THE UNIVERSITY OF ARIZONA HEALTH SCIENCES
Research Administration

RESEARCH ADMINISTRATION - CLINICAL TRIALS NEWSLETTER

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.)

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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 (HIPPA 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). 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 Re-Start 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*

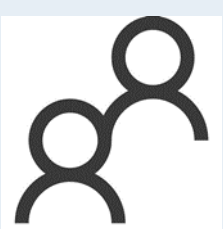
Cerner & OnCore: OnCore is now able to push "On Study" subject information to Cerner. This will add a notification on the blue banner to the patient's medical record that they are enrolled in a UA clinical trial. All active protocols with active subjects for have been pushed over to Cerner. Once a subject 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	[redacted]	123456789	[redacted]	2019-05-29	4818225	93306	ECHO/DOPPLER/COLOR FLW CMP WO CNT	$2,736.00	$1,931.62	$804.38
483	[redacted]	234567890	[redacted]	2019-05-01	4818225	93306	ECHO/DOPPLER/COLOR FLW CMP WO 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.

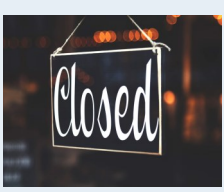
Sonora Quest Laboratories Account Set-up and/or Care360 User Request

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.

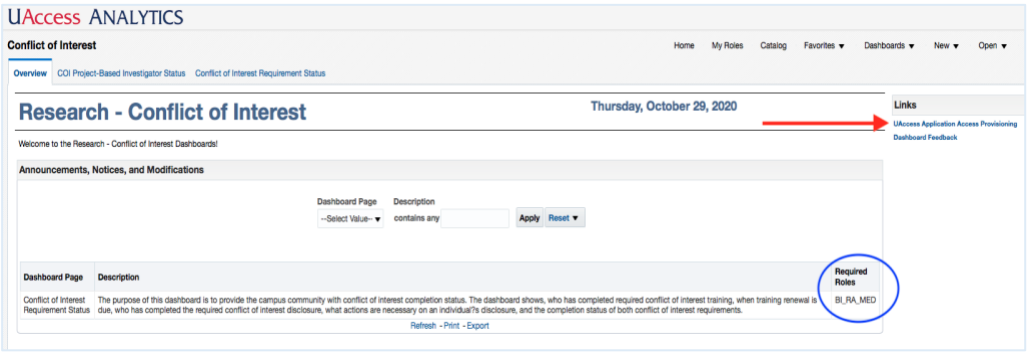
THE UNIVERSITY OF ARIZONA

Need COI Info?

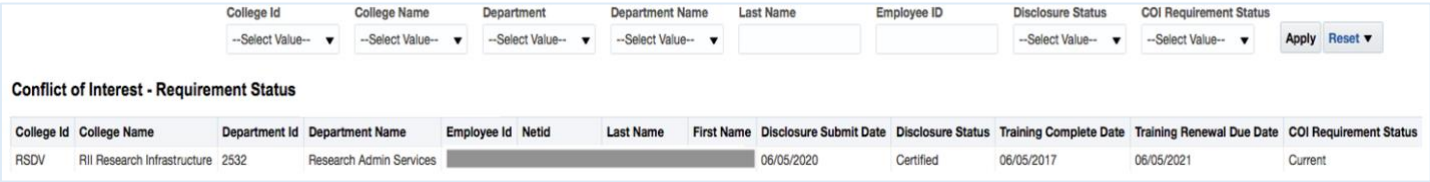
COI Analytics Dashboard

The Research – Conflict of Interest Dashboard, available in UAccess Analytics, provides COI information such as disclosure and training statuses and project-based statuses.

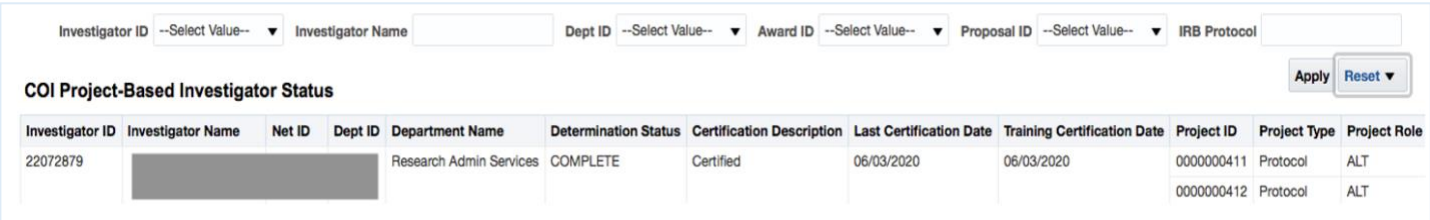
Access the Dashboard by using the link: COI Analytics Dashboard
Request access through: UAccess Analytics Provisioning Tool



Requirement Status: You can search by College Name or ID, Department Name or ID, or Employee Last Name or ID to view individuals' compliance status.



Project Status: You can search by Investigator Name or ID, Award ID, Proposal ID, or IRB Protocol Number to view the COI review status for specific projects.



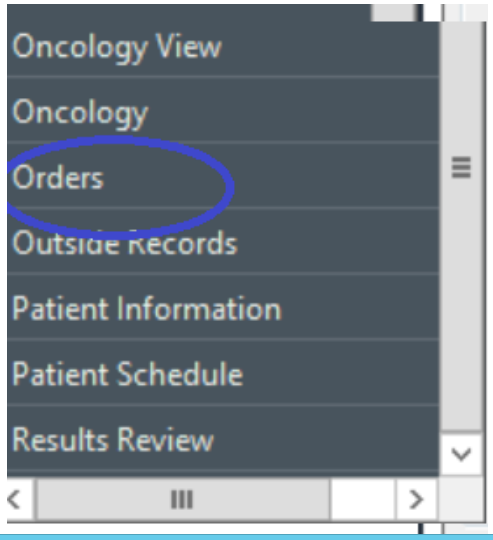
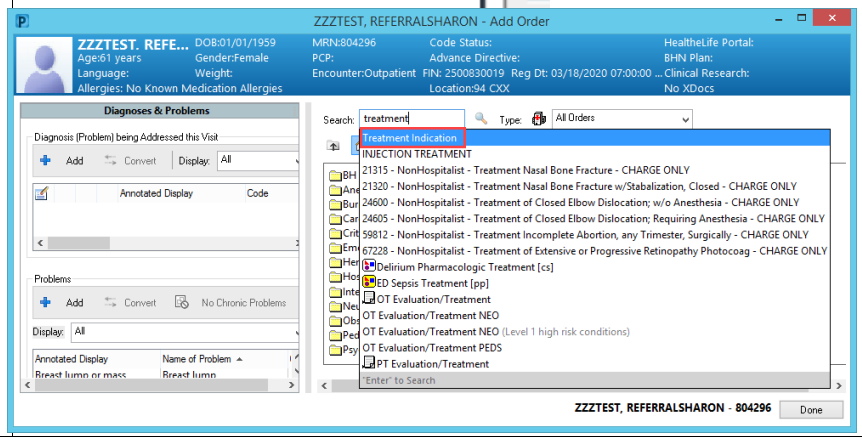
MORE INFO

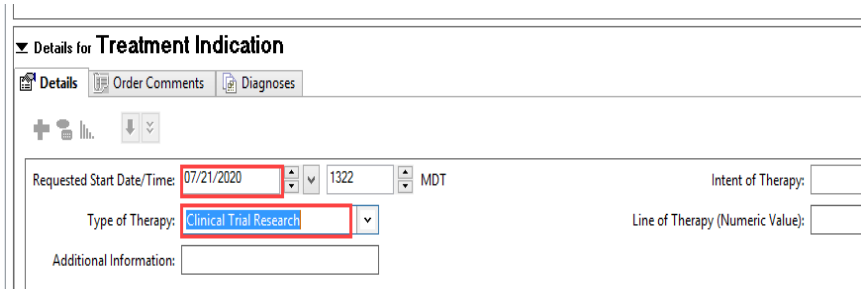
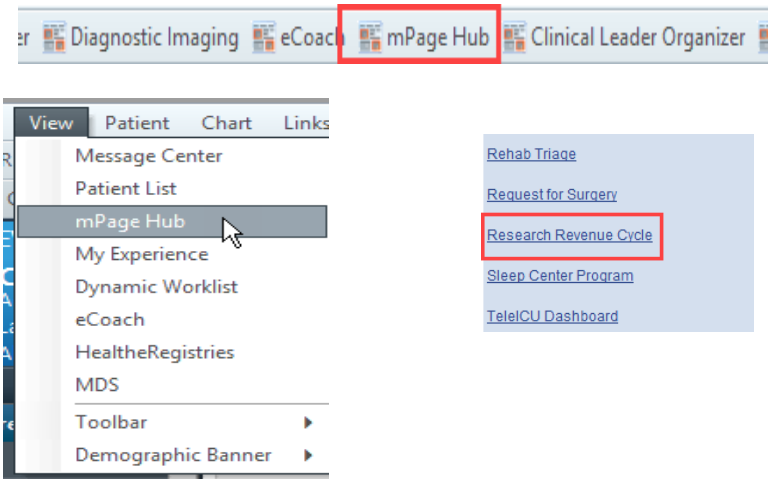
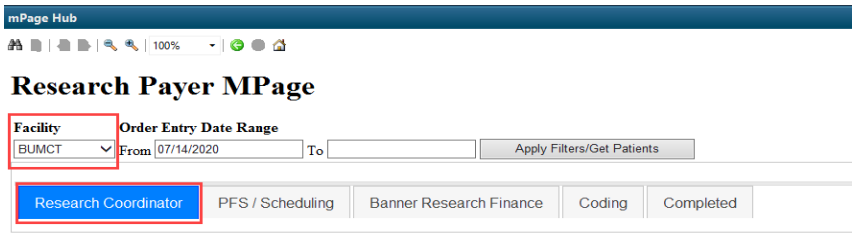
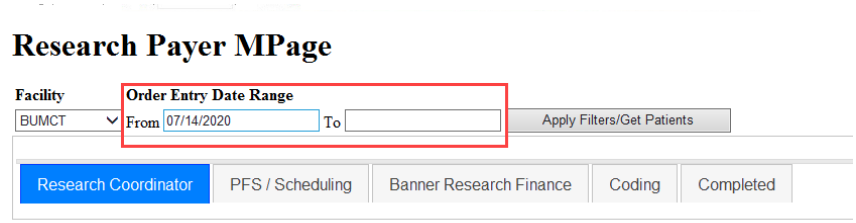
Want to receive COI announcements and updates? Join the COI & COC Listserv! Subscribe here: https://list.arizona.edu/sympa/info/coi-coc.

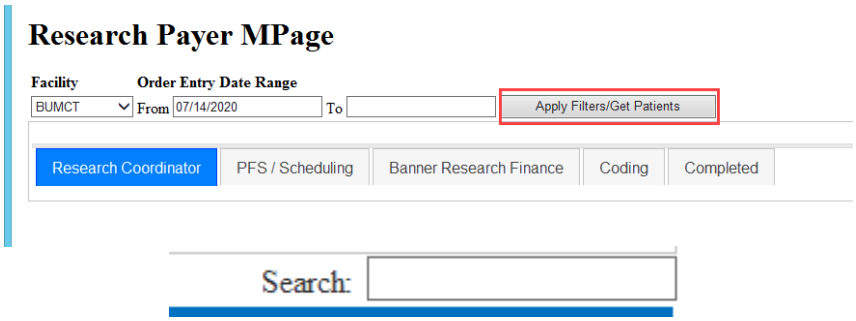
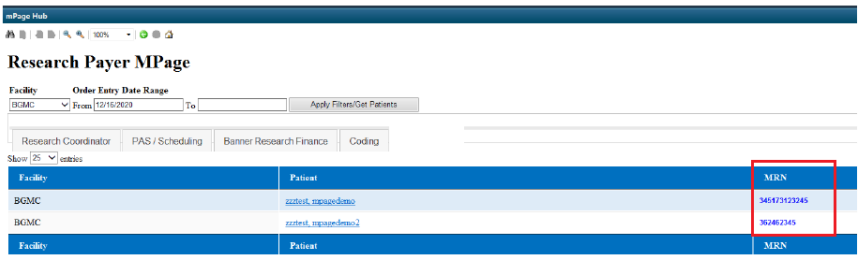
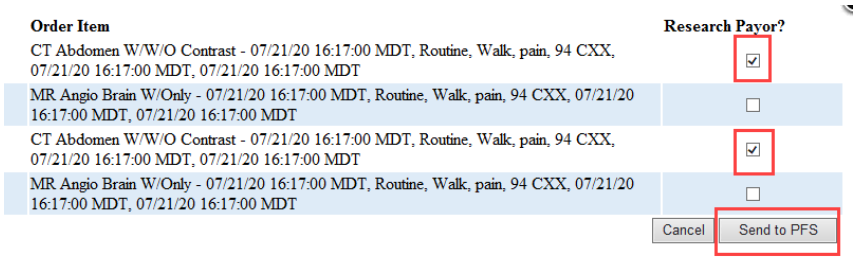
Study Coordinators

This process will guide the Study Coordinator through the workflow for adding scheduled research encounters to the mPage and identifying ordered services that are covered by the study.

Overview: A Research Revenue Cycle mPage has been developed in Cerner to create a consistent front-end process for 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.

Step	Instruction	Reference
1	Research Subjects will be scheduled per usual scheduling protocol. Once a Subject has been scheduled to receive services as part of the clinical research protocol, the study coordinator will navigate to **Cerner** and add a **Treatment Indication Order** on the corresponding encounter. **Adding this order will trigger the patient and the encounter to flow to the Research mPage.** **Encounter Type:** The mPage is for outpatient research encounters. **Orders:** All (1) Medical Imaging (2) Cardiology (3) Neurodiagnostic (4) Pulmonary Medicine (5) Vascular Lab and (6) Laboratory Orders within the scheudled encounter will flow to the mPage once the Treatment Indication Order is added.	 

2	In order to add a **scheduled study-related visit** to the Research mPage, the Study Coordinator must navigate to the "Orders" tab in Cerner, click "Add Order" After selecting "Add Order" use the Search Box and select **Treatment Indication** from the drop-down menu Set the **Requested Start Date/Time** with the Research Subject's encounter date From the Type of Therapy drop-down menu select **"Clinical Trial Research"** and enter the order	
3	To identify ordered services that are covered by the Study: **Study Coordinators** will navigate to the **Research Revenue Cycle** mPage in Cerner • Click **mPage Hub** from the dropdown menu under "View" • Select **Research Revenue Cycle** from the list of mPages by clicking on the hyperlink	
4	From the **Research Coordinator** tab**:** • Select the appropriate facility from the **Facility** dropdown	
5	• Enter the appropriate **Date Range** *(Note: **Order Entry Date Range** will default to 7 days back)*	

6	• Click on **Apply Filters/Get Patients** • *Note: You can also utilize the Search box to locate a patient*	
7	• Click on the **MRN** hyperlink to open list of ordered services *Note: Clicking on the patient name will open the patient chart*	
8	• Review each order from the scheduled encounter • Check the **"Research Payor"** box to identify ordered services that are covered by the Research Study. *Note: If the order is **Standard of Care** and **not** covered by Research, leave the box blank.* • Click **Send to PFS** when done	
	Congratulations! You are now finished.	

THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

HIPAA Privacy Program

1618 E Helen St
P.O. Box 210409
Tucson, Arizona 85721
(520) 626-6721
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October 28, 2020

HIPAA Privacy Program Security Workshops

The HIPAA Privacy Program is excited to announce a bi-weekly interactive seminar covering HIPAA Privacy & Security topics beginning on November 4th, 2020 at 3:00 P.M. We will be covering a wide range of topics in fun and interesting ways.

- HIPAA Standards
- HIPAA Security & You (HIPAA security training) (Reporting HIPAA Incidents)
- HIPAA Enforcement Actions Recap (what happened, how can we relate, lessons, etc.)
- Encryption methods & importance
- Social Engineering (spotting phishing emails, etc.)
- HIPAA One
- Working Remotely
- Smart Social Network Usage
- Acceptable Use
- Splunk Audit Log Review
- Access Control
- Incident Response
- Removable Media (Labeling, etc.)
- Approved Communication Tools
- Physical Security

The first topic in this series of workshops will be HIPAA Privacy Program Standards, covering everything from how to access the standards, to filing for an exception to a standard. With the on-going risk assessments and the implementation of HIPAA One in the coming months, knowing how to access the HIPAA Privacy Programs Standards will make the risk assessment process more efficient and easier on everyone.

You can use this link to participate in the workshops: https://arizona.zoom.us/j/94477665768

Keep a look out for future announcements regarding upcoming workshop topics and scheduling.

Remember, we are all in this together, protecting the ePHI of thousands of people. The HIPAA Privacy Program's intent of these workshops is not only to inform, but also foster teamwork and networking.

For questions please contact us at HIPAAprivacy@email.arizona.edu.

Research Administration

Research Intake Application

Amendment Application

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? --Select--
Number of Active Subjects: How many subjects are currently on study / active?	Number of Consented Subjects: How many total subjects (active & completed) have been consented for this study?

Is the project sponsor, CRO, or other vendor based in the EU?

◯ Yes ◯ No

Will UA collect/receive data from subjects in the EU?	If yes, will the data received be completely deidentified?
◯ Yes ◯ No	◯ 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 ☐ JD ☐ MBA ☐ MD ☐ MD/PhD ☐ MPH ☐ PharmD ☐ PhD ☐ RN	
New PI Lead Unit Change? ◯ Yes ◯ No	New PI Lead Unit:
New PI College: --Select--	If Other UA College or Department, specify:
New PI Clinical Department (COM only) --Select-- --Select--	New PI Center or Institute: --Select--

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 occursin 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, interventionalprocedures, 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)

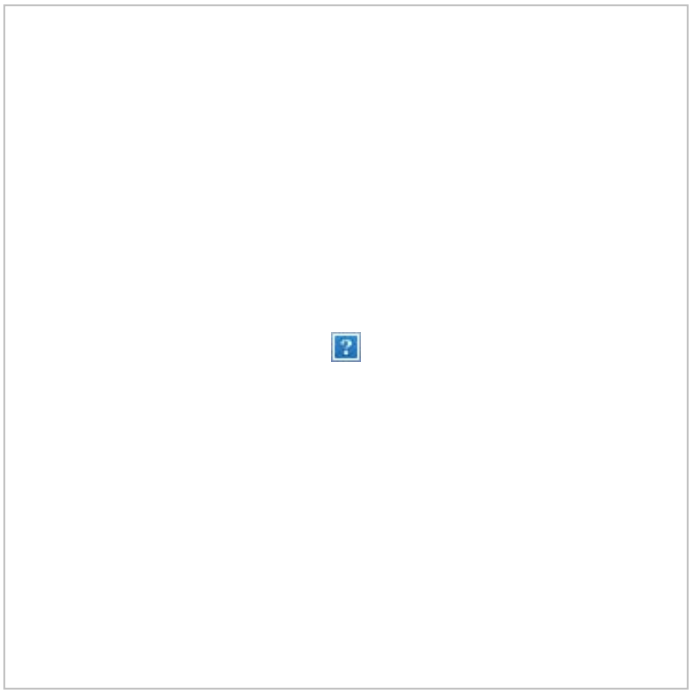
Study status	Plan	Mitigation strategies
Not open, not recruiting	May open and begin new recruitment	In addition to CDC, Banner Health and UArizona Research Restart guidelines, decrease frequency and convert in-person to remote visits whenever possible. Amend regulatoryprocedures as needed. Limit on-campus study staff and on-site roles to personnel required to conduct the in-person visit. 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.
Open, not recruiting	May begin new recruitment when appropriate. Continue monitoring as required by regulatory procedures.	In addition to CDC, Banner Health and UArizona Research Restart guidelines, decrease frequency and convert in-person to remote visits whenever possible. Amend regulatoryprocedures as needed. Limit on-campus study staff and on-site roles to personnel required to conduct the in-person visit. 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.

Open and recruiting	May continue new recruitment. Continue monitoring as required by regulatory procedures.	In addition to CDC, Banner Health and UArizona Research Restart guidelines, decrease frequency and convert in-person to remote visits whenever possible. Amend regulatoryprocedures as needed. Limit on-campus study staff and on-site roles to personnel required to conduct the in-person visit. 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.

From: clinicalresearchcoordinators-request@list.arizona.edu
To: "clinicalresearchcoordinators@list.arizona.edu"; "uahs-oncore@list.arizona.edu"
Subject: [clinicalresearchcoordinators] Restart to Clinical Research -- A Message from the Vice Dean for Research
Date: Friday, August 7, 2020 2:59:36 PM

Cross-posting – Restart to Clinical Research for COM-T & COM-P

View it in your browser.



August 7, 2020

Process to Restart Clinical Research

Dear COM-T Colleagues,

Earlier this summer, Arizona and Pima County experienced a surge in COVID-19. This appears to be regressing, albeit slowly. It is important that we continue to be vigilant, adhere to social distancing, wear masks/facial coverings and wash hands or use hand sanitizers. Below is a discussion on sensible steps to gradually re-start, on-site non-essential clinical research. Please carefully read through the topics, below. Many of these important considerations were discussed in the COM-T research town hall on July 22, 2020.

Principles: Research with human subjects must be conducted in a manner that focuses on the safety of our research subjects and study staff and decreases the risk of SARS-COV-2 transmission to the maximal extent possible as we resume a limited scale of clinical research under the phases of the UArizona Research Innovation & Impact's (RII) Research Restart Plan. With input from COM-T, UAHS, and other UArizona colleges, RII developed Guiding Principles for Restarting Human Subjects Research (HSR) that were recently updated on July 29, 2020, and can be found here along with three additional

documents to prepare research subjects and study staff for research activities (a required Consent script, During your research visit flyer, and Participant Wellness Checks). These documents can be found on the Research Restart Plan website here. PIs and study staff involved in human subjects research and those looking to start or resume non-essential research must review these documents and incorporate them into your research program. PIs should review these guidelines and — in conjunction with their department chairs and the entities where the research is to be conducted — develop a safety plan that reduces risk of SARS-COV-2 transmission. To minimize the risk of SARS-COV-2 spread, it may be necessary to pause certain aspects of research, and it is possible that some forms of resumed human subjects research may need to be curtailed in the future due to the impact of COVID-19 on our community. PIs should consider and plan for that possibility.

Considerations: It is critically important to remember that research with human subjects, or portions of that research that is being conducted remotely (e.g. virtually) should be continued in that manner. Likewise, studies or portions of studies that can shift in-person visits to virtual visits and other research activity that can be conducted virtually should be adapted as such. Consultation with the IRB may be needed. Additional mitigation measures are listed in the RII Guiding Principles document here. These are the minimum required strategies for mitigating risk for each level, and should be adapted by the PI to their study after consultation with their department chair and director of the location where the research will take place. All research subjects and study staff must wear facial coverings or masks as described in the RII Guiding Principles Document. Mitigation strategies and standards set by the governing body of the location where the research is occurring takes precedence. Important considerations, among others, include limiting number of patient visits (potentially substituting remote data collection and consent processes), reducing the duration of in-person visits (optimally to less than 15 minutes), limiting the number of research subjects in a waiting room, pre-screening study participants and research personnel for symptoms consistent with COVID-19, instituting cleaning procedures, and utilizing personal protective equipment (PPE, face coverings and other measures). The University has also published new PPE training. The official course name is “Research: Personal Protective Equipment Training-COVID-19 Specific” and the course code is UA-1662-1. Please ensure that you and your staff have completed this training.

Checklists covering non-essential research that may be able to be approved for re-start at this time: Non-essential research with human subjects in which the face-to-face research is carried out as part of an already scheduled on-site, clinically-indicated visit (e.g. not a visit strictly for research purposes) may be considered for restart. Invasive procedures must be clinically indicated, though exceptions for blood draws may be considered. Activities that can continue remotely (e.g. virtually) should continue in that manner, and activities that can be converted to a virtual interface should be conducted as such. A limited number of research personnel not already present may come on site for face-to-face, research-related activities if those activities cannot be accomplished remotely. There should be no coercion of any form. The safety of study personnel, staff and research subjects is the chief objective. Please be reminded that this should

constitute an incremental resumption of some research, carried out in a sensible manner, and not a return to pre-COVID-19 levels.

Specific research activities that remain on pause: Procedures conducted exclusively for research purposes that are aerosol generating (e.g. spirometry, bronchoscopy, intubation, etc) should not be performed at this time. Non-essential studies that require research-only, in-person visits by research subjects should not be re-started at this time. Exceptions for essential research can be considered on a case-by-case basis. These guidelines will be re-evaluated as we assess the prevalence of COVID-19 in our community.

Approval Process: Research that is and can be conducted remotely (e.g. virtually without a face-to-face visit) may continue in that manner, in addition to on-site research that is already covered under an approved research waiver. **However, every individual study will require submission of a research checklist.** Those with research waivers must still submit checklists and should indicate (in the Abstract/Brief Description section of the checklist) that a prior research waiver was obtained for that research and the rationale for the waiver at the time of issuance. COVID-19-related research will be assessed separately in the context of these waivers. Submitted human subjects checklists will be reviewed by the college associate or vice dean for research (or his or her designee) and if appropriate, the package will be forwarded to the unit where the research is to be carried out (e.g. Banner Health, CATS, etc).

- For research occurring in Banner Health facilities, once the college vice or associate dean of research reviews the checklist, it will be submitted to the Banner Clinical Trial Senior Manager, via the Research Intake Process email (researchapp@email.arizona.edu). Please be sure to provide the following information (in the Abstract/Brief Description Section) to help aid Banner in their review:

    1. What physical Banner space is being utilized for the study (this can be entered in Research Location Section) and will UArizona personnel be required to perform research-related procedures (entered in the Abstract/Brief Description Section)?
    2. Will the study require use of Banner personnel (nurses, staff, etc.)
    3. Does the study involve Banner ancillary services (medical imaging, etc.)
    4. Does the study involve invasive procedures that require pre-PCR testing prior to scheduling?

Once the unit has approved the checklist, it will be returned to the college for college-level approval and then on to RII for final review. Approval of a checklist will be signified to the PI in an email from RII stating that the “Reentry Checklist Result” is “Approved”.

Important procedures to follow regarding checklists: The Qualtrics Checklists were updated earlier this week to include: 1) a longer “Abstract/Brief Description of Research

Activities" and 2) a field to indicate the numerical level of research corresponding to the CV-19 Exposure Risk on the updated Guiding Principles for Restarting Human Subjects Research found here. When filling out the Qualtrics Checklist, *please clearly and directly detail the nature of the research in the* Abstract/Brief Description Section*; important information to include: the potential for and nature of (duration frequency) in-person visits and procedures (if any) as well as the need for already present or new on-site research staff and mitigation efforts for both research subjects and staff.* Please also include the level of research here (and in response to the specific question later in the human subjects section) covered by the checklist that corresponds to the CV-19 Exposure Risk of the planned research. Please also include your email or the best way to contact you with questions on your research.

For those who have already submitted a human subjects checklist, you will be individually emailed an edit link to update your submission with the information requested in the above paragraph. Please note that once the link is clicked it becomes immediately deactivated and cannot be accessed again without requesting a new one. Please do not access the edit link until you are prepared to complete the update.

Please only submit a checklist or edit a checklist at this time for research that is either already under a waiver or qualifies for re-start as described above. Checklists and edits for checklists covering non-essential research that is not covered by the description above will be requested at a later date, once on-site research with human subjects is further expanded.

Closing remarks: As you are all well-aware, the COVID-19 situation is fluid and ever changing, and we want to carefully evaluate the restart of all clinical research studies to ensure that we can protect our research staff and participants, especially given the surge in cases we saw earlier in the State of Arizona.

Thank you for your careful work and patience as we restart research. Please contact me as needed with questions about your studies.

Sincerely,

Jason Wertheim, MD, PhD
Vice Dean, Research
Associate Professor, Departments of Surgery & Biomedical Engineering