DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Institutional Review Board: General Procedures	Policy #: CRP-1056
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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 general procedures for the IRB in processing all IRB submissions.

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.

Verification of Training Requirements
All investigators and key personnel involved in Human Subject Research (including faculty mentors) are required to complete specific research ethic courses using the CITI training program (see CRP-1006). Only those individuals who have completed the required training are permitted to conduct human subject research. At a minimum, all users must complete courses in Human Subjects Research – Biomedical Research and Conflict of Interest. Depending on the nature of a study, other courses may be required. The CITI program can be access through www.citiprogram.org

Calculation of Approval Dates
The IRB calculates the date of initial IRB approval in the following manner:

- When a research study is approved at a convened meeting, the date of the convened meeting is the date of IRB approval.
- When the research study is approved subject to modifications at a convened meeting, the date of the IRB approval is the date that the requested changes are verified by the Chair, Co-Chair or assigned expedited reviewers.
- When a research study is reviewed and approved through an expedited review process, the date of IRB approval is the date that the primary and secondary reviewers have both reviewed and indicated their approval.

Calculation of Expiration Date
The IRB calculates the date of expiration in the following manner:

- When a research study is fully approved at a convened meeting, the date of expiration is based on the date of the convened meeting (minus one day).

- When a research study is approved subject to modifications, the date of expiration is one year from the date of the convened meeting (minus one day). It is not calculated from the date that the Chair, Co-Chair or IRB staff verifies the requested changes and grants final approval.
- When a research study is reviewed and approved by expedited review, continuing review is not required unless the IRB and Office of Human Research Protection Program staff documents a reason why a submission would be necessary.

The approval period expires at 11:59 p.m. on the expiration date set forth in the IRB approval letter.

Amendment dates
The IRB calculates the date of amendment approval in the following manner:

- When an amendment is approved through an expedited review mechanism, the amendment approval date is the date that the Primary and Secondary reviewers have both reviewed and indicated their approval of the amendment.
- When an amendment is reviewed at a full board meeting and is approved at the meeting, the amendment approval date is the date of the IRB meeting.
- When an amendment is reviewed at a full board meeting and is approved subject to modifications, the amendment approval date is the date that the response is verified by the Chair, Co-Chair or IRB staff.

Expiration dates for amendments are maintained as the date assigned upon initial or continuing review unless the IRB determines that there has been a significant change to the risk/benefit ratio which would require a more frequent continuing review. If this change occurs, the IRB will notify the principal investigator of the study of the new expiration date. The new date must never exceed the original expiration date. In the event that a study was approved with no requirement for continuing review and a determination is made to require resubmission, the date will be one year from the approval of the amendment.

New Information
Throughout the life span of a research protocol, the Institutional Review Board may determine that currently enrolled subjects need to be notified of new information or significant 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 or a modified consent form.

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 includes, but is not limited to:

- Complex protocols involving unusual levels or types of risk to subjects;
- Protocols conducted by PIs 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.

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Investigator Communications

Initial comments from the IRB – General Information

The principal investigator will be notified, in writing, of the IRB's decision to approve, reconsider (defer), or disapprove the proposed research, or of the modifications required to secure IRB approval of the research study. Correspondence will contain, at a minimum:

- the name of the principal investigator;
- the title of the project;
- the IRB number assigned to the submission;
- the decision of the IRB.

Full Board Decisions

The IRB full board decisions will be outlined in the investigator communications as follows:

- Full approval – if a convened IRB determines that the study can be approved as submitted, the investigator will be issued a full approval letter.
- Approved with conditions – if the IRB decided to approve a research study subject to modifications, the written notification will include the specific revisions stipulated by the IRB in order to obtain full approval to conduct the research.
    - The written notification provides instruction to the investigators to revise the research and informed consent document(s) in accordance with the specific revisions stipulated by the IRB and to resubmit for final IRB approval.
- Tabled without action – if the IRB decides there is not sufficient information submitted for a research activity to thoroughly review and confirm that all regulatory criteria for approval are met, the research activity will be tabled without action for review at a later date when all information is available. A written notification provides instruction to the investigators will be sent to state that additional information is required before IRB review can commence.
- Disapproval - If a convened IRB decides to disapprove a research activity, the written notification to the investigator will include:
    - a statement of the primary reason(s) for the IRB's decision to reconsider the research;
    - a listing of additional problems and/or deficiencies identified by the IRB;
    - instructions relating to resubmission of the research for full-board IRB review, including statements that the principal investigator should address in writing the comments and concerns of the first IRB review and that s/he may appear in person to address additional questions or concerns related to full-board IRB review of the resubmitted protocol.

Exempt/Expedited Submissions

Submissions that are reviewed by the Exempt/Expedited reviewers can either receive full approval or approval subject to minor modifications. In the event that the study does not meet a regulatory category which would permit an exempt/expedited review, the IRB Coordinator will document the reason for this determination and the investigator will be notified that the study will be assigned for review by the convened IRB.

Investigator Responses
Responses of the principal investigator are returned to the IRB reviewer(s) who conducted the initial review (i.e., or to another IRB reviewer if the initial reviewer will be unavailable for an extended period) for final approval.

In the event of a failure to resolve problems or concerns related to the investigator's response(s), the IRB submission (to include prior correspondence between the IRB reviewer and investigator) will be reviewed at a convened meeting of an IRB committee (i.e., full-board IRB review).

Response Deadline
The communication to the principal investigator specifies that s/he must respond to the comments or concerns of the IRB reviewer within 4 weeks of the date of the communication, and that failure to respond within this 4-week period may result in withdrawal of the project by the IRB.

Content of IRB Concurrence/Approval
The principal investigator is notified of IRB concurrence/approval through written correspondence prepared and discharged by the ORHPP staff. All correspondence contains:

- the name of the principal investigator;
- the title of the project;
- the IRB number assigned to the submission;
- the date of IRB approval/concurrence;
- the date of IRB expiration (if continuing review is required) the date of IRB modifications (for modification requests only);
- a statement that modifications to the IRB approved research study will require either notification to the IRB (for no human subjects research or exempt determinations) or approval by the IRB (for expedited or full board studies).

For studies that are designated as "not human subject research" the correspondence will indicate a concurrence that the project does not meet either the definition of "research" at 45 CFR 46.102(l) or "clinical investigation" at 21 CFR 56.102(c), or the definition of "human subject" at 45 CFR 46.102(e)(1) or 21 CFR 56.102(e).

For activities determined by the IRB Reviewer to meet either the DHHS or FDA definition of "human subject research," the principal investigator will be advised to resubmit the project for exempt, expedited or full-board IRB review as appropriate.

For studies that are designated as "exempt" the correspondence includes the basis for granting exempt status (i.e., 45 CFR 46.104(d)(1-6) and/or 21 CFR 56.104(d)). For research activities that involve human subjects but are determined to not qualify for exempt status, the principal investigator will be advised to resubmit the research for expedited or full-board IRB review as appropriate.

For studies that are approved as "expedited" the correspondence includes the basis for granting expedited approval of the research. This would not only include the minimal risk status of the

research, but the applicable category or categories of research activities listed in the OHRP and FDA document, "Categories of Research That May Be Reviewed by the Institutional Review Board through an Expedited Review Procedure". That information is documented, with justification, within the IRB Research Protocol and/or review materials. For research activities that are determined to not qualify for expedited review status, the study will be assigned to the next available convened IRB agenda with appropriate expertise.

Continuing Review Reminder Notices
For IRB approved studies that require continuing review the following procedures will be utilized.

For projects approved in the IRBNet, the system automatically generates an e-mail notification to the principal investigator and, if applicable, the study coordinator 60 and 30 days in advance of the expiration date of the IRB.

For projects that do not require continuing review, the system will send an automated message on the anniversary of the approval date reminding investigators to continue to submit Reportable Events, Amendments, and a final report when the study is complete.

Study Expiration
If the study that requires continuing review is not reviewed and approved by the IRB prior to the expiration date of the previous IRB approval, the principal investigator will be required to cease all research activities described in the IRB protocol (including data analysis) until notification of final IRB approval for continuation of the research has been issued. The approval period expires at 11:59 p.m. on the date set forth in the IRB approval letter. The notification sent to the investigator will indicate that: 1) enrollment of new participants must stop; 2) all research activities must stop; and 3) any continuation of research activity is a violation of Federal regulations. The letter also indicates that the investigator may petition the IRB Chair for permission to continue certain research activities if there is an overriding safety concern or ethical issue. However, under no circumstances can new subjects be enrolled into a research study after expiration of IRB approval. In order to preserve the historical integrity of a research study, investigators who want to continue research activities must submit a continuing review to the IRB. Research activities may not resume until a new IRB approval has been issued.