OnCore Clinical Trial Management System (CTMS) Updates (Non-oncology)

The launch of OnCore is currently in full process!

- We are currently working with departments to complete training.
  - OnCore overview & calendar validation
  - Subject entry and visit entry
  - Regulatory (document uploads)

- After department members have completed training, we are working with them to validate their study calendars and upload IRB (UA/central) approval docs & ICFs.

- Subject entry can begin when calendars have been validated and IRB docs have been uploaded.

- Once study calendars have been released and are live in the OnCore system, they will be deactivated in Banner’s Click® CTMS.
  - All future subject visits MUST be logged into OnCore within 24 hours of study visit completion. Refer to section “Billing Compliance Process for Clinical Trials Purchasing BH Services” for instructions.

- It will be VERY important for ALL departments to submit protocol amendments to the RIA as soon as they are able.
  - Protocol amendments undergo a review of the coverage analysis, and the OnCore calendar/financials will also be reviewed.
  - We would like to have the studies enter our work queue PRIOR to IRB approval.

Please email us at OnCoreSupport@email.arizona.edu with questions.

Welcome To Our New Team Members!

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

- **Me Linda Johnson** will assist with OnCore calendars & financials as well as training and system support.
  
  Me Linda’s contact information is johnson2@email.arizona.edu, 520-626-9522.

- **Susie Brown** will assist with OnCore calendars & financials as well as training and system support.
  
  Susie’s contact information is: susiebrown@email.arizona.edu, 520-621-5457

- **Wendy Chmara** will assist with OnCore calendars & financials as well as training and system support.
  
  Wendy’s contact information is: wkchmara@email.arizona.edu, 520-621-6239

Research Intake Application (RIA)

RIA forms have been revised (version dated 11Feb2020) and can be downloaded on the Research Administration website at https://research.uahs.arizona.edu/clinical-trials/research-intake-form.
Record Retention

The University of Arizona Records Management & Archives follows state regulations for the retention and disposal of records. Information for Contracts and Grants, financial records and human subject research, can be found on pages 6 and 7 of the attached schedule.

Banner Clinical Research Data Warehouse (CRDW) Requests

To support the use of Banner Health clinical data for research purposes, a protocol entitled “Clinical Research Data Warehouse and Associated Honest Broker Processes” has been approved by the Banner IRB. The protocol details how Honest Broker staff, who are neutral intermediaries between the researcher and the EHR data, will process requests for data, assess the feasibility, and fulfill the data requests.

Requests for data are initiated by using the Research Intake Application (RIA), which is located here: https://research.uahs.arizona.edu/clinical-trials/research-intake-form.

The attached form addresses the Process Overview and Frequently Asked Questions. It also includes the updated version of the CRDW Request Form.

Additional CRDW information and the request form can also be found on our website: https://research.uahs.arizona.edu/clinical-trials/resources#data

Banner Hospital Billing Update

Banner Hospital Billing for the months of October 2017 – November 2019 have been reviewed and sent out to the corresponding UA Departments via UABox Health.

An email has been sent to the Business Office and Study Team contacts notifying them that their invoices have been uploaded to the UABox Health and are ready for their review.

- Please process payment promptly. If there are any discrepancies, please email cfinance@email.arizona.edu for assistance.
- When submitting backup to FSO, please only redact the patient name and date of birth if applicable. All other information should be left visible. Please see example below (this is a fictional bill with no HIPAA information).
- Please send an email to cfinance@email.arizona.edu with your DV payment information.
- Please do not Closeout and FPC any account balances if your clinical trial protocol reflects Banner services. If you are unsure, please work with your Study Team for confirmation.

Please use GL Code #4215 for all payments and purchase orders to Banner Health.

This GL code was created to capture all research related expenses for ‘Various clinical trial procedures, i.e. imaging, venipuncture, labs, exams, etc.’.

This allows for smoother account reconciliation and reporting.
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 (Click® CTMS only):**

- 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 as verified by the coverage analysis.

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

If you have questions regarding the OnCore calendar, contact OnCoreSupport@email.arizona.edu or for Click® CTMS calendar questions (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.
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.

**Each department/division is responsible for sending at minimum one delegate to attend the CRP meeting. If a department/division cannot attend, then the manager/supervisor will need to attend a makeup session to review topics covered in the CRP meeting.**

*** The April meeting has been cancelled ***

The next meeting is scheduled for Wednesday, May 20, 2020, from 12 pm to 1:30 pm in Kiewit Auditorium, AZ Cancer Room 2951A, Tucson.

COM-Phoenix Video Conference location:
- BUMCP Conference Room 3
  1441 N. 12th Street, 1st 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>Wednesday, May 20, 2020</td>
<td>Kiewit Auditorium, 2951A Cancer Center</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
<td>12:00pm - 1:30pm</td>
</tr>
<tr>
<td>Thursday, June 18, 2020</td>
<td>pending</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
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<td>Wednesday, July 15, 2020</td>
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<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
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<td>Thursday, August 20, 2020</td>
<td>pending</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
<td>3pm - 4:30pm</td>
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<td>Wednesday, Sept 16, 2020</td>
<td>pending</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
<td>12:00pm - 1:30pm</td>
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<td>Thursday, October 22, 2020</td>
<td>pending</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
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<td>Wednesday, Nov 19, 2020</td>
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<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
<td>12:00pm - 1:30pm</td>
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<td>Thursday, December 17, 2020</td>
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<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
<td>3pm - 4:30pm</td>
</tr>
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</table>
Compliance corner

UAHS HIPAA Designation Update and HIPAA Privacy Program

Office Hours

The designation process for all University of Arizona Health Sciences colleges and units is well under way! We are making great progress and remain on schedule to have the designation process completed by the end of the year.

During this process it will be required that ALL UAHS faculty, staff, DCCs, volunteers and other workforce members complete their HIPAA certification. This can be completed by registering for the certification and the HIPAA Essentials training through UAccess Learning. The updated training takes approximately 10 minutes to complete and the certification is good for one year. If you have already completed your certification within the last year you do not need to complete it again.

For more information regarding how to register for and complete the HIPAA certification training please see our helpful FAQ here: https://rgw.arizona.edu/compliance/hipaa-privacy-program/hipaa-training-certification

During the designation process the HIPAA Privacy Program will be coordinating with UAHS administration and college leadership to implement new privacy and security procedures and standards. Please be on the lookout over the course of 2020 for important communications regarding these and other important designation updates.

The HIPAA Privacy Program will also be offering office hours to faculty and research staff every other Wednesday, starting March 25th from 1 pm to 4 pm! Drop in to HSIB 202 with all your HIPAA-related questions or schedule an appointment with us ahead of time.

To stay up-to-date on the latest HIPAA news, subscribe to our listserv by following the instructions at https://rgw.arizona.edu/compliance/hipaa-privacy-program/hipaa-resources

If you have any questions, please email our team at privacyoffice@email.arizona.edu, or feel free to call John Howard, Director of the HIPAA Privacy Program, at 621-1465.
GENERAL INFORMATION AND RESOURCES

UAHS Research Administration provides guidance and assistance with the following:

- Our website: https://research.uahs.arizona.edu/
- Coverage Analysis (CA) and Clinical Trial Budget development/negotiations: contact crc@email.arizona.edu
- Contracts (CDAs, NDAs, CTAs, amendments, data use, incoming MTAs): 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 (UA NetID Login required)

Research Intake Application (RIA): Applications and required documentation should be emailed to ResearchApp@email.arizona.edu. Instructions and application forms 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.

UAHS OnCore Support: OnCoreSupport@email.arizona.edu or https://research.uahs.arizona.edu/oncore

ClinicalTrials.gov Assistance:
- Non-cancer studies: Kerry-Ann Suckra, kerryanns@email.arizona.edu, (520) 621-2029 or Clinical Trial Regulatory: regulatory@email.arizona.edu
- Cancer studies: Amy Selegue, UACC-NCTN@uacc.arizona.edu, (520) 626-6301

UA Privacy Office: Contact PrivacyOffice@email.arizona.edu or (520) 621-1465

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

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

Data Warehouse Information: https://research.uahs.arizona.edu/clinical-trials/resources#data

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


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 Laura Wilkes at (602) 839-3266 or Laura.Wilkes@bannerhealth.com

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

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 SQLCustomerSytems@SonoraQuest.com to schedule training. Please be sure to include your SQL departmental account number when requesting training.