OnCore Clinical Trial Management System (CTMS) Updates

OnCore is currently live for all non-oncology studies!!

Thank you to all of the study staff for all of your dedication and hard work with building the OnCore CTMS. We know that this was no small undertaking and required a lot of time and effort (especially during a pandemic)!! This will be an amazing tool for all of our departments and colleges!

*Cerner & OnCore*: Phase I of the OnCore & Cerner interfaces began on May 28, 2020 for non-oncology studies. OnCore is now able to push “On Study” subject information to Cerner. This will add a notification on the blue banner to the patient’s medical record that they are enrolled in a UA clinical trial. Oncology is projected to be complete by the end of June 2020.

Phase II of the OnCore/Cerner interface is for Cerner demographics information (MRN, Name, DOB, gender, race, ethnicity and address) to push to OnCore. This is currently under development.

Upcoming Training Sessions

To schedule, contact oncoresupport@email.arizona.edu

- **Introduction to OnCore and Calendar Validations**
  Tuesday, June 9th or June 23rd
  1:00 pm – 3:00 pm

- **Subject Management Training**
  Wednesday, June 10th or June 24th
  1:00 pm – 3:00 pm

- **Regulatory Training**
  Thursday, June 11th or June 25th
  10:00 am – 12:00 pm

Subject entry can begin when calendars have been validated, IRB docs have been uploaded, and the study has been opened to accrual by the regulatory team.

Study calendars have been deactivated in Banner’s Click® CTMS. *All future subject visits MUST be logged into OnCore within 24 hours of study visit completion.*

It is **VERY** important for **ALL** departments to submit protocol amendments through the RIA submission process as soon as they are able.

- Protocol amendments undergo a review and update of the coverage analysis (as applicable), and the OnCore calendar/financials are also reviewed.
- We would like to have the studies submitted and enter our work queue **PRIOR** to IRB approval.

Next Steps

- We are working to provide additional resources on our website. Stay tuned!
- During the next several months:
  - We will work on entering study budgets into OnCore. This will aid with invoicing sponsors and tracking study payments. We will reach out to departments when we are ready to schedule training.
  - Provide overview and training on running reports from OnCore
- Planning the implementation of the eRegulatory Management System (https://forteresearch.com/forte-eregulatory-management-system-ereg/faq)

Please email us at OnCoreSupport@email.arizona.edu with questions, or for additional help.
COVID-19 Research and Sample Request Guide

The University of Arizona research community has been actively studying patients infected with COVID-19 in hopes of learning more about the virus, its pathogenesis and possible treatments.

As part of these efforts, the University of Arizona Health Sciences Biorepository created the COVID-19 Research and Sample Request Guide (attached) for researchers using biospecimens in COVID-19 studies.

Investigators wishing to initiate a COVID-19 study that would require biospecimen collection should contact Dr. Sairam Parthasarathy at sparth@1@email.arizona.edu for patient access.

The Health Sciences Biorepository provides an electronic universal consent, along with a REDCap database and linkage to electronic medical data stored in Cerner for each subject.

Please submit any request for COVID-19 samples at https://biobank.uahs.arizona.edu or http://redcap.link/covid19request.

To review available samples in the biobank, please see the Biorepository Summary.

For more information, please review the attached guide or contact Dr. David Harris, Director of the Health Sciences Biorepository at davidh@email.arizona.edu.

Banner Hospital Billing Update

Banner Hospital billing for the months of October 2017 – March 2020 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).

- 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.
Research Intake Application (RIA)

RIA forms have been revised (version dated 19May2020) and can be downloaded on the Research Administration website at https://research.uahs.arizona.edu/clinical-trials/research-intake-form.

Welcome To Our New Team Members!

We have new members who have joined our team.

Laurel Rokowski has joined the UAHS SVP Office as Director of Clinical Research Operations. She will oversee the CaTS Research Center and work with clinical trial operations for UAHS.

Laurel’s contact information is:
laurel@email.arizona.edu, 520-626-8000

Me Linda Johnson will oversee OnCore system support, as well as training.

Me Linda’s contact information is:
johnson2@email.arizona.edu, 520-626-9522.

Billing Compliance Process for Clinical Trials Purchasing BH Services

The University of Arizona is obligated to log ALL study visits into 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 OnCore within 24 hours.**

*The Click<sup>®</sup> CTMS is no longer being used to record study visits.*

- This includes research-related **AND** routine/standard of care.
- UA Coverage Analysis (CA) provides detailed information for billing designations. Study calendars in OnCore reflect these billing designations. A copy of the CA is uploaded into OnCore for the study team’s reference.
- *This process helps to ensure that bills are routed to the correct payor, and helps to protect a study subject and alleviate incorrect billing.*

BHRF reviews and validates all charges logged into OnCore 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.

If you have questions regarding the OnCore calendar, contact OnCoreSupport@email.arizona.edu.

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 scheduled for Thursday, June 18, 2020, from 3 pm to 4:30 pm and will be conducted via Zoom.

A Zoom invite will be emailed to everyone a few days before the meeting.

COM-Phoenix Video Conference location: via Zoom

### 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, June 18, 2020</td>
<td>Zoom</td>
<td>Zoom</td>
<td>3pm - 4:30pm</td>
</tr>
<tr>
<td>Wednesday, July 15, 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>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>
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<td>Thursday, October 22, 2020</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>
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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>
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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
Listserv: uahs-oncore@list.arizona.edu

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:
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
https://research.uahs.arizona.edu/clinical-trials/cerner


SQL Care360 Training: Contact the Customer System Team at (602) 685-5465 or SQLCustomerServices@SonoraQuest.com to schedule training. Please be sure to include your SQL departmental account number when requesting training.