UF Health Cancer Center
Clinical Research Office
P.O. Box 103633
Gainesville, FL 32610-6366
trials@cancer.ufl.edu

University of Florida UF Health Cancer Center Clinical Research Office Standard Operating Procedure	Effective Date: 3/15/2019 Version 3: 2/20/2019	Procedure No: ADM-004
Title: Data Requirements for Cancer Center Reporting		

I. PURPOSE: The purpose of this SOP is to outline the requirements for data reporting related to cancer relevant interventional, observational, and ancillary/correlative clinical research studies.

II. INTRODUCTION/BACKGROUND:

Each year the UF Health Cancer Center (UFHCC) is responsible for reporting information about protocol activity to the National Cancer Institute (NCI) as well as other federal and state agencies. These mandatory reports are directly tied to university funding. This information is also required for the Clinical Trials Reporting Program (CTRP) and ClinicalTrials.gov reporting. It is **critical** that this information be timely and accurate. To this end, all study status and accrual information required for NCI, other federal, and state reporting must be entered into the Cancer Center's Clinical Trials Management System (CTMS), OnCore. It is the responsibility of the Principal Investigator (PI) and their research staff to ensure that reporting is in compliance with this document.

III. SCOPE: This policy applies to all investigators and staff who are responsible for documenting and reporting study activity, including subject accruals, to the UFHCC.

IV. RESPONSIBILITY:

Principal Investigators
Clinical Research Coordinators
Clinical Research Managers
Research Administrators

V. DEFINITIONS:

Data Table 4 Categorization

Interventional: Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, 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.

Observational: Studies that focus on cancer patients and healthy populations and involve no prospective 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.

Ancillary or Correlative:

Ancillary: Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported.

Correlative: Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

Primary Purpose Classification

Basic Science (BAS): Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.

Diagnostic (DIA): Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition.

Health Services Research (HSR): Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.

Prevention (PRE): Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.

Screening (SCR): Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).

Supportive Care (SUP): Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.

Treatment (TRE): Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. Note: This equates to therapeutic trials in previous versions of the guidelines.

Other Definitions

Data Integrity and Safety Committee (DISC): The DISC is an independent committee charged with the review of interventional UF IITs that do not have an external SRMC approved DSMB. DISC concentrates on the review of safety, adverse events, subject accruals, patient response and study outcomes, protocol compliance, and data integrity.

Deviation: A protocol deviation is generally an unplanned excursion from the protocol that is not implemented or intended as a systematic change.

Scientific Review and Monitoring Committee (SRMC): The SRMC is the UF body that provides the critical review of scientific merit, methodology, validity of statistical analyses, and scientific priority for qualifying research studies. All cancer-related studies conducted at the UFHCC or otherwise supported with institutional resources must be reviewed and approved by SRMC prior to initiation of the study. SRMC ultimately verifies the Data Table 4 categorization and Primary Purpose classification of all studies.

Serious Adverse Event: Any event that meets one or more of the following criteria is considered to be a serious adverse event (SAE): Death; Life-threatening event; Hospitalization (initial or prolonged); Disability or Permanent Damage; Congenital Anomaly/Birth Defect; or Other Serious (Important Medical Events).

Sponsor: An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial.

UF Investigator Initiated Trial (UF IIT): Investigator Initiated Trials are those conducted by sponsor-investigators (hereafter referred to as IITs). The FDA defines a sponsor-investigator as "an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed." For the purposes of this plan, this definition has been broadened to include any clinical trial that was initiated and conducted by an investigator. UF IITs are further characterized as trials that both originated at UF and are centrally managed by the institution.

VI. PROCEDURES:

6.1 Protocol Regulatory Requirements (All Studies):

The protocol shells for all interventional, observational and ancillary/correlative studies must be entered into OnCore prior to the Scientific Review and Monitoring Committee (SRMC) submission. It is the responsibility of the clinical research coordinator/designee to maintain the protocol status of that study from SRMC approval until the study is terminated with the IRB. The following regulatory information should be entered and maintained for each clinical research study:

- Study Title (and short title, if applicable)
- Initial IRB Submission and Approval Dates
- Protocol IRB Number
- Clinicaltrials.gov NCT Number (if applicable)
- Protocol Open to Accrual Date
- Temporary and Permanent Closure to Accrual dates (as applicable – Suspended status should be utilized for all temporary closures to accrual)
- Protocol Termination Date and Reason
- List of Participating Sites (for multicenter trials)
- Study Staff List

OnCore entries should be made **within 5 business days** of any of the above listed status change. Please refer to OnCore User Guides: UFHCC Protocol Creation Guidance and OnCore Subject Registration and Reporting Process Guidance located on the UFHCC website. **This is a requirement for SRMC submission.**

6.2 OnCore Documentation Requirements (Interventional Studies):

- IRB Approval Letter(s)
- IRB Approved Protocol Document
- IRB Approved Informed Consent Document(s)
- All IRB Approved Subject Materials
- All IRB Protocol Amendments (upload related documents, which may include amended Informed Consent documents)
- Investigator Drug Brochure(s) and/or Laboratory Manuals (if applicable)

6.3 Subject Reporting Requirements (Interventional Studies):

Each clinical research coordinator/designee for the trial types listed above is responsible for updating each of the following required elements in OnCore for each subject enrolled on the trial. For studies involving bill review in Epic, the following steps must be completed **before any study related procedures are performed** and **no later than one business day following consent**. For all other studies, subject reporting should occur on a monthly basis:

- MRN (if applicable)
- Date of Birth
- Gender
- Race
- Ethnicity
- Zip at Registration
- Country of Residence (if not USA)
- Consent Date
- Enrolling Faculty
- Subject Disease Site
- Subject Disease Site Group

The following information should be added within OnCore as it becomes available:

- Subject Study Sequence Number
- Eligibility Date
- On Study Date – date of formal registration/randomization
- Off Study or Withdrawal Date and Reason

6.4 Subject Reporting Requirements (Non-Interventional Studies):

Each clinical research coordinator/designee for the trial types listed above is responsible for updating the following required information in OnCore for subjects enrolled on the trial by quarter (1/1-3/31, 4/1-6/30, 7/1-9/30, and 10/1-12/31):

- Summary Accrual including Gender, Race, Ethnicity, Age Range
- Alternatively, subjects may be reported in OnCore individually using the interventional parameters noted in 5.3.

6.5 Safety Monitoring Reporting Requirements for UF Interventional IITs Under DISC Oversight:

All major deviations and serious adverse events (SAEs) must be entered into the OnCore database regardless of whether they meet the IRB prompt reporting requirements. Trials completing individual patient registrations will enter the information into the SAE or Deviation tab in the Subject Console for the applicable subject. Major deviations and SAEs are reviewed by the UFHCC Data Integrity and Safety Committee (DISC) per the policies outlined in the DISC Charter.

6.6 Multicenter Reporting Requirements

Subject reporting for UF interventional IITs should also be entered for participating sites as defined above for interventional trials. Accrual for participating sites to non-interventional IITs may use the interventional or non-interventional guidelines as appropriate.

REFERENCES

OnCore Subject Registration and Reporting Process Guidance
UFHCC Protocol Creation Guidance
DISC Charter
NCI CTRP Accrual Reporting - https://www.cancer.gov/about-nci/organization/ccct/ctrp/accrual

APPROVALS

Digitally signed by Alison M Ivey
Date: 2019.02.20 14:27:58 -05'00'

Administrative Director, CRO — Date

Thomas J. George, MD, FACP
Digitally signed by Thomas J. George, MD, FACP
Date: 2019.02.20 14:52:16 -05'00'

Associate Director for Clinical Research, UFHCC — Date

VERSION CONTROL:
Version 3
Version Date: 2/20/2019
Effective Date: 3/15/2019
Last Reviewed Date: 2/20/2019

SOP REVISION HISTORY:

Version	Date	Reason for Change
1	07/22/2018	Original SOP version
2	10/12/2018	Added provision for summary accrual option for select interventional studies
3	2/20/2019	Removed option for summary accrual; minor clarifications to align policy to CTRP reporting requirements