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IRB review of human research activities is conducted either at a convened meeting of a quorum of the members of the Sunrise Health Institutional Review Board (SHIRB), including at least one physician/scientist and at least one member whose primary concerns are in nonscientific areas, or through the expedited review procedure as authorized in [45 CFR 46](#) as amended. Whether the IRB review is conducted at a convened meeting or through the expedited review procedure, the review encompasses the application form and all documents and materials submitted to the IRB for review.

## **A. Initial and Continuing Review**

### **1. Exemptions from 45 CFR 46**

The IRB Chair/Designee is responsible for determining whether human subjects research is exempt from the requirements of the Common Rule as outlined in [45CFR46.101\(b\)\(1-6\)](#), as quoted below:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the

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confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The exemptions do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C. The exemption [45 CFR 46.101\(b\)\(2\)](#) does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

The IRB Chair/Designee is responsible for reviewing and determining whether the research is exempt from 45 CFR 46. As part of this review, the IRB Chair/Designee will consider whether informed consent can be waived and whether there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of the data. The IRB

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Chair/Designee uses a review checklist to indicate whether or not the research is exempt from review. If the IRB Chair/Designee determines that the research is exempt from the requirements of 45 CFR 46, continuing review will not be required unless changes are made to the research that exceed the parameters of the exemption and require subsequent IRB review. The IRB Chair/Designee may request additional information from the PI to make the determination. If the research does not meet the criteria for exemption, the protocol is reviewed through the expedited review procedure or by full board review at a convened meeting of the IRB, as appropriate to the research activities.

Investigators are notified in writing that the research is exempt from further IRB review and that they may not make changes to the research activity without first discussing the changes with the IRB to determine whether the changes are within the parameters for exemption. If the research no longer meets the criteria for exemption, the investigator must resubmit the research for review by the IRB at a convened meeting or through the expedited review procedure.

## B. Expedited Review Procedure

New and ongoing research activities that present no more than minimal risk to human subjects *and* involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and [21 CFR 56.110](#), as quoted below:

*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [\[45 CFR 46.102\(i\)\]](#).

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  1. Research on drugs for which an investigational new drug application [\(21 CFR Part 312\)](#) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated

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with the use of the product is not eligible for expedited review.)

2. Research on medical devices for which (i) an investigational device exemption application ([21 CFR Part 812](#)) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
    2. from other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
  3. Prospective collection of biological specimens for research purposes by noninvasive means.
  4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
  5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non research purposes (such as medical treatment or diagnosis).

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6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
8. Continuing review of research previously approved by the convened IRB as follows:
  1. where (i) the research is permanently closed to the enrollment of subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
  2. where no subjects have been enrolled and no additional risks have been identified; or
  3. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Research in any of these categories may require review at a convened meeting of the IRB if the circumstances of the proposed research involve more than minimal risk.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing,

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employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risk related to invasion of privacy and breach of confidentiality is no greater than minimal. In addition, the expedited review procedures may not be used for classified research involving human subjects.

The IRB Chair/Designee is responsible for reviewing and determining whether the research is eligible for review through the expedited review procedure. The IRB Chair/Designee uses a form listing the expedited review categories published in the Federal Register at 63 FR 60364-60367 to document that the research is minimal risk and the applicable expedited review categories. The IRB Chair/Designee also documents that the consent form includes the basic elements of informed consent or approval of a waiver or alteration of informed consent on the review form.

If the proposed research is not eligible for review through the expedited review procedure, the IRB Chair/Designee requests the research protocol be scheduled for full board review at a convened meeting of the IRB.

The IRB Chair/Designee may approve, require modifications to secure approval or defer action pending receipt of additional information from the PI. The IRB Chair/Designee may not disapprove a study through the expedited review procedure; protocols can only be disapproved by the IRB at a convened meeting.

If the IRB Chair designates another voting member of the IRB to review the research through the expedited review procedure, the member is provided with all of the information provided to the IRB for review and follows the procedure for expedited review as described in this policy. The IRB member must comply with the *Sunrise Health IRB Conflicts of Interest Policy* and decline to review if a conflict exists.

When the IRB Chair/Designee requires modifications to secure approval or defers action pending receipt of additional information, the Principal Investigator is notified in writing of the required modifications or additional information required for review. The Principal Investigator is asked to submit a point-by-point response and revised documents to the IRB within 60 days of the review date. Unless there are extenuating circumstances,

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the protocol is withdrawn from further review at the end of the 60-day period if the Principal Investigator has not submitted a response.

When received, the IRB Chair/Designee reviews the Principal Investigator's response, including revised documents, and indicates whether the modifications have been made as requested and whether the protocol can be fully approved. The IRB Chair/Designee may continue to request additional modifications or information until the protocol is approved or referred for full board review at a convened meeting of the IRB.

IRB members are informed of all research activities approved by expedited review through the "Expedited" section of the agenda, which is distributed to all IRB members at least one week in advance of the next convened IRB meeting.

### **C. Full Board Review (Convened Meeting)**

#### **(1) Meeting Dates**

The Sunrise Health IRB meeting dates/times are determined by the end of each year for the following year. Members are informed of the meeting schedule prior to the end of the year in order to reserve the dates and times on their calendar.

#### **(2) Quorum**

Research activities that cannot be reviewed through the expedited review procedure are reviewed at a convened meeting of a quorum of the membership of the SHIRB, including at least one physician/scientist and at least one member whose primary concerns are in nonscientific areas. A *quorum* is defined as more than one-half the voting membership.

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**(3) Assigning Reviewers**

The IRB Chair/Designee reviews the agenda and list of members and assigns reviewers to each protocol. When making reviewer assignments, the IRB Chairperson takes into consideration the scientific area or discipline, the study population, and study procedures and the experience and expertise of the members. The SHIRB reserves the right to reschedule protocols for review based on the experience and expertise of the members attending the IRB meeting.

**(4) Use of Consultants [\[46.107\(f\)\]](#)**

At the time of preliminary review of a new proposal or a modification to an existing proposal, the IRB Chair, Manager of the Office of Research compliance, or a primary reviewer may request further review of the proposal by an outside consultant or ad hoc reviewer. The Manager of the Office of Research compliance, in consultation with the IRB Chair, will identify a consultant based on the particular issues to be addressed. Consultants are subject to the *Sunrise Health IRB Conflicts of Interest Policy* and must confirm in writing that they have no conflict of interest. If the consultant agrees to review the research and the consultant has no conflict of interest, s/he is would have access to all documents submitted to the IRB relevant to the specific project under review. Depending on the complexity of the issue, a short list of written questions may be submitted to the consultant, and the responses may be read or distributed to the IRB. The consultant may be invited to attend the IRB meeting, may participate at the deliberations and make recommendations on the project, but may not vote.

**(5) Distribution of Review Materials to IRB Members**

Approximately one week prior to the meeting, copies of forms and documents submitted for IRB review for each item on the agenda are distributed to all members. The IRB Chair, Vice-Chair, and each assigned reviewer receives copies of the entire submission packet and standardized instruments with which the IRB is familiar. All other members receive copies of the Application to Conduct

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Human Research, Protocol Summary, and proposed consent forms. Standardized instruments are provided to any member upon request.

**(6) Conflicts of Interest**

IRB members are subject to the *Sunrise Health IRB Conflicts of Interest Policy*. The agenda for every meeting includes a reminder about the conflicts of interest policy, and any member with a conflict of interest is asked to recuse him/herself and leave the room before the discussion and vote on the research protocol takes place, except if the member is providing information at the IRB's request prior to the discussion and vote. The names of those voting members who were recused from voting due to a conflict of interest are recorded in the Minutes. Recused members are not counted towards the quorum requirement; therefore, if a quorum of the membership is not present for the review of any protocol, action on the protocol is deferred automatically.

**(7) Discussion and Vote on Research Protocols on Agenda**

The Manager of the Office of Research Compliance takes attendance at the meeting and records voting members present and absent for each review by noting late arrivals, early departures, and individuals out of the room for one reason or another during the discussion and vote on each protocol. The IRB Chair and assigned reviewers lead the discussion of each new research protocol, continuing review, amendment or adverse event listed on the meeting agenda. At the end of the discussion, the reviewers make a motion to approve, require modifications to secure approval, defer action pending receipt of additional information, or disapprove the protocol. A vote on the motion is taken (for, against, abstain) and recorded in the Minutes. All motions are subject to majority vote of the members present for the review.

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**(8) Requirement for Investigational New Drug (IND) Number**

When the research activities direct drug (or biologic) administration, investigators are required to provide the IRB with information about the FDA status of the drug (or biologic) being used in the research.

If the drug (or biologic) is not marketed or is marketed but is being used for a different indication, the investigator must provide the IND# assigned to the drug (or biologic) by the FDA for the investigation. If the drug (or biologic) has not been assigned an IND #, the IRB may require the investigator to obtain an IND# unless the investigational use of the drug (or biologic) meets all of the following conditions:

- a. it is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;
- b. it is not intended to support a significant change in the advertising for the product;
- c. it does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
- d. it is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively];
- e. it is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]; and
- f. it does not intend to invoke 21 CFR 50.24.

**(9) Requirement for an Investigational Device Exemption (IDE)**

When the research activities involve the use of a non-FDA approved medical device or the off-label use of an FDA-approved device, investigators are required to provide the IRB with

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information about the FDA status of the medical device being used in the research.

The use of any commercially available medical device for research purposes must meet the same hospital safety standards as medical devices being used for patient care.

A medical device is defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis of disease and other medical conditions such as pregnancy.

When a medical device is being evaluated for safety and/or efficacy, the device is considered “investigational” and is subject to the requirements of the IDE regulations [21 CFR part 812]. As part of these regulations, the investigational device must be categorized as either “significant risk” (SR) or “nonsignificant risk” (NSR). The sponsor generally makes this determination; however the IRB is responsible for the final determination.

A significant risk device is defined in 21 CFR 812.3(m) as a device that presents a potential for serious risk to the health, safety, or welfare of a subject and:

- a. is intended as an implant;
- b. is used in supporting or sustaining human life;
- c. is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or
- d. otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

The risk determination is based on the proposed use of the device in the investigation, and not on the device alone. If the proposed use of the device involves a procedure, e.g., a

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surgical procedure, the IRB must consider the potential harm that could be caused by the procedure as well as the device.

The sponsor must submit an IDE application to the FDA for clinical investigations of SR devices, and the IDE# assigned to the device for the investigation must be provided to the IRB.

Studies of NSR devices may be submitted directly to the IRB with documentation supporting NSR status. If the IRB concurs that the device is NSR, the investigation may proceed when approved by the IRB. If the IRB disagrees with the sponsor and determines that the device is a SR device, the sponsor must submit an IDE application to the FDA.

All clinical investigations of medical devices are scheduled for review at a convened meeting of the IRB. As part of its review, the IRB makes the SR or NSR determination. If the IRB makes an NSR determination and the risk to the subjects is determined to be minimal in accordance with 21 CFR 56.102(i), the IRB may vote to conduct continuing review through the expedited review procedure [21 CFR 56.110].

#### **(10) Determining Frequency of Continuing Review**

When the motion is to approve or require modifications to secure approval, the motion includes the period for which IRB approval is to be granted, i.e., one year or less as appropriate to the degree of risk as defined in 45 CFR 46.103(b)(4) and 46.109(e). The duration for which IRB approval is granted is based upon the level of risk to subjects and, if applicable, the analysis of this risk as it relates to the risk of standard care. The IRB performs this risk assessment as part of the review of each protocol at the convened meeting. When the risk is great in relation to the risk associated with alternative procedures, if any, the IRB will consider requiring continuing review be conducted in less than one year, or one year

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with case-by-case reporting. Examples of protocols that may be considered for review more frequently than annually include:

1. Phase I studies of a new drug or biologic;
  - a. Studies involving Category A significant risk devices;
  - b. Studies in which healthy volunteers may undergo anesthesia or medical procedures involving sedation with no direct health benefits;
  - c. Studies for which there is little external oversight or data safety monitoring; or
  - d. Studies involving gene transfer or xenotransplantation.

**(11) Determining Which Studies Need Verification from Sources Other Than the Investigator**

Investigators are expected to provide all relevant information regarding the conduct of the research to the IRB. This system is based on trust between the investigators and the IRB. For quality assurance purposes, the IRB relies on random audits performed by the Sunrise Health Office of Research Compliance.

In order to ensure that the research is conducted in compliance with all state and federal regulations for the protection of human subjects, the IRB may require at its discretion, verification of information from sources other than the investigators. Such independent verification may be considered in the following situations:

1. Complex projects involving unusual levels or types of risk to subjects;
2. Studies being conducted by persons who have previously failed to comply with all regulations;
3. Study performance that comes in question as the result of a continuing review; or
4. Studies in which substantial segments of the project are conducted off site by collaborators, or in which Sunrise Health investigators conduct research off site.

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Independent verification of information may be requested by the IRB at convened meetings or by the IRB Chairperson in the course of carrying out reviews through the expedited review procedure. Such verification may include a directed audit by the Sunrise Health Office of Research Compliance.

As part of this independent verification, the IRB may also request and evaluate communications between the FDA, the sponsor/IND holder, NIH communication and reviews, back translations of consent forms or other materials for subjects, and letters of review or approval from other collaborating IRBs. Also, the IRB continues to rely on Data Safety Monitoring Board reports as a source of external verification.

**(12) Principal Investigator Notifications and Responses to Review**

**(13) Require modifications to secure approval**

When the IRB votes to require modifications to secure approval, the PI is notified in writing of the action voted on by the IRB and the required modifications to the research proposal. The Principal Investigator is asked to submit a point-by-point response and revised documents to the IRB within 60 days of the review date. Unless there are extenuating circumstances, the protocol is withdrawn from further review at the end of the 60-day period if the Principal Investigator has not submitted a response.

When received, the IRB Chair/Designee reviews the Principal Investigator's response, including revised documents, and indicates whether the modifications required by the IRB have been made and whether the protocol can now be fully approved. If the modifications have not been made as required, the response is scheduled for review at the next convened meeting of the IRB.

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**(14) Defer for more information**

When the IRB votes to defer action pending receipt of additional information, the Principal Investigator is notified in writing of the action voted on by the IRB and any questions and concerns that need to be addressed as well as modifications required to the research proposal. The Principal Investigator is asked to submit a point-by-point response and revised documents to the IRB within 60 days of the review date. Unless there are extenuating circumstances, the protocol is withdrawn from further review at the end of the 60-day period if the Principal Investigator has not submitted a response.

When received, the Principal Investigator's response, including revised documents, is scheduled for review at the next convened meeting of the IRB.

**(15) Disapprove**

When the IRB disapproves the research, the Principal Investigator is notified in writing of the basis for the disapproval. Disapproval means that the study as designed is inherently unethical and the IRB can think of no modifications or additional information that will likely result in an approval.

The decision of the IRB to disapprove human research cannot be overruled by any other institutional body or individual(s); however, an investigator may appeal the decision of the IRB in writing directly to the IRB Chair. The IRB Chair reviews the appeal and schedules the appeal for review at a convened meeting of the IRB.

**D. Review of Proposed Changes During Period of Approval**

Investigators are required to submit proposed changes to IRB-approved research activities to the IRB for approval prior to initiation of the change. The only exception is the rare circumstance in which a change is necessary to eliminate apparent immediate hazards to the subject. The IRB has developed a form for

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submission of proposed changes to the IRB for review. The form must be accompanied by all relevant documents revised with proposed changes highlighted.

The IRB Chair/Designee is responsible for reviewing and determining whether the proposed change (or amendment) is minor, and if minor, may approve the change through the expedited review procedures, as described previously. The IRB Chair/Designee uses a review form to document approval and provide the basis for approving the change through the expedited review procedure. Changes that are not minor are scheduled for review by the IRB at a convened meeting, as described previously.

When the IRB Chair/Designee is determining whether the proposed change is minor, s/he considers the nature of the change and whether the change alters the risks and benefits considered by the IRB at the time of initial or subsequent continuing review. The IRB Chair/Designee may request additional information from the Principal Investigator to make the determination.

IRB members are informed of all changes to ongoing research approved through the expedited review procedure by inclusion of the review in the "Expedited" section of the agenda. The expedited information lists all new and ongoing research approved through the expedited review procedure.

The investigator is notified of review as described previously. If ancillary committee review(s) is required, activation of the proposed change is subject to approval by the appropriate ancillary committee as described elsewhere in this policy.