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.

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, rachellkreisberg@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>
</tr>
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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>
<td>X</td>
<td>X</td>
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<td></td>
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<tr>
<td>Informed Consent Form(s) or relevant IRB Appendix</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schedule of Events/Study Schema</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRB Application for Human Research</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>IRB List of Research Personnel</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</tr>
</tbody>
</table>

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@email.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>
</tr>
</thead>
<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>
</tr>
<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>
</tr>
<tr>
<td>Wed., September 19, 2018</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor)</td>
<td>12pm - 1:30pm</td>
</tr>
<tr>
<td>Thurs., October 18, 2018</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor)</td>
<td>3pm - 4:30pm</td>
</tr>
<tr>
<td>Wed., November 21, 2018</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st floor)</td>
<td>12pm - 1:30pm</td>
</tr>
<tr>
<td>Thurs., December 13, 2018</td>
<td>UAHS Rm 4150A</td>
<td>BUMCP Classroom 1 (1441 N 12th Street, 1st 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/facilitites-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) 685-5465 or SQLCustomerSystems@SonoraQuest.com to schedule training. Please be sure to include your SQL departmental account number when requesting training.
Interim Process for Study Visit Documentation

This interim process only applies to studies that are NOT in an “Active” state in Click CTMS.

If a study is in an “Active” state, patients are logged in Click CTMS using the normal process.

Navigate to the Study Summary Page

- Logging a study visit for the interim process is completed from the Study Summary page. The Study Summary page has the study title and study details.
- Confirm that the study is in a state other than “Active”. If a study is in an “Active” state, patients are logged in Click CTMS using the normal process.
- Select Log Public Comment from the Next Steps menu.

Participant Logging – Public Comment

- In the Comments section list:
  - Patient Name
  - Patient DOB
  - Patient MRN (if available)
  - Visit Name
  - Visit Date
  - Any other applicable information about the visit
- In the Attach Documents section, you may use the Add button to attach any applicable documentation related to the visit. This is an optional step.
- Select OK to submit the public comment.

This interim process is only a temporary solution for ensuring billing compliance before a study is activated in Click CTMS.

Study coordinators, with the exception of coordinators working on a UA study, will be responsible logging past visits once a study is “Active” in Click CTMS.
Monitor Request Form

Date of Request: __________________________
Name of Coordinator Requesting Monitor access: __________________________
Dates that Monitor will access Cerner: __________________________
Coordinator Email Address: __________________________

Monitor/Auditor Information:
Name: __________________________
Monitor Email Address: __________________________
Mailing Address: __________________________
Contact Phone Number: __________________________
Name of Study Sponsor: __________________________
Is Monitor a Sponsor Employee or CRO: __________________________

Type of data requested:
Encounters only ☐ Labs only ☐ All ☐

New Request for scheduled visit: Yes ☐ No ☐
Reactivation of account for scheduled visit: Yes ☐ No ☐
New request for an unscheduled urgent visit: Yes ☐ No ☐
Reactivation of an unscheduled visit: Yes ☐ No ☐

Patients requested:
Total number of patients requested: _____

Please indicate begin and end dates appropriate for the Dates of Service (DOS) required. If all DOS are required, please indicate “All”. If more than 20 patients, please attach additional sheets.

<table>
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<th>MRN</th>
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Please add rows to the above table if needed.

When the form is completed, please email it to Mandy Childs at mandy.childs@bannerhealth.com

A new or reactivation request for a scheduled monitor visit will be processed in 10 business days from the time the request is received by Banner.

A new or reactivation request for Urgent access will be processed in 24 hrs from the time the request is received by Banner.
COMPUTER ACCESS REQUEST FORM – RESEARCH

Once completed, email to Mandy Childs at mandy.childs@bannerhealth.com for questions call the Banner Help Desk at 602-747-4444. All fields are mandatory and illegible forms will not be processed.

User Last Name User First Name User MI Credential (MD, RN, etc.)

User Email Address User Job Title

Employer Name User Phone # IRB #

If this is for Cerner access – how will requester be using this access: Banner/UA Dept:

BUMC(P/T/S) CONFIDENTIALITY / NON-DISCLOSURE AGREEMENT

It is the intent of BUMC(T/S) and this User that BUMC(T/S) corporate or patient information obtained under this Agreement will remain confidential at all times. Confidential information includes, but is not limited to, patient, employee, financial, intellectual property, quality, financially non-public, contractual, and information of a competitive advantage nature, from any source or in any form (i.e., paper, magnetic or optical media, conversations, film, etc.) (AR S 12-2291 et seq. and CFR 160 & 164). All information contained within a patient’s medical record (hard copy and electronic) is confidential. Aggregate data output (diagnosis, procedure service, specialty, physician, etc.) is also confidential and may only be released by individuals authorized to do so by their position. Passwords to any computer system that processes/stores patient specific clinical data or corporate and employee data are also confidential. This information is protected by state and federal law and by the policies of the Banner - University Medical Center Phoenix/Tucson/South (BUMC(P/T/S)). I, the undersigned User, understand that BUMC(T/S) shall take immediate action to ensure compliance with any and all applicable federal, state and local laws and regulations regarding such a violation including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Health Information Technology for Economic and Clinical Health (“HITECH”) Act. The intent of these laws and policies is to ensure that confidential information will remain confidential through its use and as a necessity to accomplish the missions of this organization.

In order to be allowed access to BUMC(T/S) systems and/or be granted authorization to access any form of confidential information identified above, I, the undersigned, agree to comply with the following terms and conditions:

- I agree to use my unique user ID and password only in the course and scope of my employment and solely for legitimate application access. Any patient or financial data available to me through access to BUMC (P/T/S) computer systems will be treated as confidential information.
- My computer user account is equivalent to my LEGAL SIGNATURE. I will not disclose this account or password to anyone or allow anyone other than myself to access the system using it and understand that I am responsible and accountable for all entries made and all retrievals accessed under my user account, even if such action was made by me or by another due to my intentional or negligent act or omission.
- I will not access or attempt to access any BUMC (P/T/S) computer system fraudulently by using an account and password other than my own.
- I agree to comply with the applicable provisions of HIPAA, HITECH and any other federal or state laws or regulations protecting Health Information Privacy and Security and to protect to the fullest extent required by state and federal laws and hospital policy the patient’s right to confidentiality of all medical and personal information.
- I will not access or attempt to access for the purpose of investigation, manipulation, deletion or alteration any data outside the scope of my responsibility, including my own electronic medical record, data regarding family members, or that of friends/associates. In addition, I will not access or attempt to access confidential information, including personnel, billing or private information outside the scope of my employment.
- I agree not to use information obtained from BUMC (P/T/S) computer systems in any way that is detrimental to the organization, its members or patients.
- I agree to use care in handling printed reports, report copies, and fax documents and appropriately destroy or dispose of non-permanent paper copies containing patient, workforce, or corporate confidential information.
- I agree that I will not leave any workstation unsecured when logged into a BUMC (P/T/S) computer application and agree to log completely off the system at the end of each workday.
- I will notify BUMC(T/S) of any change to the information provided on this form, including name, email address, job title or employment arrangement, within 24 hours of the change.
- If I supervise individuals who have been granted access to BUMC (P/T/S) systems, I will notify BUMC (P/T/S) of any change in employment status on my employees’ part within 24 hours of such change.
- I will not intentionally damage, corrupt, or inappropriately delete data or computer programs or copy data or programs to other devices or media without authorization.
- I will not tamper with any BUMC (P/T/S) network-connected device without the express written permission of the OIO or designee. Tampering includes loading of any applications.
- I understand a detailed record of user’s access to applications is recorded electronically. Access and use will be audited regularly, at any time on a random basis, or for cause. I consent to having all or any part of their use of and access to BUMC (P/T/S)’s computer systems audited and reviewed at any time to ensure compliance with this agreement.
- Annual recertification is required to maintain this access. If I do not use my account regularly, I acknowledge that it is BUMC (P/T/S) corporate policy to disable my access. If I do not use this account for more than six months, I will need to resubmit this form with appropriate authorization.

I understand and acknowledge that improper access to, use or disclosure of BUMC (P/T/S) business or patient confidential information, whether verbally or from a paper-based or a computer-based record is a violation of law and/or BUMC (P/T/S) corporate policies. I understand and acknowledge that any violation of any part of the above agreement can result in termination of medical record and/or computer access privileges, and may result in regulatory or legal action, fines or civil money penalties. I also understand and acknowledge that disclosure of confidential information is prohibited indefinitely, even after termination of business relationship, expiration or cancellation of this agreement, or unless specifically waived in writing by the authorized party.

User Acknowledgement

I, ____________________________, acknowledge having received, read, been given an opportunity to ask any questions and agree to abide by the terms of this Agreement. I understand that if I violate any part of the agreement, access to BUMC (P/T/S) systems can and may be revoked and I may be subject to legal and or regulatory action, fines or civil money penalties.

X ____________________________ User Signature

Date

Research

ISS Form # 13007 / Rev 11-6-17
# Contract Submission Cover Sheet

Please submit your contract along with this form to UAHS at UAHSContacts@email.arizona.edu. Please send any contracts in Microsoft Word format, and confirm that all exhibits and attachments described in the contract are included.

## Date:

<table>
<thead>
<tr>
<th>1. PI and Department Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator Name:</td>
</tr>
<tr>
<td>Email:</td>
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<tr>
<td>Phone:</td>
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<tr>
<td>Administrative Contact Name:</td>
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<tr>
<td>Phone:</td>
</tr>
<tr>
<td>Department:</td>
</tr>
<tr>
<td>School/College:</td>
</tr>
<tr>
<td>Center/Institute (optional):</td>
</tr>
</tbody>
</table>

## 2. Sponsor / Outside Party Information

| Entity Name:                     |
| Entity Contact Name:             |
| Email:                           |
| Phone:                           |
| Contract Type:                   |
| Specific deadline (if any):      |
| Entity provided draft or template agreement? Y / N |
| If YES, please provide as an attachment to the email. |

## 3. Project Information

| Title:                          |
| Brief description of project (if more than one paragraph, attach separately as a Statement of Work): |

### a) Please specify if this is an Amendment, a Master Agreement, Project taking place under a Master Agreement or an Incoming Sub-Award. (Circle the one that may apply)

- If this is an Amendment, please provide the account number of the main agreement or award: ____________

## 4. Funding Information (for all funded contracts)

| Funding Source/Type:            |
| Has a proposal been submitted to SPS: □ Yes □ No |
| Estimated Project Budget:       |
| Indirect Rate Included in Budget: |
| Will this project be done as an FSO-approved recharge/service center activity? □ Yes □ No |
| (If yes, please attach FSO rate study approval letter) |

## 5. Additional Information for MTA, DUA, CDA, Equipment Loan

### MTA

- Account number for source of funds for the project in which the material will be used:
- Will any materials be used on this project that were received under another agreement? □ Yes □ No

### DUA

- Will the investigator be receiving the data or disclosing the data? ____________
- Will the data contain personal health information; be a part of a limited data set; or be de-identified data? Y / N
<table>
<thead>
<tr>
<th><strong>Is IRB review required for use of this data?</strong></th>
<th>Y / N</th>
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<tbody>
<tr>
<td><strong>CDA</strong></td>
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<tr>
<td>Will the investigator be providing or disclosing confidential information to an outside party?</td>
<td>Y / N</td>
</tr>
<tr>
<td><strong>Equipment Loan</strong></td>
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<tr>
<td>Where will the equipment be located? (Please indicate the actual room/bldg. number)</td>
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</tr>
<tr>
<td>What is the approximate fair market value of the equipment?</td>
<td></td>
</tr>
</tbody>
</table>

6. **Comments** (include any relevant background information, especially on prior contract discussions with sponsor)