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Clinical Research Oversight Committee Chair or Designee		Date:	5/31/17
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Vice Dean, Research and Graduate Education, School of Medicine, University of Washington		Date:	6/9/17
Printed Name	John T. Slattery, PhD		

Background

In order to meet the reporting requirements of an NCI-designated Comprehensive Cancer Center, the partner institutions that make up the Cancer Consortium, the Fred Hutchinson Cancer Research Center (FHCRC), University of Washington (UW), Seattle Children's (SC) and the Seattle Cancer Care Alliance (SCCA), must have accurate and current accrual information across Consortium studies. These requirements depend upon centralized collection of study accrual data through the utilization of the Consortium's Protocol Accrual Tracking System (PATS) or a combination of PATS and EPIC systems.

This policy describes the responsibility of study personnel to report Cancer Consortium study accrual data to the Consortium tracking systems within a specified timeframe.

Responsible Personnel

Medical Director, Clinical Research Support

Director, Clinical Research Support

Abbreviations and Acronyms

CRS: Clinical Research Support

FHCRC: Fred Hutchinson Cancer Research Center

PATS: Protocol Accrual Tracking System

SC: Seattle Children's

SCCA: Seattle Cancer Care Alliance

UW: University of Washington

Definitions

Cancer Consortium: An NCI-designated Comprehensive Cancer Center comprised of: Fred Hutchinson Cancer Research Center (FHCRC), University of Washington (UW), Seattle Children's (SC), and Seattle Cancer Care Alliance (SCCA).

CORE: Clinical Oncology Research Entrance – a secured website for oncology related secured websites.

Clinical Trial: Any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes. (ICMJE)

PATS: Protocol Accrual Tracking System – an online secured website that collects study accrual data.

Policy

Cancer Consortium clinical trials that are reported on Data Tables 3 or 4 of the Cancer Center Support Grant must report new accruals to their studies either using the PATS system alone, or in the case of studies with research billable services, using a combination of EPIC/PATS systems. Data entry must be completed within one business day after the enrollment date and must include data in all relevant fields based on the patient status. In many cases, data entry may start with study screening activities, but the one business day requirement begins at enrollment.

Exceptions

High Accruing Protocols. For studies with exceptionally high accrual managed through the use of a database by the study team, an exception to manual data entry into PATS will be permitted and reporting may occur via bulk import. For more information, contact CRSReports@fredhutch.org.

PATS System Outages. If the PATS system is unavailable reporting timelines are extended accordingly in this unusual situation.

Procedures

PATS contacts begin accrual entry in EPIC for studies with research billable items, tests or services in order to satisfy study-billing requirements. Any time after the EPIC entry and before the end of the first business day after enrollment, study teams can enter the balance of the participant information in the PATS web-based system To get to PATS use your web browser and go to the PATS web address:

https://pats.fhcrc.org

Studies that do not require entry in EPIC are entered directly through the PATS web-based system. To get to PATS use your web browser and go to the PATS web address:

https://pats.fhcrc.org

Study personnel must inform CRS of PATS primary contact changes within five business days after any change in the study personnel who is responsible for registration of studies in PATS, so that CRS can send reminders and verification requests to an appropriate representative of the study team, when necessary. Additional PATS contacts can be added at the request of the study teams in order to ensure adequate coverage.

Failure to comply with the accrual reporting requirements outlined in this policy may result in escalation to an appropriate review body for further action.

High Accruing Protocols

Clinical Research Support (CRS) will assist study teams by bulk importing accrual data into PATS database. For more information contact CRSReports@fredhutch.org.

PATS System Outages

Clinical Research Support (CRS) will assist by bulk importing accrual data into PATS database. For more information contact CRSReports@fhcrc.org.

Applicable Regulations & Guidelines

Cancer Center Support Grant Guidelines: http://cancercenters.cancer.gov/documents/CCSGDataGuide508C.pdf

Clinical Trials Reporting Program: https://www.cancer.gov/about-nci/organization/ccct/ctrp

AACI Sub Committee Report: https://www.cancer.gov/about-nci/organization/ccct/ctrp/access-training/ctrp-strategic-subcommittee-report-2011-07.pdf

Attachments / Related References

CRS Documents and Training module

PATS 2.0 Process and User Documentation

http://cancerconsortium.org/content/dam/consortium/PATS/PATS_User_Guide.pdf

PATS Quick Reference Sheet

http://www.cancerconsortium.org/content/dam/consortium/PATS/PATS_Reference_Sheet.pdf

PATS User Training Module

https://share.fhcrc.org/sites/cancer-center/crr/Module%20Library/PATS/PATS%20OVERVIEW/story.html

Version Review History	
Reviewer	**Date**
Frederick Appelbaum, MD, Deputy Director, FHCRC	05/20/2014
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John T. Slattery, PhD, Vice Dean for Research, University of Washington	05/31/2017