



DECEMBER 2020

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 ([Refresher Course Instructions](#)).

**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](#).

**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)



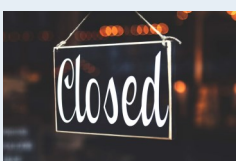
RIA forms have been revised (version dated 19May2020) and can be downloaded on the Research Administration [website](#).

Does my study require a RIA submission? If your study has a UAHS PI *or* requires the use of Banner resources, new and amended studies must be submitted to Research Administration using the RIA forms.

I'm not using Banner resources, why do I need to submit a RIA? For new studies, the RIA initiates multiple processes including Banner feasibility review, coverage analysis development, budget & contract negotiations, financial review of ICF, and entering the study into the OnCore clinical trial management system (CTMS), as applicable.

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.

Study Close-out with IRB



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@email.arizona.edu or crc@email.arizona.edu.

RII Research Restart Checklist for COVID Research



NOTE: Due to an increase in COVID-19 prevalence, Banner is minimizing access to their facilities which may impact the approval of research studies.

Please review the following information for restarting your research.

1. The RII research restart checklist needs to be prepared by the PI for each study
2. Submit each study to the [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 [Laurel Rokowski \(Tucson\)](#) or [Anna Valencia \(Phoenix\)](#).**
3. 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](#)).

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@email.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@email.arizona.edu.

Welcome To Our New Team Members!



We have new members who have joined our team:

Jade Marshall and **Karla Smith** will assist with coverage analysis development and clinical trial budget negotiation. Jade may be reached at jademarshall@arizona.edu or 520-621-3577 and Karla at karlasmith@arizona.edu or 520-621-6288.

Lynn Owens will assist with contract negotiation. Lynn may be reached at owens2@arizona.edu or 520-621-6347.

Caitlin McCarthy will be assisting with Post-Award Clinical Trials billing and may be reached at mccarthycc@arizona.edu or 520-626-8231.

Matt Peters is a member of the OnCore Team and may be reached at mwpeters@arizona.edu or 520-626-6226.

OnCore 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 and alternate weeks from each other. 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@email.arizona.edu

- **Introduction to OnCore and Calendar Validations**
Tuesdays, 1:00 pm – 3:00 pm
Dec 1, Dec 15, Jan 12, and Jan 26
- **Subject Management Training**
Wednesdays, 1:00 pm – 3:00 pm
Dec 2, Dec 16, Jan 13, and Jan 27
- **Regulatory Training**
Thursdays, 10:00 am – 12:00 pm
Dec 3, Dec 17, Jan 14, and Jan 28

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. As applicable, studies will need a fully executed or signed contract prior to being opened to accrual in OnCore.

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

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.

Regulatory in OnCore: Please be sure to update any personnel changes in OnCore, update IRB approval/closure dates and upload IRB approval documents (approval letters, ICFs, etc.)

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 Oncology studies have been pushed over to Cerner.

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 is in progress. We are anticipating a launch by February 2021.

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

Banner Hospital Billing Update



Banner Hospital billing for the months of October 2017 – September 2020 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. If there are any discrepancies, please email ctfinance@email.arizona.edu for assistance.
- When submitting backup to FSO, please only redact the patient name and date of birth if applicable. All other information should be left visible. Please see example below (*this is a fictional bill with no HIPAA information*).

Entity Code	Medical Records #	Acct #	Patient Name	DOS	Charge #	CPT4 Code	CPT4 Code Description	Charge Amount	Adjustment	Balance Due
483	██████	123456789	██████	2019-05-29	4818225	93306	ECHO/DOPPLER/COLOR FLW CMP 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

- Please send an email to ctfinance@email.arizona.edu with your DV payment information.
- Please do not Closeout and FPC any account balances if your clinical trial protocol reflects Banner services. If you are unsure, please work with your Study Team for confirmation.

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.

The Click® CTMS is no longer being used to record study visits.

- 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@email.arizona.edu.

Questions regarding the coverage analysis? Contact Research Administration at crc@email.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.****

The next scheduled meeting is Thursday, December 17, 2020, from 3:00 pm - 4:00 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	COM-Tucson location	COM-Phoenix Video Conference location	Time
Wednesday, Jan 20, 2021	ZOOM	ZOOM	12:00pm - 1:30pm
Thursday, Feb 18, 2021	ZOOM	ZOOM	3:00pm - 4:30pm
Wednesday, Mar 17, 2021	ZOOM	ZOOM	12:00pm - 1:30pm
Thursday, Apr 22, 2021	ZOOM	ZOOM	3:00pm - 4:30pm
Wednesday, May 19, 2021	ZOOM	ZOOM	12:00pm - 1:30pm
Thursday, Jun 17, 2021	ZOOM	ZOOM	3:00pm - 4:30pm
Wednesday, Jul 21, 2021	ZOOM	ZOOM	12:00pm - 1:30pm
Thursday, Aug 19, 2021	ZOOM	ZOOM	3:00pm - 4:30pm
Wednesday, Sep 15, 2021	ZOOM	ZOOM	12:00pm - 1:30pm
Thursday, Oct 21, 2021	ZOOM	ZOOM	3:00pm - 4:30pm
Wednesday, Nov 17, 2021	ZOOM	ZOOM	12:00pm - 1:30pm
Thursday, Dec 16, 2021	ZOOM	ZOOM	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@email.arizona.edu
- Contracts (CDAs, NDAs, CTAs, amendments, data use, incoming MTAs): contact UAHSContracts@email.arizona.edu
- Clinical Trial Regulatory and IRB: contact regulatory@email.arizona.edu
- Post-Award accounting and auditing: contact CTFinance@email.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@email.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@email.arizona.edu.

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

ClinicalTrials.gov Assistance:

Non-cancer studies: Kerry-Ann Suckra, kerryanns@email.arizona.edu, (520) 621-2029 or Clinical Trial Regulatory: regulatory@email.arizona.edu

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

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

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 Learning.

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

REDCap Questions/Training: Contact redcap@email.arizona.edu

Data Warehouse Information: <https://research.uahs.arizona.edu/clinical-trials/resources#data>

UA Clinical and Translational Science (CATS) Research Center:

<http://cats.med.arizona.edu>

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

Banner Badge Request: Contact clinicalresearch@email.arizona.edu

Banner Cerner Help: Contact the Banner IT service desk at (602) 747-4444 or in Tucson, call (520)-694-HELP (4357). Select Option 6 for assistance with Multi-factor Authentication.

Cerner Access/Training: Contact Laura Wilkes at (602) 839-3266 or Laura.Wilkes@bannerhealth.com

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

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.



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.

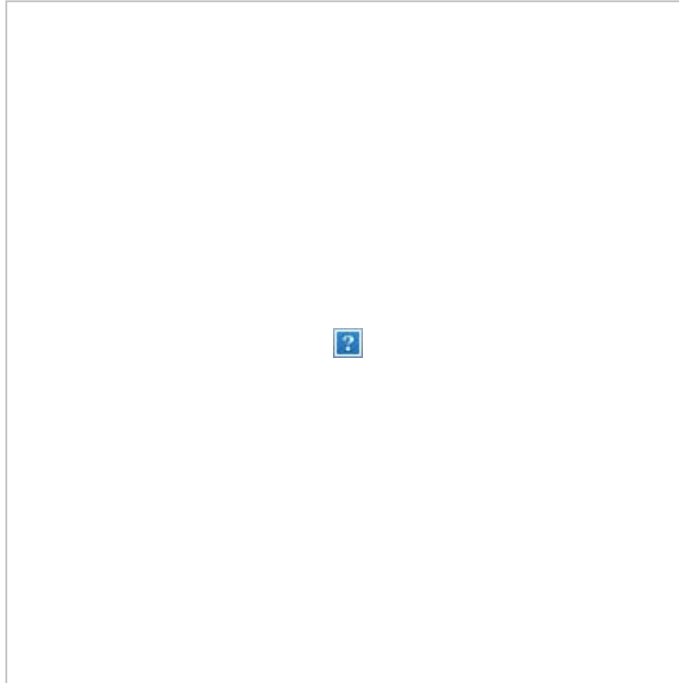
Remember, we are all in this together, protecting the ePHI of thousands of people. The HIPAA Privacy Program's intent of these workshops is not only to inform, but also foster teamwork and networking.

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

From: clinicalresearchcoordinators-request@list.arizona.edu
To: ["clinicalresearchcoordinators@list.arizona.edu"](mailto:clinicalresearchcoordinators@list.arizona.edu); ["uahs-oncore@list.arizona.edu"](mailto: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 restart 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



COVID-19 Research and Sample Request Guide

During the university shutdown investigators from the Health Sciences have been actively studying patients infected with COVID-19 in hopes of learning more about the virus, its pathogenesis and possible treatments. Major investigators have included Drs. Parthasarathy, Knox, Weinkauff, Garcia and many others.

The University of Arizona Health Sciences Biorepository has been actively collaborating with these investigators to facilitate biospecimen collection, processing, characterization and banking. Most, if not all, samples have been linked to electronic medical data present in Cerner. The research community is indebted to these PIs as well as their faculty and fellows for their willingness to participate in this research effort. Many of these individuals have placed their own health in jeopardy to assist in these efforts. To that end, we want to make sure that everyone involved in these efforts is recognized and receives their fair share of the credit on papers, grants, and other efforts. We also want to be sure that patient care is not impacted by the research efforts and that patients are not inconvenienced by these studies. Patients should not be approached multiple times requesting their participation in similar studies by different PIs, nor should they be inconvenienced by multiple requests for blood and other specimens, which could possibly exceed recommended daily limits (e.g., blood draws).

Dr. Sairam Parthasarathy has instituted a review panel to ensure that patients are treated fairly, recruited equitably, and consented for studies appropriately. He will review patient recruitment for all studies involving PCCM, facilitate PI collaboration, manage oversight of biospecimens collected and serve as the gatekeeper for these studies. Similarly, Dr. David Harris as director of the Health Sciences Biorepository serves as the second line of review for COVID-19 studies, in that all samples placed in the biobank fall under his purview. The Biorepository has a universal consent available for use by investigators that is also present in electronic formats, along with a REDCap data base and linkage to electronic medical data stored in Cerner for each subject. **Investigators wishing to initiate a COVID-19 study that would require biospecimen collection should contact Dr. Parthasarathy for patient access.**

Everyone wishing to request COVID-19 samples, including the initiating investigator, must request samples online at our website so that we may track samples in and out of the biobank, as well as document approved requests.

Individuals wishing to review available samples of any type in the biobank may go to <https://generalreporting.uahs.arizona.edu/BiorepositorySummary> to see the types of samples available.

To make an online request specifically for COVID-19 samples to be used for research PIs may visit <https://biobank.uahs.arizona.edu> or <http://redcap.link/covid19request>. Sample requests must include information about the nature of the proposed studies as well as other pertinent information.

Requests are brought before the investigator initiating the collection as well as a **Review Committee** to decide which samples can be distributed, to whom, and which studies are overlapping or duplicative. Although there are many samples available, the samples are not infinite. The Review Committee is made up of representatives from Administration, IT, the IRB, and multiple investigators. No samples will ever be distributed without consent of the initiating

investigator. However, investigators cannot reserve all samples exclusively for themselves and expect to receive gratis service. In the event of scientific overlap of such requests the COVID19 biospecimen Review Committee will request such investigator groups to collaborate and therefore avoid redundancy. If you wish to be part of this Review Committee, please contact Dr. Harris at davidh@email.arizona.edu.

Investigators taking advantage of the COVID-19 biobanking services, upon receipt of a sample from the biobank, must be willing to share data with the biobank as well as other investigators, and in some instances, share portions of a sample (e.g., DNA). This willingness to share is assumed based on submission of the request. Furthermore, investigators receiving such samples must acknowledge the role of collaborators and the biorepository.