DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Institutional Review Board Committee Membership	Policy #: CRP-1043
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DEPARTMENT: DHR Health Institute for Research & Development	
	EFFECTIVE: 02/19
APPROVED BY: Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS)	REVIEWED/REVISED: 02/19, 02/20, 11/20, 01/21, 04/21, 05/21, 03/22

Purpose: The purpose of this policy is to describe DHR Health Institute for Research and Development Institutional Review Board Committee Membership according to 46 CFR 46.107 and member responsibilities.

Applies To:
This policy applies to the following 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.

Composition of the Institutional Review Board (IRB):

1. The IRB Committee will be comprised of at least five members, with varying background and expertise to provide complete and thorough review of research activities commonly conducted by the Institution.
2. The membership of the IRB will be sufficiently qualified through the experience and expertise of its members and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human research subjects.
3. The IRB committee includes members of more than one profession.
4. The IRB committee includes at least one member who represents the perspective of research participants.
5. The IRB committee includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.
6. The IRB committee includes at least one member who is not otherwise affiliated with the institution, and who is not part of the immediate family of a person with such affiliation (i.e., “unaffiliated member”). Affiliated members include but are not limited to individuals who are: part-time employees; members of any governing panel or board of the institution of DHR Health system; paid or unpaid consultants; healthcare providers holding credentials to practice at DHR Health; and volunteers working at the institution on business unrelated to the IRB.
7. Regardless of the risk level associated with the protocol, research funded by the National Institute on Disability, Independent Living, and Rehabilitation Research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities 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.

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Alternates:
The Office of Human Research Protection Program (HRPP) at DHR Health Institute for Research and Development roster of trained alternates who may be invited vote in place of an absent voting member.

1. The alternate member will have similar expertise as the regular committee member for whom s/he is serving as a replacement (physician to physician; other scientific to other scientific; and non-scientific to non-scientific).
2. The alternate member will assume all of the responsibilities of the committee member for whom s/he is serving as a replacement.

3. Alternate members may attend IRB meetings without serving as a replacement for a regular committee member; however, in this capacity, the alternate member may not participate in any of the final approval decisions of the committee.
4. IRB minutes will document if a member present at the meeting is an alternate as well as the IRB member for whom the alternate is substituting.

Consultants:
During initial review of a proposed research study, an IRB committee member or a HRPP staff member may determine that the current membership of the IRB does not include appropriate expertise to conduct an adequate study evaluation and may invite individuals with competence in special areas to assist in the review.

1. Consultants may be chosen from past IRB members or by contacting the department chair or division chief (or their designee) of the area from which the research is being submitted.
2. Consultants will be provided with a copy of the IRB protocol and consent document as well as any attachments (investigator brochures, multicenter protocols, etc.) prior to the IRB meeting.
3. Consultants are held to the same standards as regular members of the IRB Committee.
4. Consultants 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.
5. If the consultant is unable to attend the meeting, his/her written comments will be taken into consideration by the Committee during its review of the respective research protocol and will be documented in the IRB meeting minutes.

Appointment of IRB Members
Appointments of voting IRB Committee members are made by the Institutional Official (IO) and the DHR Health Institute for Research and Development Board of Directors. Recommendations for members can be made to the IO by either the IRB Chair or Vice Chair based on the specific needs of the IRB Committee.

1. The IRB Chair or his designee requests recommendations for volunteers to serve on the IRB on an as needed basis to fulfill required committee composition; expertise and experience; knowledge of the individual's interest; recommendations of institutional leadership; and/or investigators involved in research studies currently or previously approved by the IRB.
2. The IRB Chair or his designee reviews the membership rosters and recommends appointment by the Institutional Official of potential non-scientific and/or non-affiliated members to the IRB based on considerations including, but not limited to: required committee composition, expertise and experience,

knowledge of the individual's interest, recommendations of current or past non-scientific and/or non-affiliated members, and individuals recruited from disease-related organizations or groups.

3. The IRB Chair will review each new member's CV and demographic sheet for educational background, work history, as well as his/her current vocation to determine the member's status (i.e., scientific versus non-scientific, affiliated vs. non-affiliated) on the IRB rosters.
4. A individual cannot be appointed a voting IRB committee member or be involved in the day-today operations of the review process if at any time it is determined they are responsible for business developments of DHR Health Institute for Research and Development, DHR Health, or RMF or if it is reported/determined they own equity in the organization.

Term of Service

Committee members are initially appointed to a term of two years minimum and a maximum term of three years. Committee members may be requested to accept reappointment to the IRB for an additional term of two years at the discretion of the Chair. Reappointed members will be asked for an updated CV.

Responsibilities of IRB Members

General responsibilities of all IRB Members include:

- Reviewing research study proposals and evaluating them from the perspective of the regulatory criteria for approval addressed under 45 CFR 46.111, 21 CFR 56.111 (if applicable); and any other relevant ethical, scientific or compliance considerations;
- Reviewing informed consent documents and evaluating them 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;
- Attending at least 70% of IRB meetings in person, unless exigent circumstances prevent such attendance on an occasional basis, reporting promptly at the designated time that the meeting convenes; and remaining in attendance at the meeting until the full agenda has been addressed;
- Participating in IRB deliberations concerning issues inherent to proposed research studies and related informed consent documents, and making recommendations for reducing risk and improving the informed consent process and otherwise for improving human subject protections;
- Voting for full approval, approval subject to modification(s), reconsideration, or disapproval of the human subject research
- Evaluating the risk level (i.e., minimal or greater than minimal) of the proposed research. In performing this evaluation, IRB members will use the following absolute definition for "minimal risk" at 45 CFR 46.102(i) unless the research is directed at prisoner-subjects:
  "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 (i.e., of the general population) or during the performance of routine physical or psychological examinations or tests."
- Deciding, for research studies of greater than minimal risk, if IRB continuing review of the research is warranted on a more frequent basis than the requisite annual review;
- Deciding, for research studies involving an unapproved device, if the device and its proposed use constitute a non-significant or significant risk to research subjects;

- Deciding, for research studies subject to IRB continuation approval, if verification is required from sources other than the investigator that no material changes have occurred since previous IRB review;

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- Recommending improvements to IRB policies and procedures so as to enhance the IRB review process and/or human subject protections;
- Informing the IRB Chair or Co-Chair of human subject research noncompliance problems or ethical issues of which they become aware;
- Conforming, at all times, their behavior to be within legal and ethical principles accepted by the IRB; including, but not limited to, maintaining confidentiality/non-
- disclosure of human subject research submitted for IRB review and approval, and good faith participation in IRB deliberations without appearance of discrimination or conflict-of-interest.

Responsibilities of IRB Members Designated Reviewers
In addition to the responsibilities outlined above, responsibilities of those assigned as reviewers include:

- Providing written evaluations of the research protocol and informed consent document(s) to the HRPP staff in advance of the IRB meeting;
- Utilizing the IRB Reviewer Checklist as a guide when reviewing protocol submissions;
- Basing their review and approval decisions for industry-sponsored clinical trials on the information presented in the sponsor's clinical protocol and investigator's brochure and IRB research application.

Resignation and Termination of IRB Members
Resignation of IRB membership status, based on the wishes of the IRB member, will be submitted, in writing, to the Institutional Official and copied to the IRB Chair.

IRB Membership status may be terminated by the IRB Chair due to failure to attend and/or otherwise actively participate in IRB functions. Termination of any individual from IRB membership will be reported to the Institutional Official to include a written justification for the termination.