

PROTOCOL MANAGEMENT AND RESEARCH PARTICIPANT DATA ENTRY IN CRIS

Policy Dated: October 29, 2014

Policy:

All investigators conducting interventional, observational, ancillary or correlative research studies at University of Kansas Medical Center (KUMC) must register the studies in KUMC Clinical Research Information System (CRIS). This registration process will support both research recruitment efforts and institutional requirements for reporting to the National Institutes of Health (NIH) for the Cancer Center Support Grant, NCI Clinical Trials Reporting Program (CTRP) and the NIH Clinical and Translational Science Award for protocol and participant data. This registration process will also support hospital billing compliance for patients on clinical research trials.

Purpose:

Velos eResearch, a Clinical Study Management System (CTMS), is referred to as CRIS at KUMC. CRIS is used for protocol information storage, regulatory data management, enrollment tracking, clinical study billing and compliance. It is comprised of two main modules: protocol management and participants. Between the two modules, it tracks and saves data related to start-up activities, study enrollment status, participant enrollment and status, and study financial information.

The initial entry of the protocol into CRIS outlines the basic summary information of the study. The input of initial protocol-related data into CRIS is the responsibility of the University of Kansas Medical Center Research Institute (RI) Clinical Research Administration (CRA) Division or the Cancer Center Clinical Trials Office (CTO).

The following types of studies are considered applicable studies and will be entered into CRIS:

- I. **Interventional (INT):** A study in which individuals are assigned by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.

- II. **Observational (OBS):** A study that focuses on participants and healthy populations that involve no intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.

- III. Ancillary or Correlative (ANC/COR):
 - a. Ancillary: A study that is stimulated by, but is not a required part of, a main research study, and that utilizes participants or other resources of the project to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only participants accrued to that clinical research study. Only studies that can be linked to individual participant or participant data should be reported.
 - b. Correlative: Laboratory based study using specimens to assess disease risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual participant or participant data should be reported.
- IV. Other: Studies that are in vitro studies that utilize human tissues that cannot be linked to a living individual, tissue banking, and studies that do not require patient consent (e.g., retrospective chart reviews)

Summary of Study Types to be entered into CRIS

Table 1a

CANCER OR CANCER-RELATED STUDIES

Type of Study ¹	Enter Protocol-level Information into CRIS	Enter Minimal Participant-level Data into CRIS
Interventional	Yes	All studies
Observational	Yes	All studies
Ancillary	Yes	All studies
Correlative	Yes	All studies
Other	No	No

1. See definitions of study type in sections I-IV above

Table 1b

NON-CANCER STUDIES

Type of Study ¹	Enter Protocol-level Information into CRIS	Enter Minimal Participant-level Data into CRIS
Interventional	Yes	All studies processed though the RI CRA and any additional studies that are using hospital services for research
Observational	No	No, unless using hospital services for research

Type of Study ¹	Enter Protocol-level Information into CRIS	Enter Minimal Participant-level Data into CRIS
Ancillary	No	No, unless using hospital services for research
Correlative	No	No, unless using hospital services for research
Other	No	No

Protocol Data to Be Entered:

All studies that meet the definitions above must be entered into CRIS and have the required data fields populated. These data fields correlate to particular NIH/NCI/FDA/Institutional reporting requirements. Specifically, these data fields identify/record:

Protocol Characteristics

(Refer to CRIS User’s Guide or NCI CCSG Guidelines for definitions and detailed entry instructions)

- I. Principal investigator (PI)
- II. Study Number (HSC/IRB number)
- III. Sponsor ID
- IV. Study Title
- V. Sponsor name
- VI. Therapeutic Area and Disease Site
- VII. Targeted Accrual: National Sample size and Local Sample size
- VIII. Date Open to Enrollment
- IX. Study Phase
- X. Research Type (i.e. National, Externally Peer-Reviewed, Institutional, Industrial)
- XI. Study Scope (Multi Center or Single Center)
- XII. Study Type-(i.e. Diagnostic, Health Services Research, Other, Prevention, Screening, Supportive Care, Basic Science, Treatment)
- XIII. Date closed to enrollment

The RI will enter all required non-participant data fields into the system for studies receiving assistance from the RI CRA. KU Cancer Center will enter all required non-participant data fields into the system for studies receiving assistance from the KU Cancer Center Clinical Research Office. For all non-cancer studies, PIs are required to use RI CRA if they are using hospital services for their studies to ensure hospital billing compliance for patients on clinical research trials.

For those studies that utilize hospital services, all participant information will be entered by the PI and/or PI designee(s). For the non-cancer studies that do not use hospital services, only the protocol characteristics will be entered and participant data is not required.

Participant Data to Be Entered:

Participant data will be entered for those studies as defined in tables 1a and 1b for those studies where hospital services are utilized. Participant activity on a study is tracked as each person progresses through a study. The input of participant-related data into CRIS is the responsibility of the PI, and/or PI designee(s).

Participant Characteristics

(Refer to CRIS User's Guide or the NCI CCSG for definitions and detailed entry instructions)

- I. Subject ID# or Medical Record Number (if applicable)
- II. Date of Birth or age at enrollment
- III. Gender
- IV. Race
- V. Ethnicity
- VI. Status of participant/date
- VII. Zip Code (required for cancer or cancer-related interventional studies only)

Participant information to be entered includes:

Enrollment of Participants into the System:

- The PI or designee must add research participant data into CRIS within 2 business days of obtaining legally informed consent, for any study using hospital services.
- Data entry into CRIS is to include completion of the participant demographic form, assignment to the proper clinical study and participant enrollment status

Updating Participant Enrollment Status, Visits/Procedures completed:

- The PI or designee must update participant status within 2 business days of any change in status. Refer to CRISs User's Guide for status definitions (i.e. enrolled, off treatment, off study, etc.)

Implementation will be as follows:

- Cancer and Cancer-related studies and those non-cancer studies using hospital services must be entered into the CRIS system starting July 17, 2013.

Annual enrollment updates to for non-cancer studies:

- RI CRA updates the total enrollment for each study when the continuing review is submitted to the HSC that includes the following information:

- I. HSC submission date
- II. HSC approval date
- III. Enrollment total
- IV. HSC expiration date
- V. Date IRB approval sent to sponsor

Non-compliance with the policy

Non-adherence with policy requirements will result in administrative action, including but not limited to, suspension of study enrollment. Persistent non-adherence with the policy can result in study termination.

Definitions:

Clinical Study Management System (CTMS): Information technology system used in the management of clinical studies. It is a data repository for Investigators, study team members, and administrators.

Comprehensive Research Information System (CRIS): term for Velos eResearch CTMS at KUMC.

eResearch: CTMS used by KUMC. The CTMS addresses four areas of clinical research data collection: Finance, Research Administration, Clinical Data Management and Participant Portal. The CTMS handles budgeting and billing, protocol management, calendaring, and participant management.

Human Research Study: **Research** (a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge) **that involves a human participant** (a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.)

Cancer or cancer-related research is any human research involving cancer or cancer participants, whether it is interventional, observational, ancillary or correlative. The research may further be classified as Treatment, Prevention, Screening, Diagnostic, Supportive Care, Basic Science, or Health Services Research.

Clinical Studies involving KU Hospital services means funded studies that involve a drug, device or invasive procedure or other intervention that results in a KU Hospital charge to the study participant or the study sponsor.

Human research studies that prospectively recruit participants means any study that will obtain informed consent from participants.

Responsible Parties:

This policy shall apply to all University of Kansas University Medical Center faculty, staff, postdoctoral fellows, students, trainees and any other persons at KUMC involved in the conduct or reporting of human research at KUMC.

Exemptions:

None

Related Policies and Links:

CRIS User's Guide – Research Team Member

<http://cancercenters.cancer.gov/documents/CCSGDataGuide508C.pdf> (pages 25-30)

The University of Kansas Hospital Corporate Policy Manual, Volume 1: Infrastructure and Operations, Section: Compliance Program, POLICY: Research Participant Notification

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