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, semartin@email.arizona.edu, (520) 626-8079

Paying Subjects by Check (Disbursement Voucher)

Financial Services Office (FSO) has a form on their website (https://www.fso.arizona.edu/node/25) 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 provide as much information possible to help us 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

ClinicalTrials.gov Site Information Listings

ClinicalTrials.gov is a web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. Studies are generally submitted to the web site (that is, registered) when they begin. Information should be updated throughout the study.

Please review and update study listings for your research group. Listings should contain the following information:

- Be sure a general office phone number is listed
- Be sure all staff listed are current
- Site Location should be listed as “University of Arizona”
  - Banner University Medical Center is a facility

Please contact our office with any questions: regulatory@email.arizona.edu
Billing Compliance Process for Clinical Trials Purchasing BH Services

The University of Arizona is obligated to log ALL study visits into each CTMS (Click® & OnCore). Study visits must be logged within 24 hours of occurrence 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 (Click® & OnCore) within 24 hours.

- 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 Click® 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 each 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 Click® CTMS calendar (build, activation, visit entering process, etc.), contact Barb Summers at (602)-839-6026 or Barbara.Summers@bannerhealth.com.

Questions regarding the coverage analysis? Contact Research Administration at crc@email.arizona.edu.

---

Happy Holidays
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, December 13, 2018, from 3 pm to 4:30 pm in the UAHS 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:

<table>
<thead>
<tr>
<th>Date</th>
<th>COM-Tucson location</th>
<th>COM-Phoenix Video Conference location</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wed, January 16, 2019</td>
<td>AZCC 2920</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>12:00pm - 1:30pm</td>
</tr>
<tr>
<td>Thurs, February 21, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>3pm - 4:30pm</td>
</tr>
<tr>
<td>Wed, March 20, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>12:00pm - 1:30pm</td>
</tr>
<tr>
<td>Thurs, April 18, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>3pm - 4:30pm</td>
</tr>
<tr>
<td>Wed, May 15, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>12:00pm - 1:30pm</td>
</tr>
<tr>
<td>Thurs, June 20, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>3pm - 4:30pm</td>
</tr>
<tr>
<td>Wed, July 17, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>12:00pm - 1:30pm</td>
</tr>
<tr>
<td>Thurs, August 15, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>3pm - 4:30pm</td>
</tr>
<tr>
<td>Wed, September 18, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>12:00pm - 1:30pm</td>
</tr>
<tr>
<td>Thurs, October 17, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>3pm - 4:30pm</td>
</tr>
<tr>
<td>Wed, November 13, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>12:00pm - 1:30pm</td>
</tr>
<tr>
<td>Thurs, December 12, 2019</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor), COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
<td>3pm - 4:30pm</td>
</tr>
</tbody>
</table>
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.