UC Irvine
School of Medicine

ONCORE UTILIZATION POLICY

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I. PURPOSE

This policy establishes requirements for the use of the institutional Clinical Trial Management System (CTMS), OnCore, to support accurate reporting of clinical research activities and billing compliance.

OnCore serves as the institutional system of record for clinical research management and integrates study information related to protocol status, regulatory status, and subject enrollment. Data maintained within OnCore also provides critical visibility into the clinical research activity occurring across the UCI Health system, including research utilization of clinical services, research space, and operational support resources. This transparency enables proactive risk mitigation and aids institutional decisions regarding the allocation and expansion of clinical research infrastructure. Maintaining accurate study and participant records within OnCore ensures that the research activities conducted by departments and study teams are appropriately represented in institutional data used to guide strategic planning, operational support, and research infrastructure investment.

II. SCOPE

This policy applies to all faculty, employees, trainees, and affiliates conducting clinical research within the UC Irvine School of Medicine when the research meets **one or more** of the following criteria:

1. The study utilizes UCI Health clinical space, services, or resources, including laboratories, imaging services, or clinical staff.
2. The study requires Epic integration, billing review, or coverage analysis.
3. The study is coordinated or supported by central clinical research coordinating unit, including:
    - Center for Clinical Research (CCR)
    - Stern Center for Cancer Clinical Trials and Research
    - Alpha Clinic (AC)
    - Memory Impairments and Neurological Disorders (MIND)

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This policy applies to all investigator-initiated, industry-sponsored, federally funded, or collaborative clinical studies that meet the above criteria.

III. DEFINITIONS

Clinical Trial Management System (CTMS): An institutional software platform used to manage clinical research activities including protocol tracking, regulatory milestones, participant enrollment, study calendars, and financial information.

OnCore: The enterprise CTMS used by UCI Health and the UC Irvine School of Medicine to manage clinical research studies and track operational and regulatory information related to clinical trials.

Protocol Record: The study-level record within OnCore that captures protocol information, sponsor details, regulatory milestones, study status, and operational attributes.

Participant Record: The subject-level record within OnCore that documents participant consent, enrollment, status changes, visits, and other study activities. Information from the participant record is automatically integrated to the Epic EHR.

IV. POLICY

A. Required Use of OnCore

All clinical research studies within the scope of this policy must maintain an active and accurate study record in OnCore.

The OnCore system shall serve as the institutional system of record for:

- Protocol registration
- Study activation and status tracking
- Participant enrollment and status
- Study progress monitoring
- Institutional reporting and metrics

Accurate data entry within OnCore enables institutional oversight of clinical research activity and ensures that the contributions and resource utilization of departments and study teams are

reflected in the data used to support operational planning and research infrastructure development.

B. Timeliness of Updates

All required updates to protocol records and participant records must be entered into OnCore within 24 hours of any change in protocol or participant status, including but not limited to:

- IRB approval status
- Protocol status changes
- Participant enrollment and status changes

V. ROLES AND RESPONSIBILITIES

Principal Investigators (PI): Principal Investigators are responsible for ensuring that all clinical research studies conducted under their oversight comply with this policy. This includes ensuring that:

- An OnCore protocol record is established and Opened to Accrual *prior to study enrollment* for all studies within the scope of this policy.
- All participant enrollment and status information is accurately maintained within the system.
- Study teams maintain timely updates to protocol and participant records, consistent with the 24-hour update requirement.

While operational responsibilities for data entry may be delegated to study team members, the Principal Investigator retains the ultimate responsibility for ensuring accurate study representation within OnCore.

Study Teams: Clinical research coordinators and other study personnel responsible for study management must:

- Maintain protocol records and study status updates consistent with institutional standards.
- Enter or update participant information within 24 hours of enrollment or any change in participant status.
- Work collaboratively with institutional research support units to maintain accurate study records.

Departments and Research Units: Departments conducting clinical research are responsible for:

- Ensuring that study teams are aware of and adhere to this policy.

- Supporting the operational infrastructure needed to maintain accurate study records within OnCore.

Departments should encourage consistent use of OnCore to ensure that clinical research within their units is accurately represented in institutional reporting and planning efforts.

Institutional Research Support Units: Institutional clinical research support units, including CCR, CFCCC, AC, and MIND are responsible for:

- Providing guidance, training, and operational support related to OnCore use.
- Assisting study teams with protocol registration and system navigation as appropriate.
- Supporting institutional reporting related to clinical research activity captured in OnCore to inform institutional planning, research operations support, and infrastructure allocation.

VI. COMPLIANCE AND OVERSIGHT

Compliance with this policy may be monitored through institutional research oversight and routine review of OnCore records.

Failure to maintain required study records within OnCore may result in:

- Requests for corrective action from the study team or department
- Limitations on access to certain institutional research services or resources

VII. STUDIES EXEMPT FROM ONCORE

Certain categories of research do not require the creation or maintenance of an OnCore record when they do not utilize UCI Health clinical resources, services, or clinical space.

Examples of studies that are generally exempt from OnCore requirements include:

- Basic science or laboratory-based research that does not involve human subjects receiving clinical interventions.
- Retrospective chart reviews or studies involving analysis of existing clinical data or specimens that do not involve subject encounters.
- Survey-based research that does not involve subject encounters, clinical interventions (e.g. blood draw, point-of-care testing, or buccal swab) or use of clinical services.
- Secondary data analysis or studies using previously collected datasets that do not involve subject encounters.

- Educational or quality improvement projects that do not meet the definition of human subject research requiring clinical research management as outlined by the UCI IRB.

If a study initially believed to be exempt later utilizes UCI Health clinical space, services, or clinical research infrastructure, an OnCore record must be created at that time. Investigators and study teams who are uncertain whether a study requires an OnCore record should consult with the appropriate institutional research support unit during feasibility consideration.

VIII. QUESTIONS

Questions regarding this policy can be directed to Eric Vilain, Vice Dean for Clinical Research (evilain@hs.uci.edu), Carey Berkowick, Director of Research Operations (cberkow1@hs.uci.edu) or Shauna Stark, Assistant Dean of Research Operations (starks@hs.uci.edu).

IX. REFERENCES

OnCore Support Documents