Background

Each year the IU Simon Cancer Center (IUSCC) is responsible for reporting information to the National Cancer Institute (NCI). These reports are directly tied to the funding we will receive. This information is also required for the Clinical Trials Reporting Program (CTRP) and ClinicalTrials.gov. It is critical that information be timely and accurate. To this end, all study status and accrual information required for NCI reporting must be entered into the Cancer Center’s clinical trial management system, OnCore.

Definitions

**Treatment**: Protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition. *(Interventional)*

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

**Supportive Care**: 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 subject’s health or function. In general, supportive care interventions are not intended to cure a disease. *(Interventional)*

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

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

**Health Services Research**: Protocol designed to evaluate the delivery, processes, management, organization or financing of health care. *(Non-Interventional)*
**Basic Science:** Protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention. *(Non-Interventional) (examples are not limited to this category and may fit in another: correlative only studies, ancillary)*

**Other:** Anything that does not fit in any category above (i.e. banking, retrospective chart review, registry). *(Non-Interventional) (examples are not limited to this category and may fit in another: ancillary, epidemiologic, observational, outcomes)*

*It may be necessary to reference the “objectives” in the protocol to determine the protocol category.*

**Protocol Coordinator/Designee:** The person responsible for entering accrual and other required data into OnCore. This person could be an administrative assistant, clinical research specialist, study/protocol coordinator or research nurse or the PI. Each study team is responsible for designating someone to update OnCore with the required information.

**Policy**

**Protocol Regulatory Requirements**
All interventional and non-interventional protocol information will be entered into OnCore at Scientific Review Committee (SRC) submission via the e-PRMS console. It is the responsibility of the Protocol Coordinator/designee to maintain the protocol status of that study until the time the study is terminated with the IRB. The following regulatory information is to be updated on a monthly basis:

- Initial IRB submission date and initial IRB approval date
- Protocol IRB number
- Protocol Open to Accrual Date
- Protocol Closed to Accrual Date
- Protocol Termination Date and Reason
- List of Participating Sites (for multicenter trials)

Please refer to OnCore User Guides: Subject Administration Guide and Entering Regulatory Information, Updating Protocol Status and Patient Accrual in OnCore on the Clinical Trials Office and Human Subjects Office websites (links are listed under References below).

Version Date 04/30/2015
Interventional Trials Require the Following Documents be uploaded in Oncore

- IRB Approved Protocol Document
- Informed Consent Document
- IRB Approved Protocol Summary Document (DRA)
- All IRB Protocol Amendments (upload related documents, which may include Protocol Document)
- IRB Approved Continuing Reviews

Subject Reporting Requirements (Interventional)
Each Protocol Coordinator/designee for the trial types listed above is responsible for updating the following information in OnCore each month for each subject enrolled on the trial:

Demographics Tab (Treatment trials only)

- MRN

Demographics- gender race, ethnicity, DOB (Treatment trials only) (month/year)
On Study Tab

- Subject Study Sequence Number
- On Study Date – date of registration to the protocol
- Disease Site
- Histology
- Study Site
- Zip Code

Subject Reporting Requirements (Non-Interventional)
Report Monthly* End of year reporting must be entered by January 15.

- Summary Accrual
- Gender, Race, Ethnicity
Safety Monitoring Reporting Requirements:

All programs are required to enter all deviations and serious adverse events (SAEs) into the OnCore database regardless if it meets the IRB prompt reporting requirements. Trials completing individual patient registration will enter the information into the SAE or Deviation tab in the Subject Console for the applicable subject. Trials completing summary accrual will need to enter their SAE's and deviations into the Deviation tab in the PC Console in OnCore.

Deviations, SAEs, monitoring and auditing are all reviewed or conducted per the IUSCC Data Safety Monitoring Plan.

Multicenter Reporting Requirements

All multicenter IITs must enter the following into OnCore in addition to requirements listed above:

- Management Group: list “Multicenter Network” as a management group. Primary should not be checked
- Subject reporting should also be entered for participating sites as summary accrual (non-intervetional trials) or as defined above for interventional trials

Non-interventional and Interventional Trials Require the Following Documents be uploaded in OnCore

- IRB Approved Protocol Document
- Informed Consent Document
- IRB Approved Protocol Summary Document (DRA)
- All IRB Protocol Amendments (upload related documents, which may include Protocol Document)
- IRB Approved Continuing Reviews

Signature:  
Associate Director of Clinical Research at IUSCC  
Clinical Research Committee Chair  
5/11/15  
Date

Version Date 04/30/2015  Page 4
References

OnCore Reference Guides:
https://www.iupui.edu/~cancint/cro/page.php?id=444
http://researchcompliance.iu.edu/hsoclinical/hs_forms.html

Data Safety Monitoring Plan:
http://researchcompliance.iu.edu/hsoclinical/hs_forms.html