DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Institutional Review Board: Exempt Research	Policy #: CRP-1058
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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 as exempt research activities.

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.

Investigator Responsibilities
Requests for exemption must be submitted through the IRBNet system. Investigators are required to answer questions about the proposed project which allows the IRB to evaluate the protection of human subjects participating in the exempt project, including information about risk to subjects, subject selection, and provisions for protecting the privacy interests of subjects and the confidentiality of subject data. While the informed consent process and documentation are not required to be reviewed as part of this screening, the applicable exempt forms remind researchers of their ethical obligations to ensure that participants are fully informed about the nature of the research project so they can make an informed decision to participate. When appropriate, investigators are required to develop an introductory script that describes the study requirements, indicates that it is research, and indicates that participation is voluntary.

IRB Reviewer Designation
Research specified by the investigator as qualifying for “exempt” status is reviewed by the IRB Chairman or Vice-Chairman. IRB reviewers are expected to conduct an in depth review of all materials. No one may serve as a reviewer if they have a conflict of interest.

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

- IRBNet protocol application;
- 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.

- grant application (if applicable);
- verification of approval from site(s) outside of DHR Health;
- Other materials specific to the proposed study.

Criteria for Exemption
The IRB reviewer determines if the proposed research is exempt from federal policies governing human subject protections. This determination is made in accordance with:

- The OHRP Decision Chart # 2- "Is the Research Involving Human Subjects Eligible for Exemption under 45 CFR 46.104(d)?"
- The criteria for exemption as specified under 45 CFR 46.104 (d)(1), (d)(2), (d)(3), and (d)(4) and 21 CFR 56.104(c) and (d). If an investigator wishes to request an exemption under 45 CFR 46.104(d)(5) or (d)(6), s/he is instructed to contact the HRPO for guidance. The criteria for exemption under 45 CFR 46.104(d)(7) and (d)(8) will not be utilized as the concept of broad consent is not be implemented at this time.
- If subjects are under the age of 18 years, the exemption criteria described in 45 CFR 46.104(d)(2)(i) and (ii), are not applicable with the exception of research limited to (a) the use of educational tests or (b) to observations of public behavior when the investigator does not participate in the activities being observed. For studies subject to the Department of Defense (DoD) regulations, no exemptions may be applied when children are involved as participants.
- For protocols that meet the criteria for an exemption under 45 CFR 46.104(d)(2), investigators are required to provide an introductory script that includes key elements of consent and is consistent with the principles of the Belmont Report.
    - NOTE: The exemption criteria in 45 CFR 46.104(d) do not apply to studies involving prisoners except for research aimed at involving a broader subject population that only incidentally includes prisoners.
    - The exemption criteria [with the exception of 45 CFR 46.104(d)(6) / 21 CFR 56.104(d)]do not apply to FDA-regulated research studies.

Investigator Communications
Comments or concerns of the IRB reviewer with regard to the exempt status of the research activity are documented and communicated in IRBNet to the principal investigator.

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

Documentation of Determination
After reviewing the protocol submission, the IRB reviewer documents his/her determination in IRBNet.

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Exempt Determination Notification
The principal investigator of the research activity is notified of IRB concurrence of exempt status through IRBNet. This notification letter specifies, at a minimum:

- The IRB number assigned to the submission;
- The regulatory basis for granting exempt status (i.e., 45 CFR 46.104 (d) (1-6) and/or 21 CFR 56.104(d));

Determination that Activity Does NOT Meet the Exempt Criteria
For research activities that involve human subjects but are determined to not qualify for exempt status, the principal investigator is advised to revise the submission for expedited or full-board IRB review.

Waiver of HIPAA Authorization and Exempt Review
The IRB may grant a waiver of HIPAA Authorization for an exempt project if the recording of medical information will be conducted by or under the oversight of an investigator who would normally have access to this information by virtue of his/her patient care responsibilities.

Frequency of Review
Protocols designated as exempt are not required to be submitted for continuing review. Amendments to exempt protocols are required to be reported to the IRB prior to initiation to confirm protocol continues to qualify for exempt status.