



SEPTEMBER 2021

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.

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. 25-Sept. 12** – Blackout period (No IRB system will be available for submissions).
- **Sept. 13** – eIRB is available to submit materials to the IRB.

Research Services from Sonora Quest (SQL) or Lab Services (LSA)



In order to better identify and provide research services, SQL and LSA have updated the requirements for feasibility review and contract requests. SQL is currently working with the University to establish a streamlined process for the completion of required contracts prior to the request of services. Detail and timeline of the implementation will be shared in the coming weeks.

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 12th.

- ◇ 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 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.

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 Workflows by Study Role for Study Start-up and Amendments

We are continuing to refine and enhance our training documents to educate study teams of how OnCore fits into their research studies. We have created the attached workflow chart to illustrate the study teams OnCore responsibilities and how they work with Research Administration's responsibilities.

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, Sept 14 or Oct 5, 1 pm - 3 pm
- **Subject Management Training**
Wednesday, Sept 15 or Oct 6, 1 pm - 3:30 pm
- **Regulatory Training**
Thursday, Sept 16 or Oct 7, 2 pm - 4 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.

OnCore CTMS Data Clean-up and OnCore Support

Thank you everyone who has been working with our office to update your study and enrollment data in OnCore. Data maintenance is an ongoing project for all departments. Entry of IRB approvals and dates is very important. This data will be distributed to college and department leadership regarding the clinical research portfolios. It is very important to keep your data up-to-date and minimize study queries.

- Upload regulatory documents to OnCore.
 - ◊ IRB approval letters, renewal dates, approved ICFs
- Update staff/personal changes as they occur.
- Log study subject visits within 24 hours of occurrence.

Visit our website to see updates and our library of resources (requires a UA NetId).

OnCore, continued**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.

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).

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

- We are continuing to work on entering study budgets into OnCore. We will start reaching out to department business offices to coordinate training for this beneficial tool that will aid with Please ask your business office to contact our office at ctfinance@arizona.edu to initiate start-up for your department .
- Implementation of the eRegulatory Management System (eReg) has been completed. We will start trainings in October 2021. Please contact regulatory@arizona.edu to initiate start-up for your department.

◇ We will be focusing on having departments enter new studies into eReg. Departments are welcome to enter historical studies.

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

Banner Hospital Billing Update



Banner Hospital billing for the months of October 2017 – June 2021 have been reviewed and sent out to the corresponding UA Departments via UABox Health. July 2021 invoices will be distributed during the first week of September. **Banner invoices will soon include a Transaction ID. Please be sure to include this with 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 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 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

- 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 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



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.

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

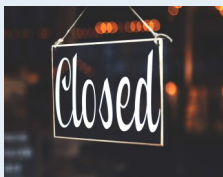


Email requests to: ctfinance@arizona.edu

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 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 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.

The next scheduled meeting is **Wednesday, Sep 15, 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
Thursday, Nov 18, 2021	3:00pm - 4:30pm
Wednesday, Dec 15, 2021	12:00pm – 1:30pm
Wednesday, Jan 19, 2021	12:00 pm – 1:30 pm
Thursday, Mar 17, 2021	3:00pm - 4:30pm
Wednesday, May 20, 2021	12:00 pm – 1:30 pm
Thursday, Jul 23, 2022	3:00pm - 4:30pm
Wednesday, Sep 21, 2022	12:00 pm – 1:30 pm
Thursday, Nov 17, 2022	3:00pm - 4:30pm
Wednesday, Dec 14, 2022	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
- Contracts (CDAs, NDAs, CTAs, amendments, data use, incoming MTAs): contact UAHSContracts@arizona.edu
- Regulatory contact regulatory@arizona.edu or schedule 1:1 session
- Post-Award Clinical Trial 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 the application forms can be found [here](#):

If you have questions, email Research Administration at crc@arizona.edu.

UAHS OnCore Support: 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 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.

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: <https://phoenixmed.arizona.edu/research/clinical-research/investigators>

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.

Frequently Asked Questions: Mandatory COVID-19 vaccine



OVERVIEW

Our purpose throughout the pandemic has been to save as many lives as possible while keeping our health care workers safe. With that mission in mind, we've closely followed CDC guidelines, aligning our practices and procedures with those guidelines when they impact either our teams or Sofia. That's why we're moving to require mandatory COVID-19 vaccines for all Banner team members by Nov. 1, 2021—to protect one another, our patients, our families and the communities we serve.

As members of the health care field, it's our duty to do anything necessary to provide the safest care environment possible for our patients and each other.

Why do I have to get the COVID-19 vaccine?

As Banner team members, we're committed to unparalleled safety, quality, service and innovation. Many of us have already been vaccinated but we must be at 100% to help stop the spread of this deadly virus and keep our patients, visitors and colleagues safe. As members of the health care industry, any steps we can take to protect our patients and one another are the right thing to do.

Why are we making the vaccine mandatory now?

We have encouraged team members to get the COVID-19 vaccine since they were first made available. Now that cases and variants are increasing, we feel it's our duty caring for the most vulnerable of our communities that we take every step possible to safeguard our patients and our teams from this deadly disease.

How do I prove I have received my vaccine?

If you've received your COVID-19 vaccine and need to submit proof, here's a quick and easy guide for the [submission process](#). If you previously submitted proof of vaccination, no further action is needed.

Why am I being asked to submit a photo of my vaccine card to Occupational Health?

Occupational Health is the official medical record for health care workers. All immunization records are currently housed in the system (such as flu, measles, etc.). Federal reporting requirements may include vaccine manufacturer and dosing information, which is displayed on the vaccine card.

I previously submitted my proof of vaccine—can I confirm Occupational Health has my record?

To verify that Occupational Health has your vaccine information, visit [this link](#). If it says you are fully vaccinated, no further action is needed. Please do not resubmit cards to Occupational Health. You may get a pop-up that says Request Access. Please do not click request access, close your browser window and click the link again to refresh your access; if it pops up again click **not now**.

Is it legal to require team members to get a COVID-19 vaccine?

Yes. State and federal employment laws allow private companies to mandate vaccinations. This is the same process we have taken with the flu vaccine and it has been an important step in delivering safe, quality care and helping to protect the health of our team members.

Will I lose my job if I don't get the vaccine?

Obtaining the COVID-19 vaccination or having an approved exemption on file is a requirement for continued employment beginning Nov. 1, 2021. We don't know yet if a booster will be required annually but if it is, that will also be mandatory.

Will there be exemptions from this requirement?

Requests for medical and religious exemptions from the COVID-19 vaccine will need to be submitted to Occupational Health for consideration. Forms to make this request will be provided in the online [COVID-19 toolkit](#) no later than Aug. 1, 2021.

What is the deadline to be fully vaccinated?

All Banner team members must be fully vaccinated or have an approved exemption on file with Occupational Health by Nov. 1, 2021.

Is getting the COVID-19 vaccine safe?

There are no reported serious safety concerns with the COVID-19 vaccines. The CDC and the FDA will continue to monitor individuals who've received the vaccine to ensure there's no evidence of even rare safety issues. As health care workers we have a duty to protect our patients and each other. Please also keep in mind that COVID-19 can be a fatal or debilitating disease, even in young, healthy people. The risks from contracting the virus are greater than the possible risks from receiving the vaccine.

Are medical staff, volunteers, Banner Staffing Services team members, external contract labor, vendors, contingent labor, and students required to receive the COVID-19 vaccine?

Yes - this is required for all these populations.

I have had COVID-19, so why am I required to get a vaccine?

At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19. The immunity someone gains from having an infection, called natural immunity, varies from person to person and the evidence suggests natural immunity may not last very long in some people.

Can't I still contract COVID-19 even if we're vaccinated?

The intent of the vaccine, like flu, is about lessening the morbidity and the mortality. The COVID-19 vaccine is designed to lessen the severity; it's not a guaranteed prevention. As members of the health care industry, any steps we can take to protect our patients and one another are the right thing to do.



Date:

Application Submitter Contact Information

Last Name:	First Name:	Phone:
UA Email Address:		

Study Information

Study UA IRB Number:	Study Sponsor:
Full Protocol Study Title:	
Sponsor Protocol Number:	Current Protocol Version:
Current Protocol Date:	What is the project's current IRB Status?
Number of Active Subjects: <small>How many subjects are currently on study / active?</small>	Number of Consented Subjects: <small>How many total subjects (active & completed) have been consented for this study?</small>
Is the project sponsor, CRO, or other vendor based in the EU? Yes No	
Will UA collect/receive data from subjects in the EU? Yes No	If yes, will the data received be completely deidentified? Yes No

Amendment

Amendment, Type

Contract Protocol Budget ICF

CTA Amendment Number:

If a Contract Amendment is involved, please provide the amendment number, if available.

Protocol Amendment Version:

Please provide the protocol amendment version and date.

Informed Consent

Was the Consent Form(s) revised with this amendment? If your answer is YES, please upload the revised Consent Form(s).

Yes No

Schedule of Events Changes

Was the Schedule of Events (SOE) revised with this protocol amendment? If your answer is YES, please upload a revised Schedule of Events table for PCA review.

Yes No

Cerner Data Warehouse (Sep 19, 2017 - present)

If you need data from Cerner, please complete and upload the CRDW Request Form. You can get the form here:

<https://research.uahs.arizona.edu/clinical-trials/resources>

Yes No

Amendment Comments:**Contract/Budget Amendment Information****UA Account Number:**

Please contact your Business Manager for this number.

Sponsor/CRO Contract Negotiator Name

Sponsor/CRO Contract Negotiator Phone Number

Sponsor/CRO Contract Negotiator Email

Sponsor/CRO Budget Negotiator Name

Sponsor/CRO Budget Negotiator Phone Number

Sponsor/CRO Budget Negotiator Email

PI Information

Current PI Name:

Current PI Email:

PI Change?

Please complete the following questions if the PI is being changed.

Yes No

New PI Employer

UA Banner

New PI Name:	New PI UA Email:
New PI Degree <input type="checkbox"/> JD <input type="checkbox"/> MBA <input type="checkbox"/> MD <input type="checkbox"/> MD/PhD <input type="checkbox"/> MPH <input type="checkbox"/> PharmD <input type="checkbox"/> PhD <input type="checkbox"/> RN	
New PI Lead Unit Change? Yes No	New PI Lead Unit:
New PI College:	If Other UA College or Department, specify:
New PI Clinical Department (COM only)	New PI Center or Institute:

Documents

Please attach the following applicable documents to your email:

Document Title	Description	Required
Budget Amendment	If there has been an amendment to the budget, please upload the amended budget provided by sponsor.	
Clinical Research Data Warehouse Form	CRDW Request Form	
Contract Amendment	If the Clinical Trial Agreement (CTA) has been amended, please upload the Word version of the CTA Amendment provided by sponsor.	
Informed Consent Form, revised	If IRB approved consent(s) are not available, please upload track changes draft consent(s).	
Protocol Amendment	Please upload Protocol with tracked changes and Protocol (clean copy) with the Protocol Summary of Changes. If a contract and/or budget amendment is due to a revised protocol, please upload the amended protocol.	
Schedule of Events (SOE), revised	Required if there is a change in the Schedule of Events previously submitted.	
Sponsor Email	Please upload any relevant sponsor correspondence related to the Amendment.	
Reimbursement Guide	For Device trials ONLY	
Purchasing Agreement	For Device trials ONLY	

Research Guidance in Response to New Visitor Restriction Policy for Banner Facilities – UPDATED 5.1.21

Guiding principles: The goal of this memo is to update the guidance surrounding non-essential research and research personnel operating in a non-clinical care capacity within Banner facilities associated with the University of Arizona (see #3 and Table, below). This update continues to balance safety to both research personnel, study subjects and compliance with local & federal (NIH) regulatory and research safety protocols that may be modified as needed. The different elements of safety that require a fine balance are derived from several avenues: COVID-19 exposure, study-related interventions that may require monitoring, and patient clinical care that oftentimes occurs in areas where research is carried out, among others. The primary focus is to protect research participants, researchers and the larger community from risk of infection with COVID-19 as well as to ensure ongoing access to research that may provide essential support and care to participants. This update focuses on changes to clinical research gating criteria at Banner in response to lower COVID-19 positivity rates and the increasing number of vaccinated research personnel and participants.

Necessary and ongoing mitigation measures: In general, any in-person research encounter or visit for both observational and therapeutic research occurring in a Banner Health facility that can be converted to a virtual or telephonic visit should continue to be conducted remotely. For those research visits that cannot be conducted remotely, the frequency of these visits should be decreased. Consenting of patients should continue to be conducted remotely whenever possible.

- 1. COVID-19 Research:** All COVID-19 studies occurring in Banner Health facilities may continue at this time. COVID-19 research activities may occur in designated COVID-19 areas and select clinics, outpatient, and inpatient environments granted that proper precautions are followed. Permissible research activities include but are not limited to facility-based participant recruitment, participant interviews, biospecimen collection, imaging acquisition, interventional procedures, physical assessments.
- 2. Clinical research involving clinical interventions that have the potential to be lifesaving or disease-altering (i.e. oncology):** These studies may continue to recruit, enroll and monitor study subjects in Banner Health facilities with proper COVID-19 safety precautions. Permissible research activities include but are not limited to facility-based participant recruitment, participant interviews, biospecimen collection, imaging acquisition, interventional procedures, physical assessments.
- 3. Research that involves clinical visits, obtaining clinical samples during planned clinical procedures or that are protocol mandated for lifesaving or disease-altering studies, or obtaining observational or safety monitoring data:** These visits may continue in conjunction with a clinical standard of care visit or procedure that the participant has scheduled or is protocol required. Permissible research activities include but are not limited to biospecimen collection, imaging acquisition, interventional procedures, physical assessments, safety monitoring. These visits should occur in close collaboration with individual Banner Health facility leadership team (specifically in the OR, ICU, ED, outpatient procedure areas/clinics), follow all proper COVID-19 safety precautions and will be subject to facility procedural triage guidelines if/where deemed necessary. Research visits that are not aligned with clinical standard of care visits or those that require additional personnel in Banner facilities may now be resumed with proper COVID-19 safety precautions in place. These activities include biospecimen collection requiring additional research personnel in Banner facilities (OR, ED, ICU, procedure areas) and observational and ancillary research that requires visits to Banner facilities outside of standard clinical visits.

4. **Sponsor Monitoring Visits:** It is encouraged that all external sponsor monitors be fully vaccinated prior to conducting monitoring visits that need to occur in Banner Health facilities. Otherwise, the visit should be held remotely. .

For studies that involve research visits/procedures (with exception of research covered under 1-3 above)

Study status	Plan	Mitigation strategies
Not open, not recruiting	May open and begin new recruitment	<p>In addition to CDC, Banner Health and UArizona Research Restart guidelines, decrease frequency and convert in-person to remote visits whenever possible. Amend regulatory procedures as needed.</p> <p>Limit on-campus study staff and on-site roles to personnel required to conduct the in-person visit.</p> <p>UArizona research staff will be allowed on site as needed but will collaborate closely with Banner Health clinics and hospital operations and will abide by all safety standards currently in place.</p>
Open, not recruiting	May begin new recruitment when appropriate. Continue monitoring as required by regulatory procedures.	<p>In addition to CDC, Banner Health and UArizona Research Restart guidelines, decrease frequency and convert in-person to remote visits whenever possible. Amend regulatory procedures as needed.</p> <p>Limit on-campus study staff and on-site roles to personnel required to conduct the in-person visit.</p> <p>UArizona research staff will be allowed on site as needed but will collaborate closely with Banner Health clinics and hospital operations and will abide by all safety standards currently in place.</p>

<p>Open and recruiting</p>	<p>May continue new recruitment. Continue monitoring as required by regulatory procedures.</p>	<p>In addition to CDC, Banner Health and UArizona Research Restart guidelines, decrease frequency and convert in-person to remote visits whenever possible. Amend regulatory procedures as needed.</p> <p>Limit on-campus study staff and on-site roles to personnel required to conduct the in-person visit.</p> <p>UArizona research staff will be allowed on site as needed but will collaborate closely with Banner Health clinics and hospital operations and will abide by all safety standards currently in place.</p>
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GENERAL ONCORE WORKFLOW BY ROLE



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