**DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT**
**POLICY AND PROCEDURE**

| | |
|---|---|
| **SUBJECT:** Institutional Review Board: Research Reviewed by the Convened IRB | Policy #: CRP-1057 |
| | PAGE: 1<br>OF: 8 |
| **DEPARTMENT:** DHR Health Institute for Research & Development | EFFECTIVE: 03/22 |
| **APPROVED BY:** Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS) | REVIEWED/REVISED: 03/22 |

**Purpose:** Investigators involved in the conduct of human subject research that falls under the authority of the Office of Human Research Protection Program will be provided with instructions and guidelines for the submission of research studies and informed consent documents for IRB review and approval. Specific instructions are found on the Office of Human Research Protection Program webpage. The following are procedures for the IRB and investigator in processing all IRB submissions that require review by the convened IRB.

**Applies To:**
This policy applies to the following: staff and members of the Institutional Review Board; potential research investigator; Physician staff employed by RMF and its affiliates; staff employed by DHR Health and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; Physicians with privileges to practice medicine in DHR Health, Physicians and staff employed by Starr County Memorial Hospital and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; staff and physicians of non-academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; Physicians with privileges to practice medicine in Starr County Memorial Hospital and its affiliates.

**Meeting Assignment**
1. Human subject research requiring full-board IRB review and approval will be assigned by the IRB staff to the next scheduled full-board IRB meeting (i.e., subject to the availability of IRB committee members with appropriate expertise as determined by review of IRB Member Rosters). Meeting agendas will typically be limited to no more than 30 protocols with a maximum of 6 to 7 new applications. In rare circumstances, exceptions can be made to these limits by IRB staff.
2. For protocols previously voted by the IRB for reconsideration, the principal investigator of the research may request reconsideration of the research submission at the next scheduled full-board IRB meeting. The principal investigator will be invited to attend the full-board IRB meeting at which the protocol is being reconsidered.
3. Protocols previously voted by the IRB for disapproval are required to be submitted as a new protocol.

**Reviewer Assignment**
1. For initial review and subsequent reviews, studies will be assigned to primary and secondary reviewers.
2. For research involving primarily biomedical intervention(s), the primary reviewer will be a physician or health care practitioner with adequate expertise in the area of the research; and the secondary reviewer will be a scientific member of the committee.
3. For research involving primarily psychosocial interventions, the primary reviewer will be a scientific member with adequate expertise in the area of the research; and the secondary reviewer will be a scientific member of the committee.
4. For research that purposefully requires the inclusion of children with disabilities or individuals with mental disabilities and is funded by the National Institute on Disability and Rehabilitation, the protocol,

regardless of level of risk, will be reviewed by at least one individual who is primarily concerned with the welfare of these research subjects. This representative will have the appropriate scientific or scholarly expertise to serve in this capacity and will serve as either a primary or secondary reviewer. In the absence of an appropriate reviewer, the IRB will identify a consultant to serve in this role.

5. For the review of research involving prisoners by the convened IRB Committee, the following membership requirements must be met:
    a. the prisoner representative must be listed on the Committee roster as a voting member if a protocol involving prisoners is on the agenda;
    b. one or more individuals who are prisoners or prisoner representatives must be present (in person, by phone, video-conference or webinar) at the meeting during the discussion and vote of the proposed research study or the study cannot be reviewed or approved;
    c. the prisoner representative must be assigned as a reviewer on research studies involving prisoners;
    d. the prisoner representative will have access to the same materials as all Committee members as outlined under “Distribution of Materials;”
    e. the prisoner representative must present his/her review orally at the convened meeting of the IRB when research involving prisoners is reviewed;
    f. a majority of the IRB must have no association with the prison involved, apart from their membership on the IRB.

**Meeting Materials – Distribution of meeting materials**

1. The committee meeting agenda and review materials will be distributed to the IRB committee members at a minimum of two weeks prior to the scheduled IRB committee meeting.
2. The agenda indicates:
    a. the meeting date, time and location;
    b. educational topics for discussion;
    c. conflict of interest disclosure;
    d. previous meeting minutes for review and approval;
    e. previously approved exempt/expedited research proposals, full board studies and full board modifications for review;
    f. Adverse event information to be reviewed;
    g. New proposals, modifications, renewals, and other unanticipated problems.

**Review of Materials Prior to the Meeting**

1. The assigned reviewers are expected to conduct an in-depth review of all materials in advance of the meeting. Reviewers are provided with access to the IRB Reviewer Checklists as a guide to ensure inclusion of the regulatory criteria and informed consent requirements that must be met as per 45 CFR 46.111 and 21 CFR 56.111 (if applicable). In addition, assigned reviewers are expected to evaluate informed consent documents from the perspective of addressing the required and additional elements of informed consent addressed under 45 CFR 46.116, 21 CFR 50.20 (if applicable) and any other relevant ethical or compliance considerations.
2. Reviewers are expected to document concerns through the Reviewer portion of each study on IRBNet.

| | |
|---|---|
| **SUBJECT:** Institutional Review Board: Research Reviewed by the Convened IRB | Policy #: CRP-1057 |
| | PAGE: 3 OF: 8 |
| **DEPARTMENT:** DHR Health Institute for Research & Development | EFFECTIVE: 03/22 |
| **APPROVED BY:** Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS) | REVIEWED/REVISED: 03/22 |

3. Committee members who are not assigned as reviewers are expected to review the provided materials in advance of the meeting in enough depth to be familiar with the materials and prepared to discuss them at the meeting.

**Meeting Activities**

**A. Verification and Maintenance of Quorum**

1. Except when an expedited review procedure is authorized and used, the IRB will review proposed research at full board meetings at which a majority (i.e., > 50%) of the IRB members are present. A quorum will also require at least one nonscientific member.
2. In order to ensure the presence of a quorum, alternate IRB members may be requested to participate as members of an IRB committee scheduled to review proposed research. IRB minutes will indicate if the members present at the meeting is an alternate as well as the IRB member for whom the alternate is substituting.
    a. A consultant may attend the meeting to participate in the review and discussion of the research study; however, s/he may not vote or count towards quorum. His/her comments are recorded either in memo format or on a reviewer report form.
3. Quorum includes those participating in the meeting via teleconference. Members present via teleconference are noted as such in the meeting minutes. Such members must receive all pertinent information prior to the meeting and be able to actively and equally participate in all discussions.
4. The IRB Coordinator will be responsible for ensuring that quorum is maintained. If at any time during the conduct of a convened IRB committee meeting the quorum is not maintained, proceedings of the meeting will be suspended until the quorum is re-established. If quorum is not realized, the meeting will be adjourned.

**B. Conflict of Interest**

Potential conflicts of interest are assessed at every meeting. No one may serve as a reviewer if they have a conflict of interest as outlined in CRP-1009. Reviewers with a conflict of interest recuse themselves and leave the meeting while the research project in which they have a conflict is being discussed. This recusal is documented in the meeting minutes.

**C. Notification of Protocols Reviewed Via Expedited Process**

All IRB Committee members are provided with a list of protocols approved through an expedited review mechanism since the last meeting. This includes exempt and expedited submissions as well as full board studies that required a response to comments. Reviewers raising concerns about protocols approved in this manner should contact the Office of Human Research Protection Program for access to the submission.

**D. Review of Meeting Minutes from Prior Meeting**

| | |
|---|---|
| **SUBJECT:** Institutional Review Board: Research Reviewed by the Convened IRB | Policy #: CRP-1057 |
| | PAGE: 4<br>OF: 8 |
| **DEPARTMENT:** DHR Health Institute for Research & Development | EFFECTIVE: 03/22 |
| **APPROVED BY:** Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS) | REVIEWED/REVISED: 03/22 |

Before each meeting, the IRB Chair will poll the members to determine if the meeting minutes from the prior meeting are approvable as submitted or if any modifications to the prior meeting minutes are warranted. Once the meeting has been called to order, a vote will be taken for this action and documented in the minutes. The IRB Coordinator will be responsible for making any corrections to the previous minutes. If requested changes affect the correspondence that was forwarded to the principal investigator, a correction will be issued.

**E. Presentation of IRB Materials**
Each research study requiring review and approval by the full board IRB will be addressed separately at the convened meeting of the IRB committee.

The reviewer leads the discussion of the study at the IRB meeting and will provide a brief summary of the proposed research followed by:

- a presentation of significant concerns related to the research and informed consent document(s);
- recommendations regarding the risk level (i.e., minimal, greater than minimal) of the research;
- recommendations for full approval, approval subject to modifications, reconsideration, or disapproval of the conduct of the proposed research.

The secondary reviewer and non-scientific reviewers will subsequently provide any additional comments or concerns.

Following the reviewer presentations, the research protocol and informed consent document(s) will be discussed by all IRB committee members.

Pertinent comments and concerns of the IRB committee members will be recorded by the IRB Coordinator for inclusion in the minutes of the committee meeting.

**F. IRB Determinations**
At the conclusion of the primary reviewer presentations, the IRB will deliberate on the following items, which will be included in the IRB minutes.

**1. Level of Risk**
When considering risks, the IRB considers physical, psychological, social, economic and legal risks. IRB members will be polled to determine the risk level (minimal, greater than minimal) of the proposed research. The basis for this determination will be documented, with justification, in the meeting minutes.

**2. Frequency of IRB Continuing Review**

- For research studies involving greater than minimal risk or other significant human subject protection concerns, the IRB determines if continuing review is warranted on a more

frequent basis than the requisite annual review and, if so, establishes the parameters for an appropriate

| | |
|---|---|
| **SUBJECT:** Institutional Review Board: Research Reviewed by the Convened IRB | Policy #: CRP-1057 |
| | PAGE: 5 OF: 8 |
| **DEPARTMENT:** DHR Health Institute for Research & Development | EFFECTIVE: 03/22 |
| **APPROVED BY:** Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS) | REVIEWED/REVISED: 03/22 |

continuing review interval. In making this determination, the following may be taken into consideration by an IRB Committee:

- Phase I and II clinical trials involving use of an unapproved investigational drug or device
- Involvement of recombinant DNA or other types of gene transfer protocols;
- Research activities that pose a significant likelihood of a life-threatening or serious adverse event to involved subjects;
- Research where multiple adverse events have been observed during the conduct of the study
- Previously raised concerns about an investigator during an audit;
- Any other concern raised by an IRB member.

**3. New Information**

Throughout the lifespan of a research protocol, the IRB may determine that currently enrolled subjects need to be notified of new information or significant new findings that alter the risk benefit ratio and may affect their willingness to continue study participation. New information may be presented to research participants via an addendum consent form or a modified consent form.

**4. Verification from Other Sources**

Protecting the rights and welfare of participants sometimes requires that the IRB verify independently, utilizing sources other than the investigator, that no material changes occur during the IRB designated approval period.

Criteria for determining if verification is required will include, but not be limited to:

- Complex protocols involving unusual levels or types of risks to subjects;
- Protocols conducted by investigators who previously have failed to comply with Federal regulations or the requirements or determinations of the IRB;
- Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.

**5. Monitoring of Informed Consent**

For research determined to be of greater than minimal risk or if potential conflict-of-interest or coercion concerns exist, the IRB members may request that random monitoring of the informed consent process be undertaken by the Office of Human Research Protection Program.

**6. Possible IRB Committee Actions for Research Studies**

The following are actions that may be taken by the IRB during the review of protocol submissions:

- require that a study be submitted for continuing review at an interval less than annually;
- request an audit of the informed consent process;
- request a complete audit of the study;

- request that the investigator appear before the Committee to provide information related to the submission;
- request review of a federally funded research study by the Secretary, DHHS if designated for approval under 45 CFR 46.407 (Subpart D – Additional Protections for Research Involving Children). If the study is not federally funded, review by an independent expert panel will be sought; request review of a federally funded research study by the Secretary, DHHS if designated for approval under 45 CFR 46.207 (Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates involved in research). If a study is not federally funded, review by an independent expert panel will be sought;
- terminate or suspend any or all research activities or approval of the research study.

When terminating or suspending some or all research activities, the IRB will consider what additional actions the principal investigator or institution should take in order to protect the rights and welfare of current human subjects. These additional actions may include but are not limited to:

- Transferring the human subjects to another research study (i.e., based on equivalent inclusion/exclusion criteria);
- Making arrangements for clinical care outside the research;
- Allowing continuation of some research activities under the supervision of an independent monitor;
- Requiring or permitting follow-up of the human subjects for safety reasons;
- Requiring adverse events or outcomes to be reported to the IRB and the sponsor;
- Notifying current and/or former human subjects of the IRB's decision to terminate or suspend the research study;
- Recommending suspension of the PI's privileges to serve as a PI or requiring a replacement of the PI for the research study in question.

**G. Types of Motions**

Based on its review of initial or ongoing review of research, the IRB decides to approve, reconsider, disapprove or stipulates specific modifications of the proposed research and/or consent document(s) as required to secure IRB approval of the research. Following is a brief description of each of the possible motions.

- Full Approval: No changes to the research or informed consent document(s) required. The investigator may initiate the research immediately upon receipt of the written notification of full approval to conduct the research.
- Approval Subject to Modifications: Conduct of the research can be granted full approval by the IRB Chair or Co-Chair pending principal investigator (PI) concurrence with specific revisions stipulated by the IRB with directive comments. The PI may not initiate the research until such time that s/he has modified the research protocol and/or informed consent document(s) to comply with the specific revisions stipulated by the IRB; such revisions have been reviewed and approved by the IRB Chair or IRB Co-Chair; and the principal investigator has received written notification of full approval to conduct the research.
-

- Reconsideration: Approval to conduct the research requires substantive clarifications or modifications of the research design or procedures or substantive revisions of the informed consent document(s). The PI must respond to the identified concerns, clarifications, modifications or revisions and resubmit the revised research and/or informed consent document(s) for full-board IRB review.
- Disapproval: The proposed research has fundamental design problems and/or presents significant ethical or safety concerns to involved human subjects. The PI must undertake a major revision of the research before it can be resubmitted for full-board IRB review.
- Tabled: Insufficient information is available to review the proposed research in an adequate manner. The PI must provide this information before it can be resubmitted for full-board IRB review. The proposed research may also be tabled due to loss of quorum or lack of appropriate expertise present at the meeting.

**H. Call for Vote**

Following open discussion of the above applicable referenced items, the IRB Chair or Co-Chair will call for a vote of the committee to grant full approval, approval subject to modifications, reconsideration, or disapproval of the proposed research.

- IRB members in attendance at the full meeting, but absent from the meeting during the discussion of the research protocol and the vote will not be counted in the committee vote.
- The absence of members due to a conflict (i.e., a listed investigator, financial or other conflict) during the discussion of the research protocol and the vote will be documented in the minutes of the full board IRB meeting to include the reason for their absence (e.g., listed investigator on research study under consideration, financial interest in sponsor of the research or the technology being evaluated).
- IRB members who provide written comments regarding the proposed research and informed consent documents, but who are not present at the meeting, will not be counted in the committee vote.
- The vote of the majority of the IRB members present at the meeting will determine the final approval status (i.e., full approval, approval subject to modifications, reconsideration, disapproval) of the conduct of the proposed research.

**Meeting Minutes**

**A. Attendance**

The minutes of the IRB meetings will specify the members of the committee who were present at the meeting; members who were absent, but provided written comments. IRB staff (i.e., not serving as members of the committee), consultants to the committee, and guests will be listed separately.

**B. Protocol Specific Information**

Each research submission reviewed by the IRB will be listed separately by IRB number, principal investigator name, and protocol title. For each research submission, the minutes address:

- the action (i.e., full approval, approval subject to modifications, reconsideration, disapproval) taken by the committee and the corresponding numerical vote;

| | |
|---|---|
| **SUBJECT:** Institutional Review Board: Research Reviewed by the Convened IRB | Policy #: CRP-1057 |
| | PAGE: 8<br>OF: 8 |
| **DEPARTMENT:** DHR Health Institute for Research & Development | EFFECTIVE: 03/22 |
| **APPROVED BY:** Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS) | REVIEWED/REVISED: 03/22 |

- Documentation of the numerical vote will address the number of IRB members voting for or against the action taken by the committee; the number of IRB members abstaining from the vote; and any IRB members listed as being present at the committee meeting, but who were recused during the discussion of the research submission and subsequent vote. The vote will be reflected as the number for the action, the number against the action and abstentions (e.g., 13 members for the action; 0 members against the action; 1 abstention).
- the risk level of the research as determined by the committee;
- the IRB approval interval designated by the committee;
- pertinent comments and concerns of the primary IRB reviewers and pertinent comments and concerns expressed during open discussion of the research submission, to include significant new
- findings to be communicated to research subjects and a summary of controverted issues and their resolution (when the IRB reached consensus).
    - In order to ensure that human subject protection issues are fully addressed at the IRB meeting, many times housekeeping problems (i.e., grammatical and typographical errors) are not presented for committee discussion. However, in preparing the meeting minutes, which are used directly to generate IRB response letters to the involved investigators, these housekeeping problems are included; especially as they relate to the consent form and ensuring its understanding by potential research subjects.

**C. Additional Documentation Requirements**

- Reconsideration or Disapproval of Protocols- for research submissions voted for reconsideration or disapproval, the following information should be recorded in the minutes:
    - a summary of the primary reason(s) for such determination by the full-board IRB;
    - where applicable (i.e., wherein there was a vote for reconsideration or disapproval in the face of majority vote for approval), a summary of the unresolved controverted issues.
- Regulatory Forms - the research review coordinator will ensure that all criteria outlined on the regulatory forms are included in the meeting minutes.

**D. Approval and Utilization of Minutes**

Minutes of the IRB committee meeting will be reviewed and accepted by the IRB Chair. Following their acceptance by the IRB Chair, the minutes of the IRB committee meeting will be directly used to generate written notifications of IRB decisions regarding the approval status of the research submission for dissemination to the listed principal investigator.

The minutes of the IRB committee meeting will be included with the materials prepared for review at the next convened meeting of the IRB committee, and will be voted for approval at the convened meeting. The minutes will be modified as necessary to obtain approval of the IRB committee. If modifications to the minutes affect the approval status of a research study, the Principal Investigator will be notified.

The Institutional Official has access to all approved IRB minutes through the IRBNet system, including a listing of research studies granted final approval by the IRB.