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.

**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 CA.

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**Banner CTMS Coordinator Training in Tucson**

Study Coordinator training on Banner’s Click® CTMS will be held on Tuesday, July 31. There will be two training sessions from 10:00am – 12:00pm and 1:00pm – 3:00pm. Training will be held in the UAHS Library computer lab, room 2102.

To sign up and/or if you have questions about the training, please contact:
- Ashwini Roy-Chaudhury at (520) 626-2527, aroychaudhury@email.arizona.edu, or
- Barb Summers at (602)-839-6026, Barbara.Summers@bannerhealth.com.
The Clinical Trials Team is Expanding!

We have new team members who have joined us in our Tucson office.

Amy Chenail worked as a Solo Librarian at several educational institutions including Mukogawa Fort Wright Institute (MFWI) in Spokane WA, an overseas department of Mukogawa Women’s University in Nishinomiya, Japan, Higher Colleges of Technology-Dubai Women’s College (DWC), and as the Librarian at the Center for English as a Second Language (CESL) at the University of Arizona.

Rachel Kreisberg worked as a program coordinator for the Helicobacter pylori infection and Gastric Cancer research project conducted through the UACC in collaboration with the CoPH, NAU, the Navajo Nation, and the Indian Health Service.

Amy and Rachel will assist with the Research Intake Form (RIF) completeness check for submitted projects, track feasibility review/approval and assist with questions regarding the RIF submission process.

Courtney Olson served as an IRB Coordinator working with the full UA IRB Committee to facilitate the approval of high-risk, FDA-regulated drug and device studies.

Lillian Mendibles served as a Research Specialist for Sarver Heart Center providing study coordination for multiple cardiovascular clinical research studies.

Courtney and Lillian will assist with coverage analyses and budgets.

Their contact information is:
Amy Chenail, achenail@email.arizona.edu, 520-626-6919
Courtney Olson, courtneyolson@email.arizona.edu, 520-626-9753
Lillian Mendibles, lmendibles@email.arizona.edu, 520-626-3593
Rachel Kreisberg, rachelkreisberg@email.arizona.edu, 520-626-4557

Cerner Access for Study Monitors

Study monitors can gain access to Cerner by following the process listed below. Cerner access for monitors should be made no less than 10 days in advance of their scheduled visit. Provisions will be made for an unscheduled urgent monitor visit which will be processed in 24 hours.

For monitors who have previously had access granted, their access will need to be reactivated for the dates that they will be on site.

To request access, please complete the two forms (see attached):
- Monitor Request Form (complete all information in the form)
- Computer Access Request (CAR) Form
- Be sure to select the "Type of data requested" when completing the Monitor Request Form
- Have your supervisor complete the signature line at the bottom of the CAR Form
- Send the two completed forms via encrypted email to Mandy Childs at mandy.childs@bannerhealth.com.
  Emails should be encrypted as the Monitor Request Form includes Protected Health Information (PHI).

If you have any additional questions, please call the BUMC Help Desk phone number: (520) 694-4357 (also located at the top of the CAR form).
Research Compliance Quality Assurance Program is new to Research, Discovery & Innovation (RDI)!

RDI’s Research Compliance Quality Assurance (RCQA) Program was recently created to enhance the University of Arizona’s research enterprise through improved quality assurance, process improvement, and documentation practices. We work with and through many of the centralized compliance programs you are already familiar with (e.g., Human Subjects Protection Program, HIPAA Privacy Program, Institutional Animal Care and Use Committee, Research Laboratory & Safety Services, and Conflict of Interest Program), as well as directly with research groups across campus. We assist with internal and external reviews, as well as conduct both trainings and audits related to research compliance.

Through process assessments and compliance metrics, the RCQA Program helps to identify areas in need of improved compliance training and resources, provides regulatory compliance oversight (often in concert with existing compliance programs), and leads process improvement initiatives.

The RCQA Program staff includes Blanca Pernic, the RCQA Officer, and Christine Melton-Lopez, the RCQA Associate.

The RCQA Program offers training on Good Documentation Practices and How to Prepare for an Audit.

Contact Blanca Pernic at bpernic@email.arizona.edu or Christine Melton-Lopez at melton1@email.arizona.edu if you would like to attend an existing training or to set up a customized training for your unit.

Contracts for UAHS

UAHS contracting services has a new email address. Please send your CDAs/NDAs, DUAs and incoming MTAs to UAHSContracts@email.arizona.edu with the attached cover sheet.

All other UAHS contracting agreements will continue routing to CRS-ORD@email.arizona.edu.

Clinical Trial Agreements will continue to be submitted via the Research Intake Form (RIF).

We will keep you updated as the transitions occur and the routing changes for other contracting agreements.

UAHS Project Status Report

The UAHS Project Status Report is published each Monday and reflects the current coverage analysis, budget, and contract status for all projects pending with UAHS Research Administration (RA). The report is provided in a downloadable excel format and is located here: https://research.uahs.arizona.edu/facilities-and-resources.

You will need to log in with your UA NetID.

The report is located on the RESOURCES page.

Click on the Contract Status Report (EXL) link to download the report.
Documents Required for the Research Intake Form (RIF) Submission

Just a friendly reminder to be sure to fully complete your application and upload all essential documents prior to submitting your application. If a question does not apply to your study please be sure to answer “N/A” or “None”. Incomplete and/or incorrect applications may cause a delay to the study startup process (e.g., receiving Banner feasibility approval, contract assignment). Please see the table below for guidance on required essential documents by study type.

<table>
<thead>
<tr>
<th>Funding Categories</th>
<th>Externally Funded</th>
<th>Internally Funded</th>
<th>Grants</th>
<th>Retrospective Chart Review</th>
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<tbody>
<tr>
<td>Contract Template (WORD draft)</td>
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<tr>
<td>Budget Template (EXCEL or WORD draft)</td>
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<tr>
<td>Protocol</td>
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<tr>
<td>Informed Consent Form(s) or relevant IRB Appendix</td>
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<tr>
<td>Schedule of Events/Study Schema</td>
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<tr>
<td>IRB Application for Human Research</td>
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<td>X</td>
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<tr>
<td>IRB List of Research Personnel</td>
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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 Wednesday, July 18, 2018, from 12 pm to 1:30 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:

<table>
<thead>
<tr>
<th>Date</th>
<th>COM-Tucson location</th>
<th>COM-Phoenix Video Conference location</th>
<th>Time</th>
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<tbody>
<tr>
<td>Wed., July 18, 2018</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor)</td>
<td>12pm - 1:30pm</td>
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<td></td>
<td>COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
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<tr>
<td>Thurs., August 16, 2018</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor)</td>
<td>3pm - 4:30pm</td>
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<td>COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
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<td>Wed., September 19, 2018</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor)</td>
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<td>COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
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<td>Thurs., October 18, 2018</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor)</td>
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<td>COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
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<td>Wed., November 21, 2018</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor)</td>
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<td>COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
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<td>Thurs., December 13, 2018</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor)</td>
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<tr>
<td></td>
<td></td>
<td>COMP BSPB Conf Room E907 (475 N 5th Street, 9th floor)</td>
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</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 crc@email.arizona.edu.

ClinicalTrials.gov Assistance:
Non-cancer studies:
Clinical Trial Regulatory: regulatory@email.arizona.edu
  Tucson: Kerry-Ann Suckra, kerryarns@email.arizona.edu, (520) 621-2029
  Phoenix: Elena Young, elenay@email.arizona.edu, (602) 827-9963

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) 2017 Reference Manual: To request an electronic copy, contact crc@email.arizona.edu

SQL Care360 Training: Contact the Customer System Team at (602) 685-5485 or SQLCustomerSystems@SonoraQuest.com to schedule training. Please be sure to include your SQL departmental account number when requesting training.