



JUNE 2021

COI Disclosure Blackout and New eDisclosure System



On July 1st, the COI Program will implement a new conflict of interest and commitment system, **eDisclosure**, that is designed to make submitting disclosures, research certifications and COC Forms easier and faster. **The last day to submit disclosures, research certifications and COC Forms in the legacy COI Disclosure System is Friday, June 11th.**

Here are the important dates in the implementation process:

- June 11, 2021 Final Submission Date
 - ◇ Last day to submit disclosures, research certifications and COC Forms in the legacy COI Disclosure System.
- June 12 - 30, 2021 Blackout Period
 - ◇ No COI or COC system will be available for submissions.
- July 1, 2021 eDisclosure Available
 - ◇ Please know that for their first disclosure or certification in eDisclosure, individuals will need to disclose all entities, including those previously disclosed in the legacy COI Disclosure System.
 - ◇ Research Certifications for which the COI review has been completed in the legacy COI Disclosure System will not need to be redisclosed in eDisclosure unless there is a modification to the project or protocol.

Please do not hesitate to contact the COI Program if you have any questions at coi@arizona.edu or (520) 626-6406. (Beginning July 1st, the COI Program will be the Office for Responsible Outside Interests.)

mPage Overview and Training



A Research Revenue Cycle mPage has been developed in Cerner to create a consistent front-end process for Banner Patient Access Services to be able to identify scheduled research encounters and ordered services that are covered by research so that the authorization, pre-registration, and registration process can be completed appropriately. [Please review the attached overview](#). The mPage became active on February 15, 2021. Guides can be found on the [Coordinator Corner](#) website.

HIPAA Training Reminder



The UA HIPAA Privacy Program (HPP) requires all faculty, staff, and DCCs of UAHS to complete annual HIPAA certification training. The training takes about 10 minutes and provides basic information about HIPAA compliance resources at the University. Information about how to complete the training can be found on the HPP [website](#). Additionally, the university requires all faculty, staff, and DCCs with access to university information resources to complete annual information security awareness training ([ISO-500 Information Security Awareness Training Policy](#)). The annual refresher course is approximately six (6) minutes in length, and updates employees on the latest threats, trends, and university security resources ([HIPAA Annual Certification](#)).

** Training is an essential part of a well-informed workforce. Please complete your training at your earliest convenience. If you have questions please reach out to the [HIPAA Privacy Program](#) or the [Information Security Office](#).

**UAHS Global HIPAA Procedures were updated in May 2021 and are available on the Research Administration [website](https://research.uahs.arizona.edu/facilitites-and-resources/uahs-hipaa-sop's) (<https://research.uahs.arizona.edu/facilitites-and-resources/uahs-hipaa-sop's>). A UA NetID is required.

**The HIPAA Privacy Program will be offering a bi-weekly interactive seminar covering HIPAA Privacy & Security topics beginning on November 4, 2020 at 3:00 pm. Please review the list of topics (attached) or visit this link to participate in the scheduled workshops:

<https://arizona.zoom.us/j/94477665768>

Research Intake Application (RIA)



New RIA for Amendments: Moving forward, please use the revised version of the amendment application [attached](#) and also available on our [website](#). The revised form asks about the status of the project; your answers will better help our team determine how to process your application.

Informed Consent Form (ICF): To ensure we have accurate documents for coverage analysis review, we have updated the required documents for Research Intake Application (RIA) submission. Effective February 15, 2021, new and amendment study submissions to the RIA require that the submitted ICF template includes tracked changes with any required Banner or UA language.

Protocol Amendments: It is *very important* that protocol amendments be submitted through the RIA process as soon as you receive them. Protocol amendments undergo a review and update of the coverage analysis (CA) and the OnCore calendar/financials. Both can be completed concurrently with IRB review and approval. ***IRB approval is not required for RIA submissions.*** This will allow us to update your OnCore calendar so it is ready for release as soon as IRB approval is received.

Clinical Trials Website: Please be sure to “opt-in” to having your study published on [this website](#). This can be found on pages 5-6 of the [Research Intake Application \(RIA\)](#). It is a great way to build collaboration within the research community and for potential study subjects to find studies. We are adding a “COVID-19 Research” heading for all studies associated with this category. If your study is not currently listed, please contact our office at crc@arizona.edu.

RII Research Restart Checklist for COVID Research



NOTE: Banner updated their Research Guidance (attached) for research studies on 05/1/2021. Access to their facilities may impact the approval of research studies.

Please review the following information for restarting your research.

1. The UA has transitioned to Phase 4 of the Research Restart Plan, which includes a new checklist. Information on Phase 4 is located [here](#), and [additional information](#).
2. Due to the transition, the old Phase 3 checklist has been closed, and approvers won't be able to go back into existing checklists.
3. The RII research restart checklist needs to be prepared by the PI for each study.
4. Submit each study using the new checklist at [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 [Anna Valencia \(Phoenix\)](#).***
5. Once approved by ADR and RII, the approval notice will be returned to the PI.

Additional information regarding the process can be found in the [Message from the Vice Dean for Research \(attached\)](#).

EDGE Learning Certificate Errors and New OnCore Requirements



Research, Innovation & Impact recently learned that the EDGE Learning system was entering incorrect expiration dates on some training certificates, including the CITI and HIPAA certificates that are required for OnCore access. The system error has been corrected, and EDGE users have been notified by email if they were affected. If you need to send OnCore support a corrected certificate, please email them at OnCoreSupport@email.arizona.edu. If you are uncertain if you were affected by the error, please contact Research-Training@arizona.edu.

If you need assistance printing or downloading an EDGE Learning certificate, a new guide has been added to the OnCore Support website.

Additionally, in the coming months, the OnCore Support team will be collecting Information Security Awareness certificates from all users. This training has been added to the OnCore user requirements after a quality improvement review with Information Security and Compliance.

OnCore Information, Training and Office Hours



The [OnCore](#) webpage provides information about scheduled trainings and office hours in the [Training & Office Hours](#) section. **Please feel free to sign up if you would like refresher training or come to Office Hours!** Trainings and office hours are scheduled two months in advance. Starting in April, training sessions will be held during the first week of each month. 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@arizona.edu

- **Introduction to OnCore and Calendar Validations**
Tuesday, June 8 and July 13, 1:00 pm – 3:00 pm
- **Subject Management Training**
Wednesday, June 9 and July 14, 1:00 pm – 3:30 pm
- **Regulatory Training**
Thursday, June 10, 10:00 am – 12:00 pm
Thursday, July 15, 2:00 pm—4:00 pm

We are 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 from the OnCore Team. Please email us at OnCoreSupport@arizona.edu to schedule a session.

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. Studies will need a fully executed or signed contract prior to being opened to accrual in OnCore (as applicable).

Please be sure to enter each subject's country and zip code on the Subject Demographics page.

All subject visits MUST be checked in/logged into OnCore within 24 hours of study visit.

OnCore System Update: OnCore will be down on Friday, June 25 from 6 -10am.

An OnCore version upgrade from 16.0.0 to 2020R3 is scheduled to take place on Friday, June 25, 2021, between the hours of 6:00 a.m. and 10:00 a.m. PST. Along with the OnCore update, associated databases currently in Oracle 12.2 will be migrated to Oracle 19. This version upgrade will include improvements to OnCore features and performance, maintain optimum system compatibility with the latest browser versions, and use Advarra's new cloud platform to ensure that OnCore is meeting the highest standards of security for clinical trial data.

During this time, OnCore will be offline and unavailable for use. The four-hour window is the estimated time needed, but the update could be finished sooner or go overtime. Please watch for status updates on June 25 from the OnCore listserv.

Thank you in advance for your patience during this brief service outage.

UAHS Sign-off in OnCore: This sign-off is done by Research Administration upon completion of the coverage analysis (CA), budget, and fully executed contract (if applicable) and receipt of the IRB approved ICF(s).

Regulatory in OnCore (REQUIRED FOR ALL STUDIES):

- **New Studies:** Please upload your approved IRB documents (approval letter, protocol, and approved ICF(s)) into OnCore. Documents should be uploaded using the PC Console (PC Console > Reviews > IRB).
- **Amendments:** Protocol amendments, IRB approval letters, and the newly approved ICF(s) (as applicable) need to be uploaded into OnCore using the PC Console. The amendment IRB approval date needs to be entered. IRB approval of the protocol amendment will help the OnCore Support team know when to release the updated calendar for the protocol amendment (as applicable).
- Please be sure to update any personnel changes in OnCore, update IRB approval/closure dates and upload IRB approval documents (approval letters, ICFs, etc.)

OnCore Information, Training and Office Hours, *continued*

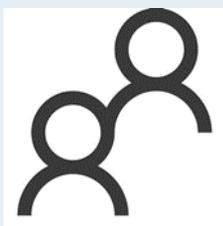
Cerner & OnCore: OnCore is now able to push "On Study" subject information to Cerner. This will add a notification on the blue banner to the patient's medical record that they are enrolled in a UA clinical trial. All active protocols with active subjects for have been pushed over to Cerner. Once a subject is marked as "On Study" be sure to check Cerner to verify that the blue banner appears. If it does not appear, verify that the first and last name, date of birth, and MRN all match. 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 are continuing to 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
- Implementation of the eRegulatory Management System was completed in March. A formal launch date is still being determined.

Please email us at OnCoreSupport@arizona.edu with questions, or for additional help.

Outlook Contacts to Add to Avoid Missed Messages



Research Administration serves investigator teams across UAHS through a wide range of pre- and post-award activities. Frequent and timely contact keeps those processes moving, and that means a large volume of email. Adding Research Administration email addresses to your Outlook contacts can ensure that time-sensitive messages don't end up unnoticed in your Junk Email folder.

Updating contacts is especially important for research teams who are working with OnCore, since the system frequently sends automated messages in batches from OnCoreSupport@email.arizona.edu. Some users have reported that messages about OnCore have ended up in their spam folder. CRC@email.arizona.edu, UAHSContracts@email.arizona.edu, and ResearchApp@email.arizona.edu are additional email addresses that should be added in Outlook due to the high volume of messages they send.

Contacts can be added from a new message by right-clicking on an email address and selecting **Add to Outlook Contacts**, or by going to the **Contacts** (or **People**) tab in your left sidebar and selecting **New Contact** from the top ribbon.

Research Administration maintains a Departmental Contacts page that includes a comprehensive list of email addresses for all of the work groups that could be in communication with you. Sponsors and clinical partners are also contacts to consider adding in Outlook.

Banner Hospital Billing Update



Banner Hospital billing for the months of October 2017 – March 2021 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. **Payments are due 30 days from receipt of the billing.** If there are any discrepancies, please email ctfinance@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*)

Entity Code	Medical Records #	Acct #	Patient Name	DOS	Charge #	CPT4 Code	CPT4 Code Description	Charge Amount	Adjustment	Balance Due
483	██████	123456789	██████	2019-05-29	4818225	93306	ECHO/DOPPLER/COLOR FLW CMP W/O CNT	\$2,736.00	\$1,931.62	\$804.38
483	██████	234567890	██████	2019-05-01	4818225	93306	ECHO/DOPPLER/COLOR FLW CMP W/O CNT	\$2,736.00	\$1,931.62	\$804.38

- Please send an email to ctfinance@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.

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.

- 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@arizona.edu.

Questions regarding the coverage analysis? Contact Research Administration at crc@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@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@arizona.edu.

Sonora Quest Laboratories Account Set-up and/or Care360 User Request



Email request to: ctfinance@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)

Study Close-out with IRB and Final Study Payments



Once your study has been closed with the IRB, remember to enter the 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 window to complete these tasks. If you are unsure or have questions, please contact our office at ctfinance@arizona.edu or crc@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 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@arizona.edu.

CRP meetings will now be held every other month starting with the May meeting.

The next scheduled meeting is **Thursday, July 22, 2021, 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:

Date	Time
Thursday, Jul 22, 2021	3:00pm - 4:30pm
Wednesday, Sep 15, 2021	12:00pm - 1:30pm
Thursday, Nov 18, 2021	3:00pm - 4:30pm

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@arizona.edu
- Contracts (CDAs, NDAs, CTAs, amendments, data use, incoming MTAs): contact UAHSContracts@arizona.edu
- Clinical Trial Regulatory and IRB: contact regulatory@arizona.edu
- Post-Award accounting and auditing: contact CTFinance@arizona.edu

UAHS Project Status Report: <https://research.uahs.arizona.edu/facilitites-and-resources> (UA NetID Login required)

Research Intake Application (RIA):

Applications and required documentation should be emailed to ResearchApp@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@arizona.edu.

UAHS OnCore Support: OnCoreSupport@arizona.edu or <https://research.uahs.arizona.edu/oncore>

ClinicalTrials.gov Assistance:

Non-cancer studies: Kirsten Anderson, regulatory@arizona.edu or (520) 621-6417

Cancer studies: Amy Selegue, UACC-NCTN@uacc.arizona.edu, (520) 626-0301

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

UAHS Global HIPAA Procedures:

<https://research.uahs.arizona.edu/facilitites-and-resources/uahs-hipaa-sop's> (Net ID Login required)

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 EDGE Learning.

<https://rgw.arizona.edu/compliance/human-subjects-protection-program/irb-training-opportunities>

REDCap Questions/Training: Contact redcap@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>

COM-P Clinical Research website: <http://bit.ly/COMP-clinical-research>

Banner Badge Request: Contact clinicalresearch@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: email request to ctfinance@arizona.edu

Sonora Quest Laboratories Reference Manual:

<https://www.sonoraquest.com/test-directory/>

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.