



**AUGUST 2021**

### eIRB System coming in September



The Human Subjects Protection Program (HSPP) will launch a new system, eIRB, designed to make submitting human research protocols easier and faster. For more information about the implementation process, please visit [\*\*RII's New Systems Information Webpage\*\*](#).

#### **Please note the following important dates in the implementation process:**

- **Aug. 13** – Last day to submit to the HSPP for **full committee** review.
- **Aug. 20** – Last day to submit to the HSPP for **non-committee** review. Any submissions received by this date but not yet finalized or any submission received after this date may not be reviewed and will be returned to you with further instruction on how to proceed.
- **Aug. 25-Sept. 12** – Blackout period (No IRB system will be available for submissions).
- **Sept. 13** – eIRB is available to submit materials to the IRB.

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### Updates to New Clinical Trials Submission Process



The introduction of the new eIRB and eDisclosure systems require updates to the existing submission process for new clinical trials. Funded studies will receive notice of feasibility approval and an approval to move forward with UA IRB submission after the coverage analysis is complete. This deferment in UA eIRB submission will eliminate duplicate COI disclosure requests and streamline consent form revisions. The change will not alter the UAHS contract and budget timelines, so the overall time for study start-up should remain the same.

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### New eDisclosure System



The Conflict of Interest Office will now be known as The Office for Responsible Outside Interests (OROI). The OROI implemented a new conflict of interest and commitment system, eDisclosure, that is designed to make submitting disclosures, research certifications and Conflict of Commitment (COC) forms easier and faster.

The UA's new Conflict of Interest (COI) disclosure system opened July 1, 2021. The new eDisclosure page is where you can find training resources:

<https://research.arizona.edu/compliance/conflict-interest-program/disclosure-requirements/edisclosure-information>.

Here is the link to the new system:

<https://edisclosure.arizona.edu/>. Please see the attached email for more information.

Anyone who is listed as a COI investigator for at least one research project should have already received notifications to submit research certifications. These should be completed as soon as possible to avoid delays with IRB submissions. Notifications for annual certifications were emailed out July 12<sup>th</sup>.

- ◇ 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.

For questions or more information, contact the Office for Responsible Outside Interests at [coi@arizona.edu](mailto:coi@arizona.edu) or at 520-626-6406.

## Research Intake Application (RIA)



**RIA Support** is available by scheduling through Microsoft Bookings. A Zoom link will be provided in your email confirmation once you schedule your session.

**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](mailto: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.**

In an effort to protect patients, team members and the community, Banner Health is now requiring all employees to receive the COVID-19 vaccine by Nov. 1, 2021. This includes all University of Arizona Health Sciences (UAHS) faculty and staff who are also employed by Banner Health. UAHS leadership and the UA Office of General Council are reviewing how this will impact UAHS research staff.

The UA has transitioned to Phase 5 of the Research Re-Start Plan, which means that restart checklist.s are no longer required. Information on Phase 5 is located [here](#).

- **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 \(Phoenix\)](#).**

## 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!**

To register for the next training sessions, please complete an OnCore Confidentiality Agreement and send your training request to OnCoreSupport@arizona.edu. The next trainings are scheduled as follows:

- **Introduction to OnCore and Calendar Validations**  
Tuesday, August 3 or September 14, 1 pm—3 pm
- **Subject Management Training**  
Wednesday, August 4 or September 15, 1 pm—3 pm
- **Regulatory Training**  
Thursday, August 5 or September 16, 10 am—12 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@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@arizona.edu to schedule a session.

### Subject Entry into OnCore

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.***

### Year-One Feedback for OnCore CTMS and OnCore Support

Thank you everyone who participated in our survey. We received some really useful feedback and we will be working on refining our communications and training documents to continue providing support to the UAHS research community. Visit our website to see updates and our library of resources (requires a UA NetId).

**OnCore, Training and Individual Consultations, *continued***

**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). Please verify that the NCT Number has been added (PC Console > Main > Details).
- **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).
- **Personnel Changes:** Please be sure to update any personnel changes in OnCore, update IRB approval/closure dates and upload IRB approval documents (approval letters, ICFs, etc.)
- **Study Closure:** Upload IRB closure notice, change the study status to "IRB Study Closure", and enter the study closure date.

**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](mailto:OnCoreSupport@arizona.edu) with questions, or for additional help.

**Banner Hospital Billing Update**



Banner Hospital billing for the months of October 2017 – May 2021 have been reviewed and sent out to the corresponding UA Departments via UABox Health. **The June 2021 invoices will include a Transaction ID. Please be sure to include this with the June payments and all future payments to Banner. This will help the BH financial team to apply payments in their system.**

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](mailto:ctfinance@arizona.edu) for assistance.

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 WO CNT	\$2,736.00	\$1,931.62	\$804.38
483	██████	234567890	██████	2019-05-01	4818225	93306	ECHO/DOPPLER/COLOR FLW CMP WO CNT	\$2,736.00	\$1,931.62	\$804.38

- 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@arizona.edu](mailto: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](mailto:OnCoreSupport@arizona.edu).

Questions regarding the coverage analysis? Contact Research Administration at [crc@arizona.edu](mailto:crc@arizona.edu).

**COVID-19 Research and Sample Request Guide**



Investigators wishing to initiate a COVID-19 study that would require biospecimen collection should contact Dr. Sairam Parthasarathy at [spartha1@arizona.edu](mailto:spartha1@arizona.edu) for patient access.

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](mailto:davidh@arizona.edu).

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

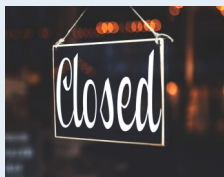


Email requests to: [ctfinance@arizona.edu](mailto:ctfinance@arizona.edu)

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 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 are unsure or have questions, please contact our office at [ctfinance@arizona.edu](mailto:ctfinance@arizona.edu) or [crc@arizona.edu](mailto: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](mailto: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](mailto:vphs-cro@arizona.edu).

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

The next scheduled meeting is **Wednesday, Aug 18, 2021, from 12:00 pm - 1:30 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
<u>Wednesday, Aug 18, 2021*</u> <b>*Review of new eIRB system</b>	12:00pm - 1:30pm
<u>Wednesday, Sep 15, 2021</u>	12:00pm - 1:30pm
<u>Thursday, Nov 18, 2021</u>	3:00pm - 4:30pm
<u>Wednesday, Dec 15, 2021</u>	12:00pm – 1:30pm
<u>Wednesday, Jan 19, 2021</u>	12:00 pm – 1:30 pm
<u>Thursday, Mar 17, 2021</u>	3:00pm - 4:30pm
<u>Wednesday, May 20, 2021</u>	12:00 pm – 1:30 pm
<u>Thursday, Jul 23, 2022</u>	3:00pm - 4:30pm
<u>Wednesday, Sep 21, 2022</u>	12:00 pm – 1:30 pm
<u>Thursday, Nov 17, 2022</u>	3:00pm - 4:30pm
<u>Wednesday, Dec 14, 2022</u>	12:00 pm – 1:30 pm

## 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](mailto:crc@arizona.edu)
- Contracts (CDAs, NDAs, CTAs, amendments, data use, incoming MTAs): contact [UAHSContracts@arizona.edu](mailto:UAHSContracts@arizona.edu)
- Regulatory contact [regulatory@arizona.edu](mailto:regulatory@arizona.edu) or schedule 1:1 session
- Post-Award Clinical Trial Accounting and Auditing: contact [CTFinance@arizona.edu](mailto: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](mailto:ResearchApp@arizona.edu). Instructions and the application forms can be found [here](#):

If you have questions, email Research Administration at [crc@arizona.edu](mailto:crc@arizona.edu).

**UAHS OnCore Support:** [OnCoreSupport@arizona.edu](mailto:OnCoreSupport@arizona.edu) or <https://research.uahs.arizona.edu/oncore> or [schedule 1:1 session](#) (calendar validations, subject management, regulatory, IT support)

### **ClinicalTrials.gov Assistance:**

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

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

**UA HIPAA Privacy Office:** Contact [PrivacyOffice@arizona.edu](mailto: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.

**REDCap Questions/Training:** Contact [redcap@arizona.edu](mailto: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: <https://phoenixmed.arizona.edu/research/clinical-research/investigators>

**Banner Badge Request:** Contact [clinicalresearch@arizona.edu](mailto: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](mailto: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](mailto:SQLCustomerSytems@SonoraQuest.com) to schedule training. Please be sure to include your SQL departmental account number when requesting training.