Research Administration Announces New Workflows

We are so thankful for the engagement and participation of the COM-T faculty who have been working closely over the past few months with Research Administration to develop and implement process improvements and improved communication for clinical research. We have developed additional workflows to explain the entire process of initiating a clinical research project, in particular the process to finalize clinical research Budgets and Coverage Analysis and overall Contracts workflow. Please direct any specific questions on the process to crc@email.arizona.edu.

Online RIA Submission Process Launched!

On March 1, 2022, UAHS Research Administration began accepting all project submissions via our new online portal. Click here for the new UAHS Project Submissions site, which requires UA NetID login. Respond to the questions to determine which submission form is applicable to our project and click on the specific form button to begin your submission. If you already know which form you need, click on the “All Forms” button, select the appropriate form and click on the plus “+” sign (upper right-hand corner) to begin your submission. All submission requirements remain the same (i.e. study related information and supporting documents). There is a minor update to the required documents for RIA New Study Submissions. The PDF printer version of the related eIRB application should be included in the RIA as this includes the Local Study Team Members, IRB number, as well as many of the required documents for a complete submission. Incomplete submissions will not enter our workflow until all requirements are met.

As of March 21, 2022, all submissions must be submitted through the online portal.

Please contact us at crc@email.arizona.edu if you have any questions or require assistance with utilizing our new online submission portal. One on one RIA support is also available by scheduling a session through Microsoft Bookings. You will receive an email confirmation with a Zoom meeting link.

Sonora Quest Laboratories (SQL) Accounts for Non-Industry Research Studies

SQL will now be assigning a second account to each department utilizing SQL services. This is being done because there are pricing differences for research studies funded by industry and non-industry (i.e. NIH, foundations, IITs). This will help SQL bill research studies at the correct research rate. Study teams will be responsible for ordering SQL labs using the correct account. Please contact CTFinance@email.arizona.edu with questions or to request a second account be set up for non-industry research studies.
New eDisclosure Dashboard in UAccess Analytics

The eDisclosure Proposal Development Status dashboard is now available in UAccess Analytics. This dashboard identifies whether Investigators on a specific proposal have met the federal requirements for COI compliance at the time of proposal submission to the funding agency. This dashboard can be searched using the following categories:

- Proposal Development Number
- Proposal Development Document
- Lead Investigator Name
- Lead Unit
- Investigator Name
- Investigator NETID
- Conflict of Interest Status

The eDisclosure – Conflict of Interest (COI) dashboard suite also includes the following dashboards:

- eDisclosure Requirement Status dashboard
  Provides individual-specific Conflict of Interest status information.

- eDisclosure Project-Based Investigator Status dashboard
  Provides Conflict of Interest information such as Determination Status and Training Certification Date for Investigators associated with a specific project.

Attached are User Guides for each of the eDisclosure dashboards. If you are not able to access the dashboards, please submit a request using the UAccess Access Provisioning Tool, AccessFlow.

The OROI team is available to assist with any questions you may have. They can be reached at coi@arizona.edu or (520) 626-6406.

Research Laboratory & Safety Services Announces Radiation Emergency Notification Procedure

In the event of an emergency that may involve radiation or radioactive material, call RLSS immediately at 520-626-6850. Outside of the office hours of Monday through Friday, 7:30 a.m. to 4 p.m., a staff member can be reached by calling the UAPD at 520-621-8273 and requesting RLSS emergency personnel be notified. You can also call the RLSS emergency line directly at 520-496-5929. If you do not receive a timely response from RLSS personnel, call Leon Harris at 520-870-7752.

OnCore Access for Banner Staff – effective 7/1/2022

All Banner staff actively working on clinical research studies will need to obtain a Designated Campus Colleague (DCC) status with UA to continue signing into OnCore. Please work with your UA research department’s HR team to establish your DCC status and obtain a UA Net ID.
OnCore & eReg – NEW WEBSITE – Clinical Trials Applications – Launched in June!!

Clinical Trials Applications is available at ctapps.uahs.arizona.edu, and it will serve as a hub for information on training, system processes, and related workflows. The Clinical Trials Applications site was developed to reflect the collaborative management of OnCore and eReg by the OnCore Support team at Research Administration and the COMHelp team at College of Medicine - Tucson IT. In addition, this unique designation and resource repository for OnCore and eReg will offer more clarity on areas of responsibility in the study start-up process. After studies have gone through the Research Intake Application workflow, regulatory coordinators, clinical research coordinators, and other study personnel can visit the Clinical Trials Applications website to find the tools they need for the next phase of their study cycle.

Clinical Trials Applications will serve as the standalone destination for policies, procedures, and ancillary information to guide users of the two systems. OnCore and eReg information that was available on the Research Administration website will be removed, and visitors will be referred to the new website.

New content will be added in the coming months as eReg is implemented across more departments. If you have questions, comments, or suggestions about the new site, please email oncoresupport@email.arizona.edu.

OnCore Technical Support

Technical support for OnCore is now handled by COMHelp. Requests for assistance should be submitted through the COMHelp ticketing system. This will require you to login with your UA NetID. Service requests include:

- Technical support
- Password resets
- User account troubleshooting
- Requests for reports

Please do not include PHI information with your ticket. If your ticket is regarding help with subject management, COMHelp will contact you regarding a secure method to transmit PHI or screenshots (i.e. secure email, UA BoxHealth, or HIPAA Zoom). Tickets that include PHI will be purged from the system and you will need to resubmit your ticket.

Technical support requests sent to OnCoreSupport@email.arizona.edu will be referred to COMHelp.

OnCore Training and Individual Consultations

OnCore Support provides self-service scheduling for support sessions through Microsoft Bookings. Individual consultations are available in a HIPAA-compliant Zoom environment in case research subject data is reviewed. A HIPAA Zoom link will be provided in your email confirmation once you schedule your session.

Monthly trainings for new OnCore users will continue on the same schedule, with training sessions held the first full week of each month (occasionally adjusted for holidays or other events). Available trainings are posted one to two months in advance.

The OnCore website provides information about scheduled trainings and individual support sessions on the Training and Consultations page. Please feel free to sign up if you would like first-time training, a refresher training, or one-on-one OnCore help!
Effective March 21, 2022, training registration by email has been discontinued and replaced with an online form. This change was implemented to streamline the registration process for new users by providing step-by-step information to explain the user information needed and the training prerequisites that are required. (see list below). In addition, the form allows users to upload their OnCore Confidentiality Agreements:

**OnCore Training Prerequisites:**
- HIPAA training, EDGE course ID 0000003302
- Information Security Awareness, EDGE course ID 0000003315
- CITI Biomedical Research Investigators (CITI-4589, Human Research), EDGE course ID 0000003282
- OnCore Confidentiality Agreement

After submitting the required information, users will receive an immediate confirmation of their training request. To register for any of the next training sessions, please complete an OnCore Confidentiality Agreement with your supervisor and go to the OnCore Training Request Form.

The next trainings are scheduled as follows:
- **Introduction to OnCore and Calendar Validations**
  Tuesday, July 5 or August 2, 1:00 pm - 3:00 pm
- **Subject Management Training**
  Wednesday, July 6 or August 3, 1:00 pm - 4:00 pm
- **Regulatory Training**
  Thursday, July 7 or August 4, 2:00 pm - 4:00 pm

If you have changed departments or need to have an additional role added to your OnCore Profile (regulatory, study coordinator, etc.), you will need to submit an updated OnCore Confidentiality Agreement to OnCoreSupport@email.arizona.edu prior to the role being added. Additional training may be required.

We are also available to attend department or research unit meetings. This is a great way to receive direct support for your team’s research studies and ask specific questions for OnCore Support. Please email us at OnCoreSupport@email.arizona.edu to schedule a session.

**OnCore’s Role in Billing and Invoicing**

Study visits must be logged into OnCore within 24 hours of occurrence whenever Banner Health (BH) or Sonora Quest Lab (SQL) services are utilized for a research study (i.e. medical imaging, ECG, clinic visits, etc.).

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.

Billing designations should ONLY be changed if there is a corresponding footnote that gives details of when and how to change the designation. In the absence of a footnote, please reach out to crc@email.arizona.edu or OnCoreSupport@email.arizona.edu.

Changes to the CA MUST be approved by the UAHS Research Administration and BH Research Finance (BHRF) teams before charges can be changed.

*This process helps to ensure that bills are routed to the correct payor, alleviate incorrect billing, and most importantly helps to protect your study subject!*

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. Requests to amend the CA must be submitted via the BIA amendment process.
Banner Hospital billing for the months of May 2018 – April 2022 have been reviewed and sent out to the corresponding UA Departments via UABox Health. May 2022 invoices will be distributed by the second week of July.

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. Payments are due 30 days from receipt of the billing in your department’s UABox Health. If there are any discrepancies, please email ctfinance@email.arizona.edu for assistance. Discrepancies need to be reported within 2 weeks of the receipt of invoices. Insurance carriers have deadlines for filing and BH has a limited window for reversing charges back to insurance carriers (as applicable).

- When submitting backup to FSO, please only redact the patient’s 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.

- Payments need to be processed within 30 days of billing receipt.

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.

Study Close-out with IRB and Final Study Payments

Once your study has been closed with the IRB, remember to enter the IRB closure date into OnCore. Please be sure to work with your business office to verify all payments to vendors have been issued and that all invoiceable items have been sent to your study sponsor (as applicable). Clinical trial contracts have a specific timeline written into the contract to complete these tasks. If you have questions, please contact our office at ctfinance@email.arizona.edu or crc@email.arizona.edu.
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."

We welcome your feedback!! Please let us know if there are specific topics that you would like to have covered at upcoming meetings. Please send an email to vphs-cro@email.arizona.edu.

CRP meetings will now be held every other month.

The next scheduled meeting is Thursday, July 21, 2022, from 3:00 pm - 4:30 pm via Zoom.

Join Zoom Meeting: https://arizona.zoom.us/j/81488925948

Meeting ID: 814 8892 5948
One tap mobile
US: +16027530140.81488925948#

CRP Group upcoming meeting schedule:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wednesday, Sep 21, 2022</td>
<td>Zoom</td>
<td>12:00 pm – 1:30 pm</td>
</tr>
<tr>
<td>Thursday, Nov 17, 2022</td>
<td>Zoom</td>
<td>3:00 pm - 4:30 pm</td>
</tr>
<tr>
<td>Friday, Dec 16, 2022</td>
<td>Kiewit</td>
<td>11:00 pm – 1:00 pm</td>
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</tbody>
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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 UAHSContacts@email.arizona.edu
- OnCore: OnCoreSupport@email.arizona.edu or https://research.uahs.arizona.edu/oncore or schedule 1:1 session (calendar validations, subject management, regulatory)
- Regulatory & eRegulatory Binder: contact regulatory@email.arizona.edu or schedule 1:1 session
- Post-Award Clinical Trial 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 the application forms can be found here. If you have questions, email Research Administration at crc@email.arizona.edu.

OnCore Technical Support: https://comhelp.arizona.edu/ Net ID Login required (password resets, user account creation, requests for reports)

OnCore Training Resources: https://ctapps.uahs.arizona.edu/oncore/resources (Net ID Login required)

ClinicalTrials.gov Assistance:
- Non-cancer studies: Kirsten Anderson, regulatory@email.arizona.edu or (520) 621-6417
- Cancer studies: UACC-NCTN@uacc.arizona.edu

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

UAHS Global HIPAA Procedures: https://research.uahs.arizona.edu/facilities-and-resources/uahips-hipaa-sop’s (Net ID Login required)

IRB Training Opportunities

Upcoming sessions are located on the IRB website with instructions for registering through UA Access EDGE Learning.

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

Coordinator Corner: https://cats.med.arizona.edu/content/coordinator-corner

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 your department’s assigned Banner Health Clinical Trial Senior Manager. https://research.uahs.arizona.edu/clinical-trials/cerner

Sonora Quest Laboratories Account Set-up and/or Care360 User Request: email request to ctfinance@email.arizona.edu. Please include the following information with your request: Name, Job Title, Net ID, UA Email, Phone and Fax numbers, Physical Work Address, Department, SQL Account Number (if known).


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.
eDisclosure Project-Based Investigator Status Dashboard User Guide

The eDisclosure Project-Based Investigator Status dashboard provides Conflict of Interest information such as Determination Status and Training Certification Date for Investigators associated with a specific project.

This dashboard can be searched using the following categories:

- Investigator ID
- Investigator Name
- Department ID
- Department Name
- Proposal ID
- Award ID
- IRB ID
- Certification Type

You can also toggle this dashboard to include all Investigators, only Active Investigators or only Inactive Investigators. The default is only Active Investigators.

**Status Key:** The Determination Status column* reflects where the Research Certification is in the Financial Conflict of Interest review process. (Information about this review process can be found on OROI’s [COC & COI Review Processes](#) webpage.)

**Complete COI Statuses**

- No Review Required
- Review Complete
- Under Management/Mitigation Plan

**Incomplete COI Statuses**

- Administrative Review (awaiting review by OROI)
- Administrative Review: Response Pending (awaiting a response from the Investigator)
- Discloser Review of Plan (awaiting Investigator’s review of management/mitigation plan)
- Draft (awaiting submission from Investigator)
- Meeting Complete: Response Pending (awaiting a response from the Investigator)
- Review Completed: Preparing Correspondence (OROI drafting correspondence to Investigator)
- Scheduled for Meeting (Research Certification on agenda for a committee meeting)
- Withdrawn (Investigator requested removal from project or project not funded)

*Please allow 1 business day for updated information in eDisclosure to be reflected in this column.
eDisclosure Proposal Development Status Dashboard User Guide

The eDisclosure Proposal Development Status dashboard provides Conflict of Interest compliance status information for Investigators associated with a specific proposal in UAccess Research. Proposals will be viewable in this dashboard 1 business day after the proposal development document is saved in UAccess Research.

*Reminder:* Pursuant to federal regulations, Investigators must have an up-to-date disclosure at the time of proposal submission to a federal funding agency.

This dashboard can be searched using the following categories:

- Proposal Development Number
- Proposal Development Document
- Lead Investigator Name
- Lead Unit
- Investigator Name
- Investigator NETID
- Conflict of Interest Status

**Status Key:** The Disclosure Status column reflects whether an Investigator has an up-to-date disclosure certification.

**Up-to-Date Disclosure Certification Status**

- OK to Submit (The individual has submitted a certification in eDisclosure in the past 364 days.)

**Incomplete Disclosure Certification Statuses**

- Incomplete (The individual needs to submit a certification in eDisclosure.)
- Not Started (The individual needs to contact the Office for Responsible Outside Interests to request that an Annual Disclosure Certification be created for them.)
- Expired (The individual’s last certification was submitted more than 364 days ago.)

*Please allow 1 business day for updated information in eDisclosure to be reflected in this column.*
eDisclosure Requirement Status Dashboard User Guide

The eDisclosure Requirement Status dashboard provides individual-specific Conflict of Interest status information.

An individual’s “COI Requirement Status” will be Complete when they have completed the following:

1. Completed the Conflict of Interest Required Disclosure Training after July 1, 2021, and
2. Submitted a certification in the last 364 days. The certification can be an Annual Disclosure Certification or Research Certification.

This dashboard can be searched using the following categories:

- College ID
- College Name
- Department ID
- Department Name
- Employee ID
- Investigator Name
- NETID
- COI Requirement Status

**Status Key:** The COI Requirement Status column reflects whether an Investigator is up-to-date on their COI requirements.

- Complete = The individual has completed their COI training and disclosure requirements.
- Incomplete = The individual needs to complete the Conflict of Interest Required Disclosure Training in EDGE Learning, submit a certification in eDisclosure or both.

*Please allow 1 business day for updated information in eDisclosure to be reflected in this column.