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. RESPONSIBILITY:
Principal Investigators
Clinical Research Coordinators
Clinical Research Managers
Research Administrators

IV. 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.

**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.

V. PROCEDURES:

5.1 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 via the ePRMS console. It is the responsibility of the clinical research coordinator/designee to maintain the protocol status of that study until the time 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 Closure to Accrual date (if 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

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

5.2 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)

5.3 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 within one business day of enrollment (i.e. consent or waiver of consent):

- MRN
- Date of Birth
- Gender
- Race
- Ethnicity
- Zip at Registration
- Consent Date
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

Interventional studies that are not subject to DISC oversight and do not involve investigational drugs, devices, or medical procedures may be eligible for accrual reporting via the requirements outlined in 5.4. Please send all requests for summary accrual reporting to Alison Ivey (aivey@ufl.edu) for review and approval.

Subject Reporting Requirements (Interventional Studies Qualifying for Summary Accrual):

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 month (reported on a quarterly basis):

- Summary Accrual including Gender, Race, Ethnicity, Age Range, Disease Site

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.

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.

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 Guidance
UFHCC Protocol Creation Guidance
DISC Charter
APPROVALS

Alison Ivey
Digitally signed by Alison Ivey
Date: 2018.10.12 13:30:24
-04'00'
Administrative Director, CRO
Date

Associate Director for Clinical
Investigation, UFHCC
Date

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