Navigating the Clinical Trial Process

New to clinical trial research at UAHS? Where do you start? How do you navigate all of the intertwined processes to get your study up and running?!?! Never fear, we are here to guide you through the process!!

Let us help you through the process by reaching out to our navigating experts.

- Clinical Trial Regulatory: regulatory@email.arizona.edu
- Kerry-Ann Suckra, kerryanns@email.arizona.edu, (520) 621-2029
- Stephanie Martinez, ssmartin@email.arizona.edu, (520) 626-8079

Paying Subjects by Check (Disbursement Voucher)

Financial Services Office (FSO) has a form on their website that should be used when requesting each payment for study subjects paid by check. Subjects are required to sign this form prior to payment. This form may be used in place of an IRS W9 form.

Please contact FSO at (520) 621-9097 or accts_pay@fso.arizona.edu with any questions.

NEW! UAHS Contract Cover Sheet

We have launched a new UAHS Contract Submission Cover Sheet. This smart form makes it easy to fill out and provide as much information possible – making it our goal to process your contracts more efficiently! Please find the new cover sheet (attached) on the UAHS Research Administration website: https://research.uahs.arizona.edu/content/contracts.

ALL contracts must be submitted with the cover sheet filled out completely.

Questions? Please contact UAHSContracts@email.arizona.edu.

Industry-Sponsored Investigational Drug Studies

Industry-sponsored investigational drug studies will have an Investigational New Drug number (IND #) assigned. This number is required to be entered into the Research Intake Form (RIF) and is required to finalize the Coverage Analysis (CA).

If you can't find the IND # on the first few pages of the protocol or the investigator brochure, please reach out to the sponsor for the number before submitting your RIF application. If the project is IND exempt, please upload the IND exemption letter from the sponsor.

If your project is an Investigator-initiated drug study, please provide the IND # and / or upload the completed IRB Appendix for Drugs for IND exempt studies.
Billing Compliance Process for Non-Oncology Studies

It is very important for study teams to log study visits into Banner’s Click® CTMS. Study visits should be logged within 24 hours whenever Banner Health (BH) services are utilized for a research study (i.e. medical imaging, ECG, clinic visits, etc.). These services are typically scheduled via Cerner on behalf of the research patient.

ALL study visits that include BH services MUST be logged into CTMS.

- This includes research-related AND routine/standard of care.
- UA Coverage Analysis (CA) provides detailed information for billing designations.
- **This process ensures that bills are routed to the correct payor and helps to alleviate and protect a study subject from being billed for research-related services.**

**UA Study Team Responsibility:**

- Non-activated study calendar – follow the interim research process (attached) and log a Public Comment in the CTMS study shell with patient name, DOB, Visit Name, BH Service.
- BHRI Finance (BHRF) is notifying study teams when the study calendars are activated in CTMS.
- Activated study calendar – log the study visit in the activated study calendar. **DO NOT log a public comment.**

BHRF reviews and validates all charges logged into CTMS against what has been billed in Cerner. Charges are then generated and billed to the research study or subject’s insurance.

- This step is comparable to the charge validation that was previously done by the study team in EPIC.

If you have questions regarding the CTMS calendar (build, activation, visit entering process, etc.) contact Barb Summers at (602)-839-6026 (Barbara.Summers@bannerhealth.com).

Contact Research Administration (crc@email.arizona.edu) with questions regarding the coverage analysis.

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**The Clinical Trials Team has Expanded!**

Stephanie Martinez has joined our team as a Regulatory Coordinator to support UAHS faculty for both Tucson & Phoenix campuses. She has been at UA for over 5 years and has experience in regulatory practices including study start-up, maintenance, IRB & FDA reporting requirements for human research. Stephanie also has a thorough understanding of drug development, clinical research, NIH practices & clinical practices associated with federal standards. In addition, she brings her experience with the NIH Clinical Trials Reporting Program (CTRP), ClinicalTrials.gov, and NIH/NCI designation reporting.

Stephanie can be reached at: ssmartin@email.arizona.edu or 520-626-8079
UAHS Clinical Research Professionals (CRP) Group Meeting

If you are new to the University of Arizona Health Sciences (UAHS) research community and/or to keep up with the ever-evolving changes in UAHS research, please feel free to attend the monthly CRP group meetings. Meeting time and location changes from month to month and an email reminder is sent out prior to the monthly meeting.

To add your name to the listserv, please send an email to clinicalresearchcoordinators-request@list.arizona.edu with "SUBSCRIBE" in the subject line.

The next meeting is Thursday, October 18, 2018, from 3 pm to 4:30 pm in the Health Sciences Library, room 4150A, Tucson.

COM-Phoenix Video Conference locations:
- BUMCP Classroom 1
  (1441 N 12th Street, 1st floor)
- COMP BSPB Conf Room E907
  (475 N 5th Street, 9th floor)

CRP Group upcoming meeting schedule:

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<tr>
<th>Date</th>
<th>COM-Tucson location</th>
<th>COM-Phoenix Video Conference location</th>
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| Thurs., Oct 18, 2018 | UAHS Rm 4150A        | BUMCP Classroom 1
(1441 N 12th Street, 1st floor)
COMP BSPB Conf Room E907
(475 N 5th Street, 9th floor) | 3pm - 4:30pm |
| Wed., Nov 21, 2018  | UAHS Rm 4150A        | BUMCP Classroom 1
(1441 N 12th Street, 1st floor)
COMP BSPB Conf Room E907
(475 N 5th Street, 9th floor) | 12pm - 1:30pm |
| Thurs., Dec 13, 2018 | UAHS Rm 4150A        | BUMCP Classroom 1
(1441 N 12th Street, 1st floor)
COMP BSPB Conf Room E907
(475 N 5th Street, 9th floor) | 3pm - 4:30pm |
GENERAL INFORMATION AND RESOURCES

UAHS Research Administration provides guidance and assistance with the following:

- Our website: https://research.uahs.arizona.edu/
- Coverage Analysis (CA) development: contact crc@email.arizona.edu
- Clinical Trial Budget development/negotiations: contact crc@email.arizona.edu
- Contracts (CDAs, NDAs, incoming MTAs): contact UAHSCONtracts@email.arizona.edu
- Routing and monitoring of contracts (CTAs, data use, amendments): contact UAHSCONtracts@email.arizona.edu
- Clinical Trial Regulatory and IRB: contact regulatory@email.arizona.edu
- Post-Award accounting and auditing: contact CTFinance@email.arizona.edu

UAHS Project Status Report: https://research.uahs.arizona.edu/facilities-and-resources

Research Intake Form (RIF):
Instructions and the form can be found here: http://research.uahs.arizona.edu/clinical-trials/research-intake-form

If you have questions, email Research Administration at regulatory@email.arizona.edu.

ClinicalTrials.gov Assistance:

- **Non-cancer studies**: 
  - Clinical Trial Regulatory: regulatory@email.arizona.edu
  - Kerry-Ann Suckra, kerryanns@email.arizona.edu, (520) 621-2029
  - Stephanie Martinez, ssmartin@email.arizona.edu, (520) 626-8079
- **Cancer studies**: Amy Selegue, UACC-NCTN@uacc.arizona.edu, (520) 626-0301

IRB Training Opportunities

The IRB offers training on a variety of topics each month. This is a great way to stay updated on current processes and have your questions answered.

The list of upcoming sessions is located on the IRB website with instructions for signing up through UAccess Learning.

https://rgw.arizona.edu/compliance/human-subjects-protection-program/irb-training-opportunities

UA Clinical and Translational Science (CATS) Research Center website: http://cats.med.arizona.edu/home

Banner Badge Request: Contact clinicalresearch@email.arizona.edu

Banner Cerner Help: Contact the Banner IT service desk at (602) 747-4444 or in Tucson, call (520)-694-HELP (4357). Select Option 6 for assistance with Multi-factor Authentication.

Cerner Access/Training: Contact Ashwini Roy-Chaudhury at (520) 626-2527 or aroychaudhury@email.arizona.edu

Banner CTMS Training and General Questions: Contact Barb Summers at (602) 839-6026 or Barbara.Summers@bannerhealth.com

REDCap Questions/Training: Contact redcap@email.arizona.edu

Sonora Quest Laboratories (SQL) 2018 Reference Manual: To request an electronic copy, contact crc@email.arizona.edu

SQL Care360 Training: Contact the Customer System Team at (602) 685-5465 or SQLCustomerSystems@SonoraQuest.com to schedule training. Please be sure to include your SQL departmental account number when requesting training.