



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:

Visit dates in the OnCore subject calendar are based on the protocol schedule of events and are unique to each subject. Dates calculate automatically based on status dates entered by the CRC in the subject console.

You can easily check to see which status dates will affect the subject calendar by going to the Specifications console in OnCore and looking at the Treatment Visits tab. The Start Date column shows the status dates that will open each section of the calendar.

Treatment				
Seq. No.	Name	Start Date		
** 10	Screen - Arm 1	Consent Signed		
** 20	Screen - Endo	Consent Signed		
** 30	Screen - Imaging	Consent Signed		
40	Arm 1 Part 1 - Ibuprofen/Placebo	On Treatment		
50	Arm 1 Part 2 - Ibuprofen/Placebo	On Treatment		
60	Arm 2 - Ibuprofen	On Treatment		
70	EOT Visit	Off Treatment		
Follow-Up				
Seq. No.	Name	Start Date	Unit	Visit(s)
100	Follow Up	On Follow Up	Day	30,60,90,120,150,180

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.

OnCore Access and Use Policy:

More information on this policy can be found [here](#).

OnCore Billing Compliance Requirements:

- **Compliance:** The billing designation is set using Medicare Billing rules, input from PI, approval by Banner (the medical biller), and the signed contract between the sponsor and the University of Arizona.
- **Financial Equality:** Each procedure must be billed the same way for all subjects. If a procedure is billed to insurance for one subject, the sponsor cannot pay for that same procedure for another subject.

- The **correct** billing designation is built into the OnCore calendar, so the CRC can confidently log visits and procedures.
 - If the CRC has a question or concern about a billing designation, please reach out to OnCore Support (OnCoreSupport@arizona.edu), so we can review the situation and discuss with the coverage analysis/budget team.

Inability to follow the requirements will result in remediation including training and supervisor inclusion.

Banner Hospital Billing Update:

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

[JOIN MEETING](#)

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?

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/82277308307>

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

You are receiving this email from the **UAHS Research Admin Clinical Trials** mailing list.

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[Land Acknowledgment](#)