

**DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT  
POLICY AND PROCEDURE**

<b>SUBJECT:</b> Eligibility and Enrollment	Policy #: CRP-1029
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<b>DEPARTMENT:</b> DHR Health Institute for Research & Development	OF: 3
	EFFECTIVE: 02/19
<b>APPROVED BY:</b> 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:**

This SOP describes the process to be followed for screening and enrolling participants in clinical trials at Doctors Hospital at Renaissance.

**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:**

- A. Clinical Trial/Study:** Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.
- B. Eligibility Criteria:** Summary criteria for participant selection; includes inclusion and exclusion criteria
- C. Enrollment:** Number of subjects in a clinical trial
- D. 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.
- E. Legally Authorized Representative (LAR):** An individual or judicial or other body authorized under applicable law to consent on behalf of a potential subject to the subject's participation in the procedure(s) involved in the research
- F. Screening:** Procedures performed to determine whether a potential participant is eligible to take part in a particular clinical trial.

**Policy:**

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements involved in participant recruitment and screening.

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**PROCEDURE**

- 1) Pre-Screening Activities:
  - a) After initial IRB approval, the study/ regulatory coordinator will develop a Subject Eligibility Checklist that includes all inclusion/exclusion criteria listed in the protocol if one is not provided by the sponsor or CRO for the trial.
  - b) He/she will prepare a Screening and Enrollment Log, if not provided by the sponsor or CRO, for use at the study site.
- 2) Screening Activities:
  - a) The research team will count Day Zero as the day on which the prospective participant or legally authorized representative signs the informed consent document. The screening period for a clinical study may take several days
  - b) During the screening period, the research designee will assess the prospective participant's eligibility for participation in the study per the inclusion and exclusion criteria detailed in the study protocol.
  - c) Every individual considered as a potential candidate for the study should be entered on the screening and enrollment log.
  - d) The designee will review the Screening Criteria Checklist developed or provided by the sponsor to determine if the participant meets criteria for screening.
  - e) If the potential study participant meets screening criteria, they must be consented and sign the informed consent form **before** any screening procedures are initiated.
    - i) Screening evaluations and procedures will be followed according to the study protocol.
    - ii) Review the Screening Visit Checklist if provided by the sponsor to ensure all screening procedures have been completed.
    - iii) If a prospective study participant is found to be ineligible, the screening evaluations will be stopped. The patient or legally authorized representative will be informed that he/she is not eligible to join the study and the final case report form (CRF) will be completed.
- 3) Eligibility Determination:
  - a) The Investigator, study coordinator or designee is responsible for reviewing all information pertinent to the prospective participant's eligibility status (all chart notes, checklists, laboratory results and information obtained via medical examinations and interview) after all screening evaluations and test results have been completed and received. He/ she will then record on the chart note the prospective participant's current eligibility status.
  - b) The research designee will review all documents as stated above, as well as the screening evaluation documentation to determine if the prospective participant is eligible for the study.
  - c) If the prospective participant is found to be ineligible, the patient or LAR will be informed that he/she is not eligible to join the study and the final CRF will be completed.
  - d) If the research designee finds the prospective participant to be eligible, then the prospective participant or LAR will be informed of his/her status. If they are still interested in becoming a study participant, the study staff may begin the process of enrolling the participant into the study.

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- 4) Enrollment Procedures:
  - a) Designated research staff will provide informed consent if the participant agrees to participate in the study.
  - b) After informed consent is signed by the participant or LAR, he/ she will be randomized to a study drug treatment, if applicable, or begin study treatment as described in the protocol.
  - c) Research staff will complete the Inclusion Criteria and Exclusion Criteria case report forms.
  - d) The remaining participant information will be entered into the Master Log if applicable.
  - e) Research staff will complete the appropriate case report forms (CRFs).
- 5) Subject Numbering
  - a) Each Investigator participating in a study must have procedures for assigning a unique participant numbering system that includes a site number and sequential subject number. Subject numbering procedures may be developed by the sponsor or CRO.
  - b) Once a participant's eligibility to participate in the clinical study has been confirmed, the participant will be assigned the unique subject number according to the predetermined numbering system.
  - c) All study records that are maintained on each participant will use the unique subject number where possible to protect the participant's confidentiality.