OnCore Training and Office Hours

The OnCore webpage (https://research.uahs.arizona.edu/oncore) provides information about scheduled trainings and office hours in the Training & Office Hours section. Trainings and office hours are scheduled two months in advance and alternate weeks from each other. The zoom links can be found on the OnCore Resources page which requires your UA NetID and password to login. Note: The zoom links are for office hours only!

Training Sessions
To schedule, contact OnCoresupport@email.arizona.edu

- **Introduction to OnCore and Calendar Validations**
  Tuesdays, 1:00 pm – 3:00 pm
  Aug 4, Aug 18, Sept 1, Sept 15, or Sept 29

- **Subject Management Training**
  Wednesdays, 1:00 pm – 3:00 pm
  Aug 5, Aug 19, Sept 2, Sept 16, or Sept 30

- **Regulatory Training**
  Thursdays, 10:00 am – 12:00 pm
  Aug 6, Aug 20, Sept 3, or Sept 17

Subject entry can begin when calendars have been validated, IRB documents have been uploaded, and the study has been opened to accrual by the regulatory team. As applicable, studies will need a fully executed or signed contract prior to being opened to accrual in OnCore.

All future subject visits MUST be logged into OnCore within 24 hours of study visit.

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.

Cerner & OnCore: 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. All active protocols with active subjects for Oncology studies have been pushed over to Cerner.

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.

Next Steps

- 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 running reports from OnCore
- Planning the implementation of the eRegulatory Management System (https://forteresearch.com/forteregulatory-management-system-ereg/#faq)

Please email us at OnCoreSupport@email.arizona.edu with questions, or for additional help.
Research Intake Application (RIA)

RIA forms have been revised (version dated 19 May 2020) and can be downloaded on the Research Administration website at https://research.uahs.arizona.edu/clinical-trials/research-intake-form.

Does my study require a RIA submission? If your study has a UAHS PI or requires the use of Banner resources, new and amended studies must be submitted to Research Administration using the RIA forms.

I’m not using Banner resources, why do I need to submit a RIA? For new studies, the RIA initiates multiple processes including Banner feasibility review, coverage analysis development, budget & contract negotiations, financial review of ICF, and entering the study into the OnCore clinical trial management system (CTMS), as applicable.

Welcome To Our New Team Member!

We have a new member who has joined our team.

Laurel Rokowski, RN has joined the UAHS SVP Office as Director of Clinical Research Operations. She will oversee the CATS Research Center and the new Sleep Research Center while working with clinical trial operations for UAHS.

Laurel’s contact information is: laurel@email.arizona.edu

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.).

ALL study visits that include BH services MUST be logged into OnCore within 24 hours. The Click® 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.
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 spartha1@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 – April 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 cffinance@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 cffinance@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.
RII Research Restart Checklist for COVID Research

Please review the following information for restarting your research.

1. The RII research restart checklist needs to be prepared by the PI for each study
2. Submit each study to the RII research restart checklist (Qualtrics system).
   - For COVID studies occurring in Banner space, approval from the UA-COVID committee is required. If you have approval, please indicate this in the abstract section. If you are not sure you have approval, please email Laurel Rokowski (Tucson) or Anna Valencia (Phoenix).
3. Once approved by ADR and RII, the approval notice will be returned to the PI.

UAHS Clinical Research Professionals (CRP) Group Meeting

If you are new to the University of Arizona Health Sciences (UAHS) research community and/or would like 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, August 20, 2020, from 3:00 pm - 4:30 pm and will be conducted via Zoom.

Join Zoom Meeting
https://arizona.zoom.us/s/98780518660
Meeting ID: 987 8051 8660
One tap mobile
US: +16027530140,,98780518660# or +16699006833,,98780518660#

**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, Aug 20, 2020</td>
<td>ZOOM</td>
<td>ZOOM</td>
<td>3:00pm - 4:30pm</td>
</tr>
<tr>
<td>Wednesday, Sept 16, 2020</td>
<td>ZOOM</td>
<td>ZOOM</td>
<td>12:00pm - 1:30pm</td>
</tr>
<tr>
<td>Thursday, Oct 22, 2020</td>
<td>ZOOM</td>
<td>ZOOM</td>
<td>3:00pm - 4:30pm</td>
</tr>
<tr>
<td>Wednesday, Nov 19, 2020</td>
<td>ZOOM</td>
<td>ZOOM</td>
<td>12:00pm - 1:30pm</td>
</tr>
<tr>
<td>Thursday, Dec 17, 2020</td>
<td>ZOOM</td>
<td>ZOOM</td>
<td>3:00pm - 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 UAHSContacts@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: 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 SQLCustomerSytems@SonoraQuest.com to schedule training. Please be sure to include your SQL departmental account number when requesting training.
COVID-19 Research and Sample Request Guide

During the university shutdown investigators from the Health Sciences have been actively studying patients infected with COVID-19 in hopes of learning more about the virus, its pathogenesis and possible treatments. Major investigators have included Drs. Parthasarathy, Knox, Weinkauf, Garcia and many others.

The University of Arizona Health Sciences Biorepository has been actively collaborating with these investigators to facilitate biospecimen collection, processing, characterization and banking. Most, if not all, samples have been linked to electronic medical data present in Cerner. The research community is indebted to these PIs as well as their faculty and fellows for their willingness to participate in this research effort. Many of these individuals have placed their own health in jeopardy to assist in these efforts. To that end, we want to make sure that everyone involved in these efforts is recognized and receives their fair share of the credit on papers, grants, and other efforts. We also want to be sure that patient care is not impacted by the research efforts and that patients are not inconvenienced by these studies. Patients should not be approached multiple times requesting their participation in similar studies by different PIs, nor should they be inconvenienced by multiple requests for blood and other specimens, which could possibly exceed recommended daily limits (e.g., blood draws).

Dr. Sairam Parthasarathy has instituted a review panel to ensure that patients are treated fairly, recruited equitably, and consented for studies appropriately. He will review patient recruitment for all studies involving PCCM, facilitate PI collaboration, manage oversight of biospecimens collected and serve as the gatekeeper for these studies. Similarly, Dr. David Harris as director of the Health Sciences Biorepository serves as the second line of review for COVID-19 studies, in that all samples placed in the biobank fall under his purview. The Biorepository has a universal consent available for use by investigators that is also present in electronic formats, along with a REDCap data base and linkage to electronic medical data stored in Cerner for each subject. Investigators wishing to initiate a COVID-19 study that would require biospecimen collection should contact Dr. Parthasarathy for patient access.

Everyone wishing to request COVID-19 samples, including the initiating investigator, must request samples online at our website so that we may track samples in and out of the biobank, as well as document approved requests.

Individuals wishing to review available samples of any type in the biobank may go to https://generalreporting.uahs.arizona.edu/BiorepositorySummary to see the types of samples available.

To make an online request specifically for COVID-19 samples to be used for research PIs may visit https://biobank.uahs.arizona.edu or http://redcap.link/covid19request. Sample requests must include information about the nature of the proposed studies as well as other pertinent information.

Requests are brought before the investigator initiating the collection as well as a Review Committee to decide which samples can be distributed, to whom, and which studies are overlapping or duplicative. Although there are many samples available, the samples are not infinite. The Review Committee is made up of representatives from Administration, IT, the IRB, and multiple investigators. No samples will ever be distributed without consent of the initiating
investigator. However, investigators cannot reserve all samples exclusively for themselves and expect to receive gratis service. In the event of scientific overlap of such requests the COVID-19 biospecimen Review Committee will request such investigator groups to collaborate and therefore avoid redundancy. If you wish to be part of this Review Committee, please contact Dr. Harris at davidh@email.arizona.edu.

Investigators taking advantage of the COVID-19 biobanking services, upon receipt of a sample from the biobank, must be willing to share data with the biobank as well as other investigators, and in some instances, share portions of a sample (e.g., DNA). This willingness to share is assumed based on submission of the request. Furthermore, investigators receiving such samples must acknowledge the role of collaborators and the biorepository.