UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

Clinical Research Participant Enrollment and Tracking

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Effective Date: 3/1/2013

Revision History (dates of amendments): 02/4/2013**,** 11/15/2011, 11/14/2008, 09/17/2007

Responsible University Officers: Executive Dean for Research, Research Education and Innovative Medicine

Responsible Offices: Miller School of Medicine Office of Research, Research Education and Innovative Medicine (RIM), Regulatory Support and Quality Assurance (RSQA), University of Miami Office of Research Administration (ORA),

Policy Statement

All human participants (inpatient and outpatient) enrolled in clinical research protocols conducted at the University of Miami Miller School of Medicine (including any University of Miami facility, all affiliated and satellite locations as well as at any Jackson Health Systems (JHS) facility) **must** be registered in the Velos clinical trial management system, if the clinical research protocol meets any of the following criteria:

- The clinical research protocol involves testing a drug, device or biologic;
- The clinical research protocol involves a pharmacovigilance study;
- The clinical research proposal involves the study of an interventional or surgical procedure;
- The clinical research protocol involves clinic visits or conducting procedures, lab tests and/or medical interventions on a research subject billed through a commercial laboratory.

Research protocols **not** meeting the above criteria:
Research protocols limited to the following activities are **not** required to be registered in Velos; however, these **must** be registered in a university-recognized electronic system/database that is compliant with HIPAA and electronic security regulations:

- Registry studies
- Survey and questionnaire studies

- Retrospective chart studies
- Studies collecting samples for tissue banks, blood draws, pregnancy tests, urinalysis and other low cost screenings, etc. where the processing services on the sample(s) are performed within a UM research laboratory and ARE NOT sent to a commercial laboratory.

Note: Routine audits of electronic systems will be conducted to ensure that information is captured and maintained in an appropriate system, in accordance with this policy.

Note: Non-adherence with policy requirements by any Principal Investigator will result in Accountability Measures defined by the *UHealth Accountability Measures: Clinical Research Participant Enrollment and Tracking Policy* (issued concurrently with this policy revision effective 03/01/2013).

Reason for Policy

To ensure the protection of human subjects and billing compliance, this policy enforces the tracking of all clinical research subjects and any associated billing charges. Research billing charges and clinical care charges must be correctly associated, as necessary, to satisfy university policies and procedures and applicable federal regulations, including but not limited to those related to billing and regulatory compliance.

In addition, this policy enforces the tracking of all research protocols involving registry and survey studies as well as sample collection where the analysis of samples is not outsourced and not billable, by ensuring that all participants are enrolled in an appropriate electronic system / database that are compliant with HIPAA and electronic security regulations.

Who Should Know This Policy

Principal Investigators, Study Coordinators, Research Administrators, Office of Billing Compliance staff, Office of Research, Research Education and Innovative Medicine staff, Office of Research Administration staff, Vice Provost for Research, RSQA Office staff, Office of Research Information management staff, Centralized Research scheduling staff, University of Miami Hospital and JHS Clinical Trials Office staff, UMH staff, scheduling staff for Radiology, Cath Labs, Imaging Labs and Operating Rooms, Patient Registration staff, and Billing staff at all University of Miami Health System Facilities where clinical research is taking place, Central Billing Office staff.

Definitions

Clinical Trial Management System (CTMS)	An electronic or paper-based system that records clinical research participant enrollment data. The system must have properties appropriate to the characteristics of the study. The appropriateness of the CTMS will be assessed in audits.
JHS	Jackson Health Systems
Medicare Coverage Analysis (MCA)	Billing grid created for relevant studies that identifies how items and services delivered in connection with the study will be billed.

Office of Research Administration (ORA)	Responsibilities include initiating clinical research, including contract negotiation, budget, billing grids; and monitoring clinical research participant's research-related billing activity related to the items and services delivered in connection with a study.
Pharmacovigilance	Collecting, monitoring, researching, assessing and evaluating information on the adverse effects of drugs, devices, medications and biologicals
PI	Principal Investigator
RIM	Office of Research, Research Education and Innovative Medicine
RSQA	Regulatory Support and Quality Assurance
UChart	Electronic Medical Record used to manage study visit schedules, billable events and billing.
UM	University of Miami
UMH	University of Miami Hospital
Velos	Clinical Trials Management System for tracking participants in studies

Procedures

1. All Principal Investigators, research coordinators, as well as anyone with the ability to enter participants into the clinical research tracking systems must complete all required training on this policy and the Velos Clinical Trial Management System.

2. The Miller Office for Research, Research Education and Innovative Medicine will monitor study enrollments to ensure compliance with this policy.

3. If the PI disagrees with the requirement to enroll her/his study participants in Velos, s/he can submit a written appeal via email to the Executive Dean for Research, Research Education and Innovative Medicine (copy Assistant Vice President for Research Support Operations). The decision of the Executive Dean is final.

4. Select the appropriate Clinical Trial Management System to be used for each clinical trial, as defined above.

5. For all studies monitored in Velos:

    - Enter each participant within 48 hours of obtaining informed consent.

    - Enter the de-enrollment status of each participant within 48 hours of study withdrawal or the completion of all in-person study visits.

6. Within 24 hours of each participant visit, the PI or designee will call the centralized research scheduling staff to schedule all Research Services identified in the Medicare Coverage Analysis as billable to the study budget, with the exception of Radiology appointments and JHS or UMH hospital visits where UChart is not utilized.

   - The PI or designee will work with the centralized research scheduling staff to electronically link the study visit to the appropriate study protocol. In the absence of advance scheduling, the linkage of study visits to the appropriate study protocol within UChart must occur within 24 hours of the study visit.

   - For Radiology appointments that involve Research Services, the PI or designee will call the Department of Radiology to schedule the Radiology Research Services identified in the Medicare Coverage Analysis as billable to the study budget. The PI or designee will work with the Radiology scheduling staff to link the Radiology visit with the appropriate study account, by following the standard operating procedures for Radiology research studies.

   - For interventional or operative procedures or appointments that involve any Cath Lab or Imaging Lab, the PI or designee will call the clinical unit involved to schedule the intervention, procedure or imaging study identified in the Medicare Coverage Analysis as billable to the study budget. The PI or designee will work with the scheduling staff for the specific clinical unit to link the clinical service (intervention, operation or imaging) with the appropriate study account, by following the standard operating procedures for the involved research study.

   - In the event that a routine visit is converted to a Research Service visit, the PI or designee will be responsible to call the appropriate unit (e.g., centralized research scheduling staff or Radiology department, Cath Labs, Operating Room, or other Imaging Labs) immediately and direct them to electronically (or otherwise as needed) link the visit to the appropriate study account.

History

Amended: 02/04/2013, 11/15/2011, 11/14/2008, 09/17/2007

Effective: 03/01/2013

Related Information

UHealth Accountability Process: Clinical Research Participant Enrollment and Tracking Policy (url pending)

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Approval

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Name of Final Approver

Interim Executive Dean for Research, Research Education and Innovative Medicine

Title

[redacted]

Signature for Final Approval

March 1, 2013

Date of Final Approval

UHealth Accountability Measures: Clinical Research Participant Enrollment and Tracking Policy

Purpose

The Health System has established a Compliance Plan that articulates standards of behavior and ethical conduct. All Health System personnel shall comply with the standards set forth in the Compliance Plan and with all compliance-related policies and procedures. This document is specific to compliance with the Clinical Research Participant Enrollment and Tracking Policy.

Responsibility

The Chief Medical Compliance Officer is responsible for disciplinary policy. Actions will be reviewed and implemented in collaboration with the academic department Chair/Unit Director, the Office of Research, Research Education and Innovative Medicine (RIM), human resources and faculty affairs, as appropriate.

Policy and Procedure

Monthly reports are used by staff in the RIM office to analyze compliance with the Clinical Research Participant Enrollment and Tracking Policy. The following defines a progressive system of accountability measures which provides the flexibility to impose training and disciplinary actions consistent with the severity and repetitive nature of the violation.

1. **Notice of non-compliance**
   Each month, the PIs of studies that appear to be non-compliant (or only partially compliant) will receive a notice from the RIM Office. The PI will have 48 hours to respond in one of two ways: with a commitment to be compliant within a week or with an explanation of why this commitment is not required for this particular study. In the case of the latter, RIM will review the study and send a response to the PI. If after assessment by the RIM Office with final decision by the Executive Dean of Research, Research Education and Innovative Medicine, it is deemed that Velos enrollment is required for the study, the PI must bring the study into compliance within a week.

2. **Letter of Counseling**
   If a study has been marked for Velos compliance after a review and remains non-compliant (or only partially compliant) in the next month's analysis, a written letter of warning will be sent to the PI from the Executive Dean of Research, Research Education and Innovative Medicine, with copies to her/his Chair and the Chief Medical Compliance Officer. The letter will state that re-training via ULearn, *"Clinical Research Participant Tracking & Enrollment Training"* must be completed by the PI and all Research Coordinators actively working on the study within 7 days. In addition, the PI must bring the study into compliance within a week from re-training.

3. **Letter of Reprimand**
   Conduct justifying a Letter of Reprimand could include, but is not limited to:
   - A violation of Velos participant enrollment after the PI has received one Letter of Counseling
   - Failure to complete required compliance training or re-training
   - Engaging in patterns and practices that an appropriate compliance office determines should have been known to be improper.

   The letter will state that re-training via ULearn, *"Clinical Research Participant Tracking & Enrollment Training"* must be completed by the PI and all Research Coordinators actively working on the study within 7 days. The letter will detail the reason for the reprimand and request a written explanation from the PI as to the reason for policy violation and a summary of intent to bring the study into compliance and avoid future violations. The PI's Chair and the

Chief Medical Compliance Officer will be copied on the letter. The PI must bring the study into compliance within a week from re-training.

4. **Temporary Withhold of Permission for Continuation of Clinical Study**
   Circumstances that could warrant the temporary withhold of permission for continuation of a specific clinical study include, but are not limited to:
   - A violation of the Clinical Research Participant Enrollment and Tracking Policy, including training and re-training requirements, after receipt of a Letter of Counseling and a Letter of Reprimand.
   - A determination of a continuing pattern of policy violations by Executive Dean of Research, Research Education and Innovative Medicine and/or the Chief Medical Compliance Officer.
   - The Executive Dean of Research, Research Education and Innovative Medicine would request this action be taken by the Associate Vice Provost for Human Subject Research.

   The study could be reactivated upon re-training of the PI and Research Coordinators and having the study reach full compliance in enrollment.

5. **Suspension of Ability to Start or Continue Any Clinical Study**
   The most extreme sanction is the loss of the right to conduct any clinical studies on campus. This suspension letter can be issued, based on repeated violations or IRB recommendations, by the Associate Vice Provost for Human Subject Research or by the Institutional Official for Human Subject Research.