University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section: **Clinical Research Center** Date Created: **March 09, 2021**

Title: **Removing Paper Consent from COVID+ Room** Version Date: **January 1, 2023**

SOP Number: **CO51**

PURPOSE: The purpose of this standard operating procedure (SOP) is to describe the process for removing paper consent forms from COVID+ patient rooms after signing.

SCOPE: This SOP applies to all staff that need to consent COVID+ patients.

PERSONNEL RESPONSIBLE: All Clinical Research Center staff.

DEFNITIONS:

- **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.

PROCEDURES:

1. Person entering the patient room does so after donning and following hospital policy for appropriate PPE.
2. After following the informed consent process and the consent is signed, the person consenting gently puts the consent into a manila envelope that is held by a person standing outside the room. The pen is also dropped into that envelope.
3. The envelope is sealed, then carried to another location where it will be left for at least 3 days before being opened.
4. Once the envelope is opened, the consent will then be scanned into the Electronic Medical Record.
5. Patients are marked as enrolled the day that they sign consent.

RESOURCES:

Department Approval

Signed Serena Gaines Signed: 2/9/2023
Research Nurse Manager

Signed _____ Signed: 2/7/2023
Assistant Vice Chancellor for Clinical Research