THE UNIVERSITY OF ARIZONA

Clinical Trials Newsletter

Clinical Research Administration provides support to Health Sciences Investigators and Study Staff throughout the life cycle of clinical research projects. Our experienced and knowledgeable team can provide regulatory support, coverage analysis and budget development, contract and budget negotiation, assist with tracking your studies in OnCore, and offer post award support.

Click here for a checklist and more information about approvals you may need to initiate your project, and check out the **Coordinator Corner** for additional resources and tools!

Announcements

Simple Solutions from OnCore Support:

It is important that subject demographic information in OnCore is entered exactly as it appears in Cerner. OnCore shares information about a subject's participation in a research study with Cerner once the subject is accrued (listed as On Study in OnCore). If the subject demographic information is not accurate, the OnCore-Cerner connection cannot be made.

Also, never add characters to an MRN, such as letters or leading zeros. The only exception is a screen failure when the subject needs to be rescreened. This does not affect the OnCore-Cerner connection because screen failed subjects are not accrued to the study.

Reminder - Export Control Checklist Review:

Export Control Checklist review is required prior to signature of all Sponsored Agreements and all Confidentiality Agreements when any of the criteria specified in the instructions or on the respective checklist are met.

When Export Control Checklist review applies to your agreement, please:

1. **Complete the applicable sections** of the appropriate checklist form
2. **Identify the person completing Part A** with their printed name
3. **Include the completion date**
4. **Submit the partially completed form** along with your **Research Administration Portal (RAP)** submission.

IIT/IIS Review Rebranded to Study Readiness Assessment (SRA):

Effective July 1st this new review process will be mandatory for any **investigator-initiated COM-T**.

Which Studies Require SRA Review?
The SRA is required for all **COM-T Investigator-Initiated**. This includes **ANY** study that meets the following criteria:

- **UA Origin & Management** – The study originated at and is centrally managed by the University of Arizona.
- **PI-Led Design** – The study is developed, designed, initiated, and led by a UA Principal Investigator (not an external sponsor).
- **Flexible Funding** – The study can be funded by academic institutions, government agencies, foundations, or industry, provided the investigator drives the study design and execution.

This assessment will thoroughly evaluate the following key areas of your project:

- **Merit Review** – Scientific validity, peer review status, and study design importance.
- **Feasibility** – Recruitment practicality, timeline viability, and target population access.
- **Budget/Funding** – Financial coverage, billing details, and secured funding sources.
- **Human Subjects Protection** – Informed consent processes and participant safety monitoring plans.
- **Regulatory Compliance** – IRB status, FDA/IND/IDE tracking, and conflict of interest disclosures.
- **Personnel/Resources/Procedures** – Staff credentials, training, clinical space, and equipment availability.

- **Data/Specimen Collection & Management** – Secure data storage, coding methods, and biospecimen logistics.
- **Risk Assessment** – Identification and mitigation of clinical, financial, and organizational risks.
- **Banner Resources/Involvement** – Coordination with Banner Health facilities, EHR systems, and ancillary approvals.
- **AI/Machine Learning** – Software algorithm vetting, data privacy protocols, and institutional AI governance.

Ready to Submit?
Please submit your project via the portal:
Click Here to Submit Your Study Readiness Assessment

Questions?
If you have questions regarding this transition or the assessment criteria, please contact **SRA-Committee@arizona.edu.**

Clarifying MTA Submissions:

The Office of Research Contracts & Agreements recently distributed important updates regarding Material Transfer Agreements (MTAs) through the RAM Talk listserv on May 20, 2026. We want to highlight an important distinction regarding MTA submissions to avoid delays.

Special Handling for Human Materials:
Please note that there is **no change** to your submission process through Clinical Research Administration's **Research Administration Portal "RAP"** for the following MTA requests:

- Human materials (outgoing) – MTAs transferring materials to an external partner which originated from a human subject
- Human materials (incoming) – MTAs receiving materials from an external partner which were collected under an IRB Protocol. Note: If these materials are being PURCHASED by UofA (excluding transfer fees), please contact Supply Chain team for assistance at **fnsv-purchasing@arizona.edu**

Lapse in Insurance Coverage:

As a reminder, if a study subject participating in a clinical trial has a lapse in insurance, we may not be able to shift routine care costs to sponsors.

Please reach out to the following teams with questions:

- **Patient Assistance Services (PAS) Department** can help patients explore financial options. Patients must qualify for additional assistance under a standard Banner policy in order to have the sponsor pay for routine costs of a clinical trial.
- **Clinical Research Administration**: can help if you have any questions about the coverage analysis and/or billing designations.

Banner Hospital Billing Update:

May 2026 bills have been reviewed and emails have been sent out to the corresponding UA Departments via UA Box Health. June 2026 invoices will be distributed by the second week of August 2026.

Additional resources available on our **website**

OnCore Training

OnCore Trainings in EDGE:

OnCore users can complete training modules according to their own schedule or retake refresher trainings when needed.

Subject Management Training is now available in EDGE Learning for individual completion.

MORE INFORMATION

Next - Clinical Research Professional Meeting

Thursday,
August 20th
3:00-4:30pm

Are you new to the University of Arizona Health Sciences (UAHS) research community and would like to keep up with the ever-evolving changes in UAHS research?

JOIN MEETING

Please join us for our Bi-Monthly CRP meeting.

Join Zoom Meeting:
https://arizona.zoom.us/j/82277308307

Email **here** if there are specific topics you would like covered at upcoming meetings.

Calendar Updates

OCT 21

Clinical Research Professional Meeting

Location: https://arizona.zoom.us/j/8227730830
Time: 12:00 pm - 1:30 pm

DEC 17

Clinical Research Professional Meeting

Location: https://arizona.zoom.us/j/8227730830
Time: 3:00 pm - 4:30 pm

Land Acknowledgment