

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

<b>SUBJECT:</b> Clinical Trial Unblinding: VRC705	Policy #: CRP-1037
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<b>DEPARTMENT:</b> DHR Health Institute for Research & Development	OF: 1
	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 document describes how the Doctors Hospital at Renaissance Research Institute site manages unblinding.

**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:**

Unblinding: A term of art used in clinical trials for the identification of the treatment code of a subject/patient or grouped results in studies where the treatment assignment was unknown to the subject and investigators.

**References (Upon Request)**

VRC 705 protocol  
Other VRC 705 protocol-specific documents

**Policy:**

This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol or other protocol-specific documents that may deviate from this SOP.

**Procedure:**

Procedures

A. Unblinding

- a. The DHR Health Institute for Research & Development staff and investigators will follow the VRC 705 protocol and the applicable study-specific documents when unblinding

B. Training

- a. Each staff member receives or has direct access to applicable Standard Operating Procedures (SOPs).
- b. Each staff member reviews the applicable SOPs every 3 months or as needed.
- c. All SOP training is documented and tracked; SOPs and training documentation is available upon request and can be located in the DHR Health Institute for Research & Development Regulatory Room.
- d. New staff is trained on applicable SOPs within 10 days of employment.
- e. Staff members whose duties fall within this SOP scope are retrained within 10 days of the approval of each SOP revision.