

SUBJECT/TITLE: **DOCUMENTATION OF PATIENT PARTICIPATION AS A SUBJECT IN A RESEARCH PROTOCOL OR USE OF AN INVESTIGATIONAL MEDICATION, STUDY MEDICATION, INVESTIGATIONAL DEVICE, OR BIOLOGIC**

PURPOSE: To provide a mechanism to identify for healthcare providers that a patient is a participant in a research protocol or using an investigational medication, study medication, investigational device, or biologic and to provide a means to ensure that health care providers have appropriate clinical information related to the study in the event that participation may have clinical significance to the patient's care. To provide guidelines for documenting research subjects who are not patients that are participating in protocols within UI Health Care facilities.

DEFINITIONS: Investigational Medication/Drug: A medication or dosage form that is not approved by the Food and Drug Administration (FDA) for use in humans (e.g., not commercially available in the US); this includes non-FDA approved medications that are obtained for individual patients as part of a treatment IND (investigational new drug), single-patient use, emergency use, compassionate use, or similar protocol.

Study Medication/Drug: A medication or dosage form that is approved by the FDA but is part of a Biomedical Institutional Review Board approved research protocol. This includes FDA-approved medications that are being studied for a non-FDA-approved indication (i.e., an investigational use of a medication).

Investigational Device: A device, including a transitional device, that is the object of an investigation. This includes FDA-approved devices that are being studied for a non-FDA-approved indication (i.e., an investigational use of a device).

Biologics: Biologics include, but are not limited to, vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances,

or may be living entities such as cells and tissues.

POLICY:

A. For any research protocol occurring in a UI Healthcare facility and involving the following requirements:

- Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit.
 - EXCEPTIONS: If a study does not meet the above requirements of having an EPIC Research Study link in the Electronic Health Record (EHR), the Principal Investigator is responsible for recording subject information in the Low-Risk Research Database that has been established by the Institute for Clinical and Translational Science, and may be accessed at <https://redcap.icts.uiowa.edu/redcap/surveys/?s=yjnt3X> .
 - Observational studies (that don't require physical interaction with the subject), participating in a written survey, oral interview or requesting an individual to participate in a data repository would *not* require documentation in either the UIHC EHR or the Low-Risk Database.

Documentation must be made in the subject's UIHC electronic medical record (either directly entered or scanned) and must include:

1. The "EPIC Research Study Description" (formerly known as the Record of Consent) approved by the Biomedical Institutional Review Board (IRB-01) is entered into the electronic medical record in EPIC under the "Research Studies" link.
 - a. When accessing a patient on a study, there are multiple avenues to find the study information for the patient. Below, the user is in the visit navigator and there is a tab for "Research Studies" (1). Selecting this scrolls them to the study list for the patient. See example below:

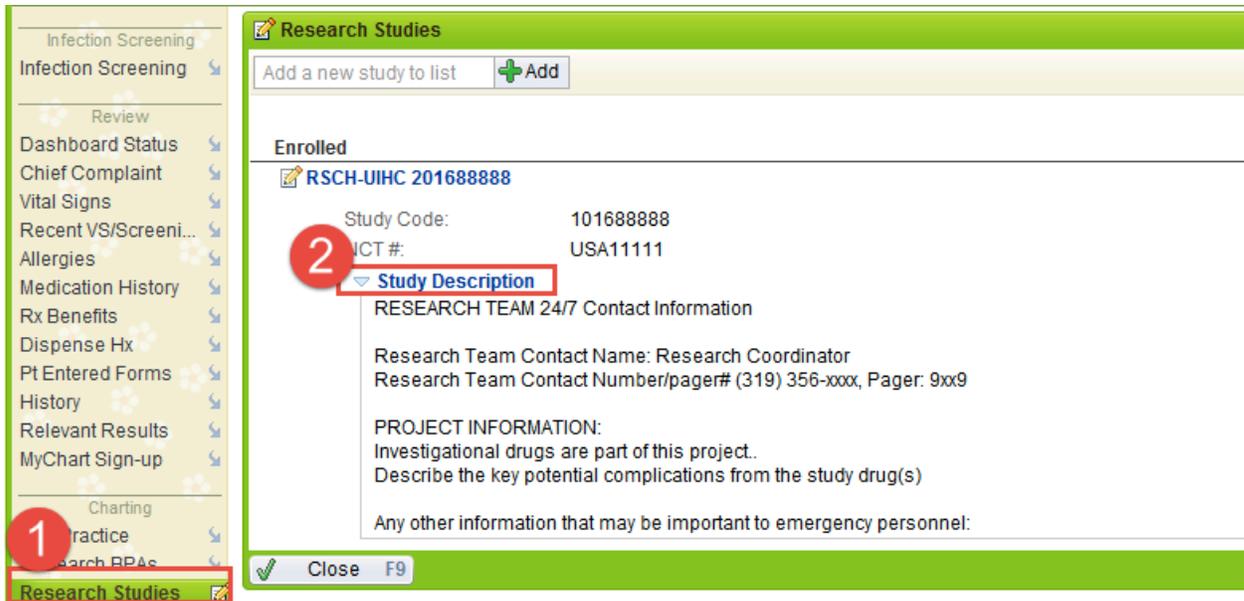


Figure 1. © 2017 Epic Systems Corporation. Used with permission

2. Documentation to support billing, if appropriate.

B. For any use of an investigational medication, study medication, investigational device, or biologic occurring in a UI Healthcare facility, documentation must be made in the subject’s UIHC electronic medical record and must include:

1. The “EPIC Research Study Description” language approved by the Biomedical Institutional Review Board (IRB-01)) is located in the research link which contains research study details relevant to clinical care.
2. Any applicable [G-12 New Drug Data Form](#) {entered or scanned into the electronic medical record}.
3. Documentation to support billing, if appropriate.

PROCEDURE:

Research/Study Protocols

- A. If a research subject has any of the following occurring in a UI Healthcare Facility occur:

- Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit

Documentation must be made in the subject's UIHC medical record. If the subject has a current UIHC medical record, the IRB approved content of the "EPIC Research Study Description" must be included in the EPIC Research Module found within the subject's UIHC electronic medical record. If the subject has no existing record, the subject must be registered as a UIHC patient and given a UIHC hospital number.

To create an EPIC Research Study, contact ICTS. ICTS uses the I-CART system to manage requests for various services to track progress and time spent on fulfillment. This guide will provide you with steps to submit a request via I-CART to create an EPIC Research Study.

<https://wiki.uiowa.edu/display/ICTS/How+to+request+a+service+in+I-CART>

- B. If services provided as part of the study will be billed to third party payors, appropriate documentation and required coding and billing regulations must be followed. Please refer questions to the [Joint Office for Compliance Research Billing](#).

Research/Study Protocols Involving Investigational Medications or Study Medications

- A. The investigator also must submit a completed [G-12 New Drug Data Form](#) to the Pharmacy and Therapeutics Subcommittee (form available from UIHC's medical record form site at <http://forms.uihc.uiowa.edu/medicalrecordsforms.htm>).

After receiving appropriate approvals, and obtaining the patient's consent, the Principal Investigator must ensure that the EPIC Research Study Description is complete and the G-12 Form are scanned into the patient's electronic medical record, as applicable.

- B. For investigational medications that are obtained for individual patients as part of a treatment IND, single-patient use, emergency use, compassionate use, or similar protocol, the Principal Investigator must ensure the appropriate consent document and the G-12 Form are scanned into the patient's electronic medical record. The "Guide for Human Subject Research at the University of Iowa" (see section Emergency Use of an Investigational Drug or Device) provides additional information regarding Human Subjects Office requirements.
- C. If services provided as part of the study will be billed to third party payors, appropriate documentation and required coding and billing regulations must be followed. Please refer questions to the [Joint Office for Compliance Research Billing](#).

References:

UIHC Formulary and Handbook

Guide for Human Subject Research at the University of Iowa, found at the following link to the Human Subjects Office website: <http://research.uiowa.edu/hso/index.php?get=about>

CORRESPONDING POLICIES:

Medication Management policy MM-3.1, [Prescribing Medications for Hospitalized Patients \(Inpatients\) and Clinic Patients](#)

Date created: May 5, 2004

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Clarifications added 6/21/10