RESEARCH ADMINISTRATION - CLINICAL TRIALS NEWSLETTER

FEBRUARY 2020

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.

Research Intake Application (RIA)

RIA forms have been revised (version dated 15 January 2020) and can be downloaded on the Research Administration website at https://research.uahs.arizona.edu/clinical-trials/research-intake-form.

Important Conflict of Interest (COI) Reminders

Below are some important COI reminders related to Investigational New Drug (IND) and Investigational Device Exemption (IDE) applications:

- All IND/IDE applications must be reviewed and approved by the Executive Review Committee (ERC) prior to any clinical work being performed.
- Please submit an IND/IDE COI Worksheet (attached) as far in advance of your anticipated IND/IDE clinical start date as possible.

This information is also available on the IND/IDE website at https://rgw.arizona.edu/compliance/conflict-interest-program/investigators/investigational-new-drug-or-device-exemption.

If you have questions about starting a Human Subjects protocol, please contact the Human Subjects Protection Program at VPR-IRB@email.arizona.edu.

If you have any questions or concerns about the COI review process or IND/IDE COI Worksheet, please contact the Conflict of Interest Program at COI@email.arizona.edu or (520) 626-6406.

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

The launch of OnCore is scheduled to start beginning in March 2020!

- We are planning on a rolling implementation plan; this means we will launch a few departments at a time. We will have more information in February.
- Dates for each department’s implementation are TBD.
- Thank you to everyone for your timely responses in confirming active studies for your PI/research team.
- We are building protocols/calendars/financials for non-oncology studies by departments.
- Upon completion of study builds within OnCore, we will reach out to the department’s research manager/staff to schedule training.
- Once training has been completed, the department will go live in the OnCore system and all studies will be closed out in the BH’s Huron CLICK system.
- There are no changes for oncology studies that already utilize OnCore.
- Additional announcements will be made for upcoming transition and training plans.

Stay updated by visiting our website at: https://research.uahs.arizona.edu/oncore
Welcome To Our New Team Members!

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

- **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

- **Veronica Buckley** will assist with development of coverage analyses and budget development/ negotiations.
  Veronica’s contact information is: vbuckley@email.arizona.edu, 520-626-9303

Banner Hospital Billing Update

Banner Hospital Billing for the months of October 2017 – September 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 ctfinance@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).

<table>
<thead>
<tr>
<th>Entity Code</th>
<th>Medical Record #</th>
<th>Acct #</th>
<th>Patient Name</th>
<th>DOS</th>
<th>Charge #</th>
<th>CPT4 Code</th>
<th>Description</th>
<th>Charge Amount</th>
<th>Adjustment</th>
<th>Balance Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>483</td>
<td>123456789</td>
<td>1234567</td>
<td>John Doe</td>
<td>2018-05-30</td>
<td>4812345</td>
<td>5303</td>
<td>ECHO/EQUIP/COLOR</td>
<td>$2,750.00</td>
<td>$1,951.62</td>
<td>$898.38</td>
</tr>
<tr>
<td>483</td>
<td>234567890</td>
<td>1234567890</td>
<td>Jane Smith</td>
<td>2018-05-31</td>
<td>4812345</td>
<td>5303</td>
<td>ECHO/EQUIP/COLOR</td>
<td>$2,750.00</td>
<td>$1,951.62</td>
<td>$898.38</td>
</tr>
</tbody>
</table>

- Please send an email to ctfinance@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:**

- 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.
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 next meeting is Thursday, February 20, 2020, from 3 pm to 4:30 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>Thursday, February 20, 2020</td>
<td>Kiewit Auditorium, 2951A Cancer Center</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
<td>3pm - 4:30pm</td>
</tr>
<tr>
<td>Wednesday, March 18, 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>Wednesday, April 15, 2020</td>
<td>Kiewit Auditorium, 2951A Cancer Center</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
<td>3pm - 4:30pm</td>
</tr>
<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>
<td>3pm - 4:30pm</td>
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<tr>
<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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<tr>
<td>Thursday, August 20, 2020</td>
<td>pending</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
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<tr>
<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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<tr>
<td>Thursday, October 22, 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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<tr>
<td>Wednesday, Nov 19, 2020</td>
<td>pending</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
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<td>Thursday, December 17, 2020</td>
<td>pending</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
<td>3pm - 4:30pm</td>
</tr>
</tbody>
</table>
Compliance corner

UAHS HIPAA Designation Update and HIPAA Privacy Program

Office Hours

The designation process for all UArizona 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) 626-0301

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