UHealth
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UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy

Effective Date: April 30, 2019

Revision History (dates of amendments): 09/17/2007, 11/14/2008, 11/15/2011, 02/04/2013, 03/01/2013, 03/15/2019

Policy Owners: Dean and Chief Academic Officer, University of Miami Miller School of Medicine; Chief Compliance Officer, Health Affairs, University of Miami Health System

Responsible Offices: Clinical Research Operations and Regulatory Support (CRORS); Miller School of Medicine Office of Research, Office of the Executive Dean for Research (EDR).; Research Compliance and Quality Assurance (RCQA); University of Miami Office of Research Administration (ORA), Office of the Vice Provost for Research, University of Miami Health System, Office of Compliance

1. **Policy Statement:** It is the policy of the University of Miami (UM) that each clinical research study that includes services billable to any 3rd party payer, except as noted in section 4 below, shall be registered in the Clinical Trial Management System (the "CTMS") called Velos. In addition:

   a. The Medicare Coverage Analysis (the "MCA") must be uploaded in the CTMS before any participants are enrolled in the study;

   b. The CTMS must be updated as follows:

      - each individual participant's status must be updated to "Informed Consent Signed" in the CTMS within 2 business days after informed consent is obtained;
      - "Off Study" status of each participant must be entered in the CTMS within 2 business days of participant withdrawal or completion of all in-person study visits;

   c. Faculty and staff engaged in clinical research studies must be trained on this policy and CRORS shall monitor compliance with this policy.

   Each invoice, or milestone report that generates an invoice, that will be presented to a study sponsor for payment in connection with a study, must be recorded in Velos, even if the study falls within an exception pursuant to section 4 below.

2. **Purpose:** To ensure that participant information and related study activities furnished pursuant to a clinical research study involving billable services are entered in the CTMS without delay so that the services are appropriately billed to the correct financially responsible party.

3. **Scope:** This policy shall apply to all UM investigators and research team members engaged in clinical research study activities performed in any UM hospital, clinic, physician's office, medical office building or ambulatory surgery center and any Jackson Health System (JHS) facility, including satellite locations, as well as research conducted in the community.

4. **Exceptions:** The following study types shall be exempt from the provisions of section 1.a and 1.b of this policy, provided there are no services billable to 3rd party payers performed in conjunction with the study activities:

a. Registry studies.
b. Survey and questionnaire studies.
c. Retrospective and prospective chart review studies.
d. Studies *ONLY* collecting samples for tissue banks, non-invasive exams, or conducting tests (such as pregnancy tests), blood draws, urinalysis and other procedures where the processing services on the sample(s) are performed within a UM or JHS research facility/laboratory and *ARE NOT* sent to a commercial laboratory.

5. **Duties of Principal Investigator:** Principal investigators are ultimately responsible for ensuring that study team members working under their supervision adhere to this Policy. In addition, Principal Investigators submitting new clinical research protocols for IRB approval shall be accountable for ensuring that all questions in the IRB electronic protocol submission and tracking system (eProst) are correctly answered. Principal Investigators must also notify the Office of Research Administration Pre-Award Team of any protocol amendment that results in a change to the Study Calendar or MCA within two (2) business days of the amendment's IRB approval. While a Principal Investigator may delegate any task set forth in this policy to a study team member, the Principal Investigator retains responsibility for ensuring such tasks are performed in compliance with this policy.

6. **Monitoring and Enforcement:** Compliance with this policy shall be monitored in accordance with the the Clinical Trial Management and Participant Enrollment Monitoring, Auditing and Reporting Procedures. Academic Department Chairs and/or Unit Directors are responsible for enforcing this policy. Principal Investigators and members of their study teams who fail to adhere to this policy shall be subject to corrective measures, which may include

training and disciplinary sanctions, up to and including the loss of the right to conduct any clinical studies as a UM Principal Investigator.

APPROVED BY

Name	Title	Signature	Date
Henri Ford, M.D.	Dean, Miller School of Medicine	*Signature on File*	4/30/2019
John L. Bixby, Ph.D.	Vice Provost for Research	*Signature on File*	4/30/2019
Barry Grosse, J.D.	Chief Compliance Officer, Health Affairs	*Signature on File*	4/30/2019