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OnCore Access and Use Policy

OnCore is an Online Collaborative Research Environment (OnCore) that is a comprehensive, web-based Clinical Trial Management System (CTMS). It was developed to support investigators, regulatory and research coordinators as a centralized place to manage all their study protocols and subjects. To effectively track and manage clinical research studies, the University of Arizona requires certain studies to use OnCore to create a portfolio of active clinical research studies, ensure compliant research billing, and capture study accruals.

Studies that must be entered into OnCore

Any study requiring an informed consent form that meets either of the following requirements must utilize OnCore:

- The study PI is a faculty member with a primary appointment in any UAHS college; or
- The study involves procedures that will be billed by Banner Health

Studies that do not meet the above criteria (e.g. retrospective studies, retrospective chart reviews, or registry studies) must be entered in OnCore only when required by the department or center.

Requirements to Access OnCore

Prior to obtaining access to OnCore, all users much complete the following:

- OnCore User Agreement
- CITI Human Research Training, as required by the University for personnel in research involving human subjects, with refresher training done every four years
- HIPAA Training, with annual recertification
- Information Security Awareness Training, with annual recertification
- OnCore Training consistent with the OnCore role, with annual recertification

Requirements for Additional or Refresher Training

Additional training may be required in the following circumstances:

- New OnCore role added to existing account
- Account is inactive in OnCore for six months or more
- Lack of understanding or compliance is demonstrated with the user role in OnCore
- Recertification as required by each training module

Requirements for Updating Activity in OnCore

- IRB approved protocol or consent documents, changes to the IRB expiration date, and associated IRB approval letters must be entered into OnCore in a timely manner
- Changes in protocol status must be recorded in OnCore in a timely manner
- Subject consent document(s) must be uploaded into OnCore at the time of consent
- Subject status dates must be entered into OnCore within 24 hours of a change in status
- Subject visits must be checked into OnCore within 24 hours of occurrence
- When a new calendar version is released, active subjects must be moved to the new version of the calendar where calendar changes are applicable

There are two options to capture accruals in OnCore. Subjects will either be registered to a study and study visits will be checked in or accruals will be captured as Summary Accrual.

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Use of Summary Accrual

Summary Accrual refers to an OnCore function that reports the total number of subjects enrolled in a clinical research study using minimal subject information. Summary Accrual can track subject accruals "in bulk" rather than individual subject registration and subject visit tracking and is appropriate for some studies that do not require use of Banner facilities or Banner billing, and for which detailed use of OnCore may not be practical. Studies with the following characteristics may qualify for Summary Accrual:

- The study does not have an NCT #, there are no procedures occurring in Banner space in the Payor Coverage Analysis (PCA) and no Financials to be entered into OnCore.
- The study has an NCT # but there are no procedures occurring in Banner space in the PCA and no Financials to be entered into OnCore.

If your study meets all of the criteria above and has not been designated as Summary Accrual in OnCore and you would like your study to be considered for Summary Accrual, please email OnCoreSupport@arizona.edu. Clinical Research Administration makes the final decision as to whether a study will qualify as a Summary Accrual study.