Important Conflict of Interest (COI) Reminders

Below are some important COI reminders related to Investigational New Drug (IND) and Investigational Drug 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 webpage.

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

- The OnCore Kickoff Meeting occurred November 19th. The Zoom recordings are available at the Research Administration website.
- The Cancer Center completed their migration to the OnCore Enterprise environment on December 4th and everything went smoothly!
- We are continuing to work with Forte to prepare the OnCore system for all of the non-oncology studies. We will be reaching out to individual departments starting the week of January 6 to verify active studies and collect general enrollment information. Please be on the lookout for these emails. They will be coming from our new email address: OnCoreSupport@email.arizona.edu.
- Thank you in advance for your prompt responses!
- The launch of OnCore is scheduled for April 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.
- Additional announcements will be made for upcoming transition and training plans.

Stay updated by visiting our website: [https://research.uahs.arizona.edu/oncore](https://research.uahs.arizona.edu/oncore)

Welcome To Our New Team Member!

We have a new member who has joined us in our Tucson office. 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
Clinical and Translational Sciences Research Center (CaTS) Website

The CaTS website has been updated and is available here: www.cats.med.arizona.edu. The website has been redesigned with the clinical research professional in mind. The primary objective of the site is to provide frequently sought information and resources at your fingertips. Explore the site to learn more.

Be sure to check out the Coordinator Corner where you will find the following resources and much more.

- Clinical Trial Start-up Process
- Clinical Research Professionals (CRP) meeting dates and locations, and other events
- Toolbox with resources for audits; source documents; Standard Operating Procedures (SOPs); and Lab certificates for CaTS, Sonora Quest, and Banner University Medical Center
- Banner UMC information on security badges for Tucson, Cerner training and access, and Huron Click CTMS training and information
- Research Administration newsletter archive

Your feedback is very important to us as we aim to develop a website that is valuable to you. Please submit comments, questions, and suggestions to VPHS-CRO@email.arizona.edu.

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 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).

<table>
<thead>
<tr>
<th>Entity Code</th>
<th>Medical Records #</th>
<th>Act #</th>
<th>Patient Name</th>
<th>DOS</th>
<th>Charge</th>
<th>CP#</th>
<th>CP# Code</th>
<th>Charge Amount</th>
<th>Adjustment</th>
<th>Balance Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>403</td>
<td>123456789</td>
<td>2019-05-26</td>
<td>401234567</td>
<td>9320</td>
<td>$2,756.00</td>
<td>$1,051.62</td>
<td>$894.38</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>403</td>
<td>234567890</td>
<td>2019-05-01</td>
<td>401234567</td>
<td>9320</td>
<td>$2,756.00</td>
<td>$1,051.62</td>
<td>$894.38</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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:**

- 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 Wednesday, January 15, 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, January 15, 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, 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>
</tr>
<tr>
<td>Wednesday, July 15, 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, August 20, 2020</td>
<td>pending</td>
<td>BUMCP Conference Room 3 (1441 N 12th Street, 1st floor)</td>
<td>3pm - 4:30pm</td>
</tr>
<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>
<td>12:00pm - 1:30pm</td>
</tr>
<tr>
<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>
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

COM-P Clinical Research website: https://phoenixmed.arizona.edu/research/clinical-research/investigators

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