DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Institutional Review Board: Expedited Research	Policy #: CRP-1059
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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 procedures for the IRB and investigator in processing all IRB submissions that qualify for expedited review including but not limited to: initial IRB review, modifications/amendments, continuing review, continuing review with modifications.

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.

Reviewer Designation
Research studies submitted for "expedited" review status are reviewed by the IRB members assigned as expedited reviewers for the month. The IRB Expedited Reviewer Scheduled is drafted by the IRB Coordinator and approved by the convened IRB. Each month consists of a primary reviewer and a secondary reviewer.

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 will be reviewed by at least one individual who is primarily concerned with the welfare of these research subjects and who has the appropriate scientific or scholarly expertise to serve in this capacity. In the absence of an appropriate reviewer, the IRB will identify a consultant to serve in this role. This will be documented on the minutes by the IRB Coordinator.

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No one may serve as a reviewer if they have a conflict of interest as outlined in CRP-1009.

Provision of Review Materials
The IRB Reviewer has access to the complete IRB submission including the following (as applicable):

- IRBNet protocol application;
- Renewal Report Form;
- Investigator- or sponsor-provided protocol informed consent documents;
- Recruitment materials (e.g., advertisements, flyers, phone screening procedures, scripts, and/or screening questions, etc.);
- Measures that will be utilized in the study (e.g. survey instruments, questionnaires, interview scripts, recruitment material, etc.

- Confirmation of scientific review;
- Grant application;
- Other materials specific to the proposed study (e.g. Investigator's Brochure or relevant investigator correspondence with regulatory agencies. etc.) .

IRB reviewers are expected to conduct an in-depth review of all materials and are provided access to Reviewer Checklists found in IRBNet 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/or 21 CFR 56.111. 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(if applicable).

The IRB reviewer completes applicable documentation forms to ensure that all regulatory issues are addressed as part of the review.

Categories of Expedited Review
The IRB reviewer determines whether the proposed research qualifies for expedited review in accordance with the "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure" as published by the OHRP, 45 CFR 46.110 and FDA 21 CFR 56.110.

Initial expedited review is not applicable to research studies where the subjects are known to be prisoners.

Minor modifications that would not materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims of the study are eligible for expedited review. Modifications that do not meet this definition will be reviewed at a convened meeting. Examples of minor modifications may include:

- the addition of research activities that meet expedited criteria under 45 CFR 46.110 or 21 CFR 56.110;
- an increase or decrease in proposed human research subject enrollment supported by a statistical justification;
- narrowing the range of inclusion criteria;
- broadening the range of exclusion criteria;
- alterations in the dosage form (e.g., tablet to capsule or oral liquid) of an administered drug, provided the dose and route of administration remain constant;
- decreasing the number or volume of biological sample collections, provided that such a change does not affect the collection of information related to safety evaluations;
- an increase in the length of confinement or number of study visits for the purpose of increased safety monitoring;
- a decrease in the length of confinement or number of study visits, provided that such a decrease does not affect the collection of information related to safety evaluations;
- alternations in human research subject payment or liberalization of the payment schedule with proper justification;

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- changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement;
- the addition or deletion of study sites;
- minor changes specifically requested by the IRB, Human Use Subcommittee, Radiation Safety Committee, Radioactive Drug Research Committee, or Clinical and Translational Research Center.

Review of Grant Application
For Federally-supported research, the IRB reviewer ensures that the research application is essentially consistent with the grant application. This determination is documented as a note in IRBNet.

Investigator Communications
Comments or concerns of the IRB reviewer are documented in IRBNet and provided to the investigator. This is done through IRBNet via issuance of a stipulations letter to the investigator.

Responses of the principal investigator are reviewed by the IRB reviewer who conducted the expedited review (or to another non-conflicted IRB reviewer if the initial reviewer is unavailable for an extended time).

In the event of a failure to resolve problems or concerns related to the investigator's response(s), the IRB submission (including 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).

- Expedited reviewers cannot disapprove an IRB submission or modification. In the event that an expedited reviewer cannot make a determination, the study will be referred to a convened meeting for discussion by a committee.

Documentation of Determination
After reviewing the protocol submission, the IRB reviewer documents his/her determination in IRBNet. Once all of the issues are appropriately addressed final expedited approval of the research study and corresponding informed consent document(s) is granted. If an IRB submission is determined to not meet the criteria for an expedited review, the principal investigator will be advised by the IRB that the submission has been referred for full-board IRB review.

Basis for Approval
The minimal risk status of the research and the applicable category or categories of research activities listed "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure" will be documented, with justification, within the IRB Research Protocol and/or review materials.

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Expedited Approval Notification
The principal investigator is notified of IRB approval for initial or continuing review via an electronic letter sent from IRBNet. This letter specifies, at a minimum:

- The IRB number assigned to the submission
- The basis for granting expedited review and approval, including identification of the applicable category or categories
- the date of IRB approval and the date the IRB approval expires

Studies originally reviewed via full board meeting
For renewals or modification, the IRB reviewer determines if research that was initially approved by the full-board IRB, may now qualify for expedited review. This determination is made based on the risk level or status of the research and in accordance with the "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure."

Studies originally approved via expedited review
For renewals or modifications, IRB protocols originally approved by the expedited process are re-evaluated to ensure that the submission continues to qualify for expedited review as specified in "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure." If the research no longer meets these requirements, it will be forwarded for review by a convened IRB Committee and the principal investigator so informed.

New Information and Significant New Findings
The IRB reviewer evaluates whether any new information/significant new findings obtained during continuing review should be provided to subjects when this information might relate to the subjects' willingness to continue to take part in the research.