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| **SUBJECT/TITLE:** | **Research Documentation in the Legal Medical Record** |
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| **PURPOSE:** | To provide requirements for documenting research subjects participating in human subject’s research within UI Health Care facilities.  |
| **SCOPE:**  | System |
| **DEFINITIONS:** |  |
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**POLICY:**

1. Research studies where procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any clinical care will occur at a UI Health Care facility must be documented in the electronic health record (EHR) under the subject's name and medical record number.
	1. If a study does not meet the above requirements, the Principal Investigator is responsible for recording subject information in the [Low-Risk Research Database](https://redcap.icts.uiowa.edu/redcap/surveys/?s=yjnt3X) or OnCore.
	2. Documentation in the EHR, Oncore, or Low-Risk Database is not required for the following:
		1. Observational studies that do not require physical intervention with the subject
		2. Participation in a written survey
		3. Oral interview
		4. Requesting an individual to participate in a data repository
2. Documentation in the subject’s EHR must include the following:
3. In the subject’s EHR, the subject is associated to the research study, that has been approved by the designated IRB of record.
4. Documentation to support billing, if appropriate.
5. If a subject does not have an existing record, the subject must be registered as a UI Health Care patient. Registration can be contacted at 319-356-3511 or via email at PFSRegistration@healthcare.uiowa.edu. Subjects will need to provide basic demographic information to be registered.
6. Principal Investigator or study team member conducting research related to a Federal Public Health Emergency are able to use the EHR to query other healthcare facilities for additional subject clinical information, using Epic Care Everywhere.
7. 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 researchbilling@healthcare.uiowa.edu.

**PROCEDURE:**

1. Research/Study Protocols:
	1. To create an EPIC Research Study, question ROC.1 in the HawkIRB application must be answered as “does meet,” and the subsequent questions that appear must be answered by the research team. The EPIC Research Study is then automatically created within 24-48 hours after the study is IRB approved and released in HawkIRB.
2. Research/Study Protocols Involving Investigational Medications or Study Medications:
3. After obtaining the patient’s consent, the Principal Investigator must ensure the patient-study association is complete.
4. For investigational medications that are obtained for emergency use, the Principal Investigator must ensure the appropriate consent document is scanned into the patient’s electronic medical record. The [Guide for Human Subject Research at the University of Iowa](https://hso.research.uiowa.edu/get-started/guides-and-standard-operating-procedures-sops) section Emergency Use of an Investigational Drug or Device provides additional information regarding Human Subjects Office requirements.

### REFERENCES:

[Guide for Human Subjects Research at University of Iowa](https://hso.research.uiowa.edu/get-started/guides-and-standard-operating-procedures-sops)

[Epic Research Support](https://epicsupport.sites.uiowa.edu/epic-resources/research)

**RELATED POLICIES:**

CC.P.98, [Prescribing Medications for Hospitalized Patients (Inpatients) and Clinic Patients](https://uihealthcare.policytech.com/docview/?docid=10108&anonymous=true&app=pt&source=unspecified)

Source: Health Information Management Systems Working Group

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