DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Subject Recruitment and Screening	Policy #: CRP-1032
	PAGE: 1 OF: 4
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 recruitment phase of a clinical study is frequently difficult and challenging. Successfully recruiting subjects involves the development and implementation of a well- coordinated plan that may require the efforts of the entire research team and designated staff of the DHR Health Institute for Research & Development. Once in place, subject recruitment efforts must be constantly assessed, with new strategies implemented as necessary. After potential subjects have been identified through recruitment efforts, the process of subject selection begins. This policy describes the steps for fulfilling the regulatory and clinical requirements involved in subject recruitment and selection.

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.

Definition:
The following definitions apply to this policy.

A. **Informed Consent:** A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.
B. **Subject/Trial Subject**: An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.
C. **Vulnerable Subjects:** Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. Vulnerable populations also include in accordance to 45 CFR 46 and 21 CFR 56, children, pregnant women and fetuses, and prisoners.

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Policy:
Investigators and study coordinator will develop and monitor a subject recruitment plan for trials regulated by the Food and Drug Administration (FDA). Subject screening activities will be recorded and maintained.

Procedure:

A. Develop and implement an overall recruitment plan

• Designated staff of the DHR Health Institute for Research & Development • Clinical Research Coordinator	Based upon the specific inclusion/exclusion criteria for a prospective or retrospective study, identify the target population for potential study subjects. Establish a recruitment timeline if one is not provided by sponsor. Identify sources of potential participants.
• Clinical Research Coordinator	Determine recruitment methods (e.g., space/radio ads, letters, community talks, newspaper articles, patient support groups, Internet). Develop recruitment materials and submit to the IRB as appropriate. Sponsor will provide if available.
• Designated staff of the DHR Health Institute for Research & Development • Clinical Research Coordinator	Project costs associated with each recruitment strategy.

B. Assess the effectiveness of the recruitment plan

• Designated staff of the DHR Health Institute for Research & Development • Clinical Research Coordinator	Monitor progress and assess results of the recruitment strategy. Develop appropriate alternative strategies, if necessary. Institute alternative strategies if enrollment projections lag. Evaluate final results.

C. Initiate screening procedures

• Clinical Research Coordinator	Develop a screening log based upon the study inclusion/exclusion criteria to collect screening information on all potential subjects (Attachment A, Screening and Enrollment Log). Only applicable if sponsor does not provide a log. Note if individuals went on to enroll in the study; if they were not enrolled, document the reason.
• PI • Clinical Research Coordinator	Obtain informed consent. Retain all signed informed consent forms from subjects who terminate their participation in the study during the screening process.

RESPONSIBILITY

This policy applies to those members of the clinical research team involved in conducting clinical trials at this research site. This includes the following:

- Principal investigator
- Sub-investigator
- Designated staff of the DHR Health Institute for Research & Development
- Research Coordinator
- Support staff

Attachment A

SCREENING and ENROLLMENT LOG *(Sample)*

Screening				**Enrollment**			
Screen Date	**ID #**	**ICF Signed**	**Consented by**	**Enroll Date**	**ID #**	**If not enrolled, explain**	**Staff Initials**