University at Buffalo
Research and Economic Development

Use of University OnCore Clinical Trial Management System (CTMS)

Category: Research
Responsible Office: CTSI/Clinical Research Office
Responsible Executive: Vice President for Research and Economic Development
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Summary

The University at Buffalo has as its goal to be among the top 25 public research institutions in the US. UB has put in place a clinical trial management system (CTMS), OnCore, with the express purpose of increasing functionality, efficiency, reporting and compliance for clinical research studies. A CTMS system will serve to aid in achieving this goal through study management throughout the lifecycle of the trial. This includes subject management, financial reconciliation, and reporting. The use of a CTMS system is essential to having a highly functioning and high volume clinical trial program in addition to providing up-to-date reporting to federal, state, institutional and affiliate stakeholders. OnCore is a comprehensive, web-based suite of research modules that integrates all of the components of research activity administered by the University at Buffalo, all affiliated institutions and satellite locations. The system is designed to serve the needs of research teams, departments and support the continued strengthening of standards for efficiency, safety, quality, and compliance.

The objective of the Clinical Trials Management System is to improve and automate processes that support clinical trials through providing functionality that will cover Protocol and Subject Management, Clinical Trials Budgeting, Clinical Trials Routing and Workflow, visit Scheduling, sponsor Invoicing and financial reconciliation.

Policy

POLICY STATEMENT

This policy establishes the University at Buffalo requirements for the use of OnCore. This is to include: the studies that are to be managed within the CTMS system and the data input required for each type of study.

SCOPE

Compliance with this policy statement is required across all Schools of the University in relation to Clinical Research involving human subjects.

BACKGROUND

The OnCore Clinical Trials Management System (CTMS) has been used at the University at Buffalo since 2016 by research teams at UB and affiliated institutions to track Protocols, study participants, financials and provide reporting for PIs, Department Chairs and University leadership.

Subject management through the use of the system will allow the coordinator and study staff to dispense with administrative duties to invoice, track and reconcile payments received. This will allow study staff to focus on subject enrollment and management.

APPLICABILITY

This policy applies to all Principal Investigators and study teams conducting clinical research involving human subjects within the University at Buffalo.

DEFINITIONS

Clinical Trial: The University utilizes the National Institutes of Health (NIH) definition of a clinical trial - **A research study** in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Clinical Research: The current NIH definition of clinical research is human subjects research that is:

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin, such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that use human tissues that cannot be linked to a living individual. This definition includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2. Epidemiologic and behavioral studies.
3. Outcomes research and health services research.

CRO: UB's Clinical Research Office

CTMS: Clinical Trial Management System

Principal Investigator (PI): The individual who is responsible and accountable for conducting the clinical trial.

Study Team/Staff: individuals that have been delegated the various study management and participant oversight activities for a research study.

RESPONSIBILITY

Please note that Oncore data entry is mandatory and not optional. Timely and accurate Standard accrual data entry by research staff is essential. This data is utilized for invoicing and financial management/reconciliation of the study by the Clinical Research Office (CRO). This will ensure billing compliance, accurate and timely invoicing and proper reconciliation of accounts prior to study closure.

The Clinical Research Office (CRO) has been delegated as the representative for the Research Foundation for the financial management and reporting of studies within Oncore by the VPRED and VPHS. This delegation includes: budget approval, sponsor invoicing, payment receipt and reconciliation as well as account management through the Research Foundation system (Oracle). Therefore, all sponsor invoicing for industry funded trials (with the exception of invoicing automatically triggered by data entry in the study clinical

research forms), is to be performed only by the CRO staff. The CRO will work with SPS to establish which studies funded by other means will require financial management through the CRO.

It is the responsibility of the Principal Investigator to ensure that all required data has been entered into he CTMS system as outlined in the flow sheet attached to this policy as APPENDIX A.

PROCEDURE

For all studies that require OnCore data entry, the Clinical Research Office will work with the study team to construct a study grid. Oncore will produce a calendar of study events and provide to the study team for review and comment prior to finalizing in the Oncore system for use. It is the responsibility of the study team to work with the Oncore Coordinators to ensure an appropriate calendar for study activities.

Data entry as Standard Accrual is required for all clinical trials, by NIH definition, that involve a drug/device/ intervention. In this, per patient entry and all study activities details are required. The time to complete new a subject enrollment is approximately 5-10 minutes, with subsequent visit information entered in 1-2 minutes. Data entry in OnCore as Limited Standard Accrual is required for all funded behavioral intervention studies and non-interventional prospective clinical research studies. In this, per patient entry of the following data is required: Date enrolled, Gender, Age Group, Ethnicity, Race, Zip code, Insurance Type (optional but strongly encouraged). Time to complete each entry is approximately 1 minute.

CONSEQUENCE OF NONCOMPLIANCE

Non-compliance with this policy statement will result in the suspension of research award/account activities.

System training is available through the Clinical Research Office by reaching out to the Oncore Specialists.

Contact Information

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Attachments

Appendix A: Studies and Level of Data Collection Required in Oncore CTMS System for Clinical Research

Related Information

Related Links:

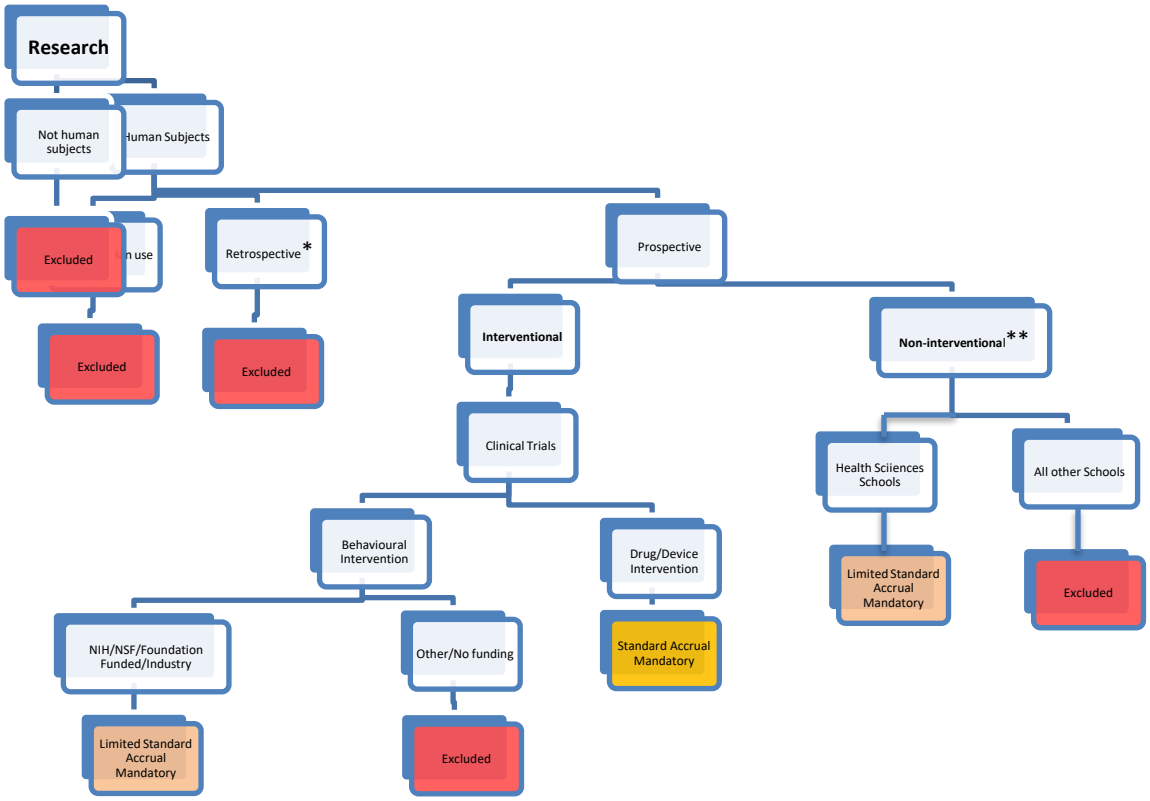
CTSI: Clinical and Translational Science Institute - University at Buffalo

Training: OnCore - An Introduction - Vice President Research and Economic Development - University at Buffalo

OnCore - Subject Administration for Full Studies - Vice President Research and Economic Development - University at Buffalo

APPENDIX A:

Studies and Level of Data Collection Required in Oncore CTMS System for Clinical Research



* No consent signed, includes chart reviews, previously collected biological samples (unless industry-sponsored/funded)

** Includes registries, surveys, observational studies and industry-sponsored chart review.

Standard Accrual: Per patient entry and all study activities details required.

Limited Standard Accrual: Per patient entry of the following data:

a. Date enrolled
b. Gender
c. Age Group
d. Ethnicity
e. Race
f. Zipcode
g. Insurance Type (optional but strongly encouraged)

**In limited circumstances aggregate enrollment data is permissible – Contact Oncore Coordinator for more information/direction.

Excluded: Study will not be entered into OnCore – No data required