Policy Statement: Required use of University Clinical Trial Management System (OnCore CTMS)

Dear Colleagues,

As many of you know, UB has as its goal to be among the top 25 public research institutions in the US. The University at Buffalo has put in place a clinical trial management system (CTMS) with the express purpose of increasing functionality, efficiency, reporting and compliance in relation to certain 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 web-based clinical trial management system (CTMS) designed to aid in the tracking of all aspects of the clinical trial lifecycle. 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.

The Clinical Research Office (CRO) has been delegated for the financial management and reporting of studies within Oncore by the VPRED to address: budget approval, invoicing, payment receipt and reconciliation as well as account management through the Research Foundation system (Oracle). **See VPRED delegation policy attached.** The use of the system for invoicing and financial management/reconciliation has proven to be very effective to ensure all funds earned have been recouped and accounts are properly reconciled prior to study closure by the CRO.

Subject management through the system will allow the coordinator and study staff to dispense with many administrative duties to invoice, track and reconcile payments received thus allowing them to get back to fundamentals of subject enrollment and management while ensuring billing compliance for study related procedures and ensures accurate and timely invoicing to study sponsors in accordance with the contract for the study.

This communication will serve to identify those studies for which the use of OnCore is mandatory. This clarification should also result in less confusion among departments and expedite the administration of clinical research. The accompanying flow sheet will serve as notice which studies require OnCore entry and tracking as well as the level of data input required for those studies. (See Attachment).

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

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 (ctms@buffalo.edu).

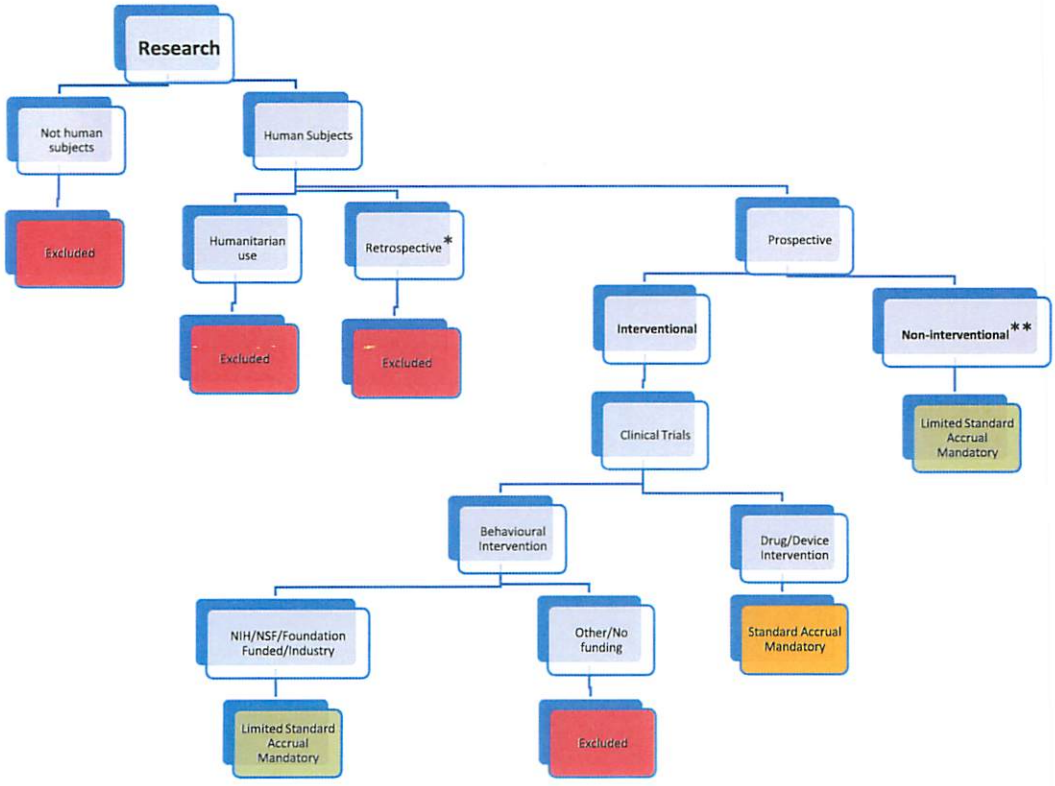
Thank you,

Sethi M.D.

Sanjay Sethi MD
Professor of Medicine
Assistant Vice President for Health Sciences
Director, Clinical Research Office

Deputy Director, Clinical and Translational Science Institute (CTSI)
Division Chief, Pulmonary/Critical Care/Sleep Medicine
University at Buffalo, State University of New York

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. The time to complete new a subject enrollment is approx. 5-`10 minutes, with subsequent visit information entered in 1-2 minutes.

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

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

**In limited circumstances aggregate enrollment data is permissible – Contact Oncore Coordinator (ctms@buffalo.edu) for more information/direction.

Time to complete each entry is approximately 1 minute per entry.

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

2021/2022 University Clinical Research Office Approval Authorities

Clinical Research Office

Pre Award Activities

Initiation of Funding Proposal for Industry, Assoc Director of Clinical Research
Approval of Coverage analysis, (Clinical Research Certified Coverage analysis manager or Assoc Director of Clinical Research)
Budget approval, Clinical Research Certified Coverage Analyst /Finance Associate

Post-Award Activities

Account balance Adjustments * need clarification of what this is

≤50% of direct cost balance Clinical Research Finance Manager CRO
≥50% of direct cost balance CRO (Associate Director)/Assistant VP OVPRED

Reconciling billing summary against Oracle

Clinical Research Finance Manager, Clinical Research Office
Clinical Research Certified Coverage Analyst /Finance associate
Clinical Finance Coordinator

Check Deposits

Clinical Research Finance Manager, Clinical Research Office
Clinical Finance Coordinator Associate, Clinical Research Office
Assoc Director Clinical Research office

Final Direct Expenditure Closeout Approval

** no staff member can approve his/her own expenditure
Direct Expenditure
Certified Coverage Analyst /Finance Associate
Clinical Research Finance Manager, Clinical Research Office
Clinical Finance Coordinator Associate, Clinical Research Office
>50% of direct cost balance on fixed price clinical trail contract to residual requires approval by the Associate Director of Clinical Research Office and VPRED/SPS

Financial Reports

Clinical Research Finance Manager, Clinical Research Office
Clinical Research Certified Coverage Analyst /Finance associate

Invoices to sponsors

Clinical Research Finance Manager
Clinical Research Certified Coverage Analyst /Finance associate
Clinical Research Finance Coordinator
Associate Director of Clinical Research Office

Wire Transfers

Clinical Research Finance Manager, Clinical Research Office
Clinical Research Certified Coverage Analyst /Finance associate
Clinical Research Finance Coordinator

Approved By:

Clinical Research Finance Manager Mary Beth Gareis
Clinical Research Certified Coverage Analyst /Finance Associate Rosanne Johnson
Clinical Research Finance Coordinator Kathy Abramowski