DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: IRB Recordkeeping and Retention	Policy #: CRP-1047
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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

Purpose:
The Office of Human Research Protection Program (OHRPP) is responsible for maintaining records related to the functions and activities of the IRB.

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.

IRB Membership Records:
The OHRPP maintains a database of IRB committee members. This information will be utilized in formulating the roster for OHRP.

Changes in IRB committee membership will be reported to OHRP in a timely manner by the Human Research Protection Program Administrator.

Research Submissions:
OHRPP will maintain records of all research submitted for IRB review and approval.

Electronic records will be maintained within the IRBNet system. Submissions will be retained for a period of at least three years beyond the termination date regardless of whether subjects were enrolled.

No Human Subjects Research Designation/Exempt Submissions:
For projects determined by the IRB to qualify for a no human subject research designation or exempt status the IRB record will contain the applicable application form, all investigator-IRB correspondence related to the submission and the letter of exempt concurrence.

Expedited or Full Board Submissions:
For research submitted for expedited or full board review, the IRB record contains:

- the initial research application;
- the approved informed consent document (if applicable);
- the initial IRB approval letter;

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- modification requests and the applicable IRB approval letter;
- continuing review requests and the applicable IRB approval letter;
- for multicenter studies, the sponsor's protocol;
- for studies involving an investigational drug or device, the investigational drug brochure;
- for federally funded studies, the federal grant application;
- for investigator-initiated studies involving a drug or device, all correspondence with the FDA including the IND or IDE application and any other pertinent documentation;
- any reports of unanticipated problems involving risks to human subjects or others (including adverse events) encountered in the conduct of the research;
- advertisement used to recruit potential subjects as well as screening scripts;
- non-standard measures;
- all correspondence between the investigator/research team and the IRB;
- documentation of actions taken in response to unanticipated problems involving risks to human subjects or others and/or identified non-compliance and the corresponding responses of investigators.

Research files are maintained by the OHRPP until three years following termination of IRB approval of the research (21 years for research involving children). Following the required maintenance interval, research files will be shredded.

IRB Minutes:
The agendas and minutes of full-board IRB meetings will be maintained indefinitely with the OHRPP.

Research Subject Complaints:
OHRPP maintains files of research subject complaints and the actions taken by OHRPP staff, the IRB committee, or investigators to resolve such complaints. Such files are maintained until 3 years following termination of IRB approval of the research study.

Reportable Events:
Reportable events are submitted by the principal investigator through IRBNet and are maintained for at least three years following termination of IRB approval of the research study.

Emergency Use Reports:
Emergency Use requests are submitted by the requesting physician through IRBNet. Records pertaining to emergency use requests will be maintained in IRBNet for an indefinite period of time.

Inspections by Authorized Representatives:
IRB records are accessible for inspection and copying by authorized representatives.