federal regulations require the SHIRB to provide additional protections for children involved as subjects in research. Complete this form if you plan to enroll neonates.

[Application Appendix K: Additional Protections for Pregnant Women Or Human Fetuses Involved in Research](#)

Federal regulations require the SHIRB to provide additional protections for pregnant women or human fetuses involved as subjects in research. Complete this form if you plan to enroll pregnant women or human fetuses.

[Application Appendix L: Research Limited to the Use of Medical Records](#)

Investigators seeking a waiver of subjects' informed consent to the research and a waiver of subjects' written authorization to use and disclose individually identifiable health information for research must

request such waivers from the IRB. Complete this form if applicable to your research.

[Application Appendix M – Additional Protections of Individuals with Impaired Decision-Making Capacity](#)

Federal Regulations require the SHIRB to provide additional protections for individuals taking part in research when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as individuals with impaired decision-making capacity. Complete this form if this is applicable to your research.

[Protocol Summary](#)

Summary document describing protocol and investigator's plan for recruitment and enrollment of subjects. Includes important regulatory information needed for SHIRB review.

**CONTINUING REVIEW SUBMISSIONS**

The [Continuing Review Application](#), and the [Protocol Summary](#) **must be submitted by email to [sunrise.orc@hcahealthcare.com](mailto:sunrise.orc@hcahealthcare.com)**. The IRB Staff will review the submission to be sure it is complete. We will then email you as to whether or not the application can be expedited or will need full board review, as well as any requested changes, and to inform you as to how many complete sets are required.

If the submission meets determination for [expedited review](#), we will notify you within 2-3 working days. In that case, you will need to print your submission, obtain necessary signatures, and submit the original to the IRB.

If the submission needs [full board review](#), we will notify you within 2-3 working days. In this case, you will need to print your submission, obtain necessary signatures, and submit the original and the required number of packets to the IRB.

In either case, a copy of the consent document you wish to have approved by the IRB **must be sent electronically to [sunrise.orc@hcahealthcare.com](mailto:sunrise.orc@hcahealthcare.com) in addition to any required hard copies**.

[Adverse Event Log](#)

The IRB requires the use of this log, which should be maintained by the investigator and submitted with the Continuing Review Application. For every AE reported to the IRB, please utilize only one entry or line on the Adverse Event Log.

[Deviation / Violation Log](#)

The IRB requires the use of this log, which should be maintained by the investigator and submitted with the Continuing Review Application. For every deviation/violation reported to the IRB, please utilize only one entry or line on the Deviation / Violation Log.

***Proposed Informed Consent (if applicable)***

You must provide a copy of this document electronically to

[sunrise.orc@hcahealthcare.com](mailto:sunrise.orc@hcahealthcare.com).