Research Administration Announces New Workflows

We are so thankful for the engagement and participation of the COM-T faculty who have been working closely over the past few months with Research Administration to develop and implement process improvements and improved communication for clinical research. We have developed additional workflows to explain the entire process of initiating a clinical research project, in particular the process to finalize clinical research Budgets and Coverage Analysis and overall Contracts workflow. Please direct any specific questions on the process to crc@email.arizona.edu.

Clinical Trial Billing Update

ALL PAYMENTS for Banner and Sonora Quest services May 2018-December 2021 must be submitted by the deadlines below. Please reach out to ctfinance@arizona.edu with any discrepancies.

2022 Fiscal Year End Deadlines

- Deadline for creating new DV version for FY 2022 payments to ensure the DV to disbursement payment is fully approved by June 30.
- All PO invoices and documentation for FY 2022 must be received in Accounts Payable by no later than July 11 to be processed. They will require final approval by departmental business offices by 5 p.m. July 11 to ensure expenditures in FY 2022.

New eDisclosure Dashboard in UAccess Analytics

The eDisclosure Proposal Development Status dashboard is now available in UAccess Analytics. This dashboard identifies whether Investigators on a specific proposal have met the federal requirements for COI compliance at the time of proposal submission to the funding agency. This dashboard can be searched using the following categories:

- Proposal Development Number
- Proposal Development Document
- Lead Investigator Name
- Lead Unit
- Investigator Name
- Investigator NETID
- Conflict of Interest Status

The eDisclosure – Conflict of Interest (COI) dashboard suite also includes the following dashboards:

- eDisclosure Requirement Status dashboard
  Provides individual-specific Conflict of Interest status information.

- eDisclosure Project-Based Investigator Status dashboard
  Provides Conflict of Interest information such as Determination Status and Training Certification Date for Investigators associated with a specific project.

Attached are User Guides for each of the eDisclosure dashboards. If you are not able to access the dashboards, please submit a request using the UAccess Access Provisioning Tool, AccessFlow.

The OROI team is available to assist with any questions you may have. They can be reached at coi@arizona.edu or (520) 626-6406.
Research Laboratory & Safety Services Announces Radiation Emergency Notification Procedure

In the event of an emergency that may involve radiation or radioactive material, call RLSS immediately at 520-626-6850. Outside of the office hours of Monday through Friday, 7:30 a.m. to 4 p.m., a staff member can be reached by calling the UAPD at 520-621-9273 and requesting RLSS emergency personnel be notified. You can also call the RLSS emergency line directly at 520-496-5929. If you do not receive a timely response from RLSS personnel, call Leon Harris at 520-870-7752.

Online RIA Submission Process Launched!

On March 1, 2022, UAHS Research Administration began accepting all project submissions via our new online portal. Click here for the new UAHS Project Submissions site, which requires UA NetID login. Respond to the questions to determine which submission form is applicable to your project and click on the specific form button to begin your submission. If you already know which form you need, click on the “All Forms” button, select the appropriate form and click on the plus “+” sign (upper right-hand corner) to begin your submission. All submission requirements remain the same (i.e. study related information and supporting documents). There is a minor update to the required documents for RIA New Study Submissions. The PDF printer version of the related eIRB application should be included in the RIA as this includes the Local Study Team Members, IRB number, as well as many of the required documents for a complete submission. Incomplete submissions will not enter our workflow until all requirements are met.

As of March 21, 2022, all submissions must be submitted through the online portal.

Please contact us at crc@email.arizona.edu if you have any questions or require assistance with utilizing our new online submission portal. One on one RIA support is also available by scheduling a session through Microsoft Bookings. You will receive an email confirmation with a Zoom meeting link.

“Discover” – A New Powerful Tool for Data Projects at Banner

Banner has a new, powerful, self-service, user-friendly data exploration tool called Discover that allows Banner/UA researchers to create patient cohorts based on their specific needs. It provides access to de-identified EMR and billing data from current day, going back to 2014.

Individual trainings and demos are available and can be coordinated through Porter Foulger, Sr. Director of Population Health and Research. Please reach out to porter.foulger@bannerhealth.com with any specific requests or trainings.

A Discover training video created for Banner/UA can be viewed here: https://youtu.be/6sKHfp-hXvg

About Discover:

- Discover provides self-service access to de-identified/aggregated data. It is for the initial purpose of cohort creation, data exploration, and trial feasibility.
- In order to get identifiable information for recruitment, researchers still need to go through the IRB and Honest Broker processes. Please contact Don Saner at Banner for more detail on this.
- Discover training guides and resources can be found in the Research Catalog, or by going to the Teams folder: Discover Resources.
OnCore’s Role in Billing and Invoicing

Study visits **must** be logged into OnCore within 24 hours of occurrence whenever Banner Health (BH) or Sonora Quest Lab (SQL) services are utilized for a research study (i.e. medical imaging, ECG, clinic visits, etc.)

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.

Billing designations should **ONLY** be changed if there is a corresponding footnote that gives details of when and how to change the designation. In the absence of a footnote, please reach out tocrc@email.arizona.edu or OnCoreSupport@email.arizona.edu.

Changes to the CA **MUST** be approved by the UAHS Research Administration and BH Research Finance (BHRF) teams **before** charges can be changed.

This process helps to ensure that bills are routed to the correct payor, alleviate incorrect billing, and most importantly helps to protect your study subject!

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. Requests to amend the CA must be submitted via the RIA amendment process.

HIPAA Transmission of Protected Health Information (PHI) Data

If you are sending an email that contains subject PHI, you MUST send the email in a secure email. New controls, collectively known as Data Loss Prevention (DLP), have been implemented. Please review the full list of approved methods for communicating health information online.

- HIPAA Resources
  - Definition of Key Words
  - HIPAA Data Reference Guide
- HIPAA Encryption Standards Policy
  - Methods for Securely Emailing PHI
- Box Health Policy
  - Box Health Requirements
- HIPAA Zoom
RII Research Restart 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. This includes an update for masking practices. Please see attached Infographic.

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.

The UA has transitioned to Phase 6 of the Research Re-Start Plan. Information on Phase 6 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 Access for Banner Staff – effective 7/1/2022

All Banner staff actively working on clinical research studies will need to obtain a Designated Campus Colleague (DCC) status with UA to continue signing into OnCore. Please work with your UA research department’s HR team to establish your DCC status and obtain a UA Net ID.

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!

Effective March 21, 2022, training registration by email has been discontinued and replaced with an online form. This change was implemented to streamline the registration process for new users by providing step-by-step information to explain the user information needed and the training prerequisites that are required. (see list below). In addition, the form allows users to upload their OnCore Confidentiality Agreements:

OnCore Training Prerequisites:
- HIPAA training, EDGE course ID 0000003302
- Information Security Awareness, EDGE course ID 0000003315
- CITI Biomedical Research Investigators (CITI-4589, Human Research), EDGE course ID 0000003282
- OnCore Confidentiality Agreement

After submitting the required information, users will receive an immediate confirmation of their training request. To register for any of the next training sessions, please complete an OnCore Confidentiality Agreement with your supervisor and go to the OnCore Training Request Form.
OnCore, continued

The next trainings are scheduled as follows:

- **Introduction to OnCore and Calendar Validations**
  Tuesday, May 3 or June 7, 1:00 pm - 3:00 pm

- **Subject Management Training**
  Wednesday, May 4 or June 8, 1:00 pm - 4:00 pm

- **Regulatory Training**
  Thursday, May 5 or June 9, 2:00 pm - 4:00 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@email.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@email.arizona.edu to schedule a session.

### OnCore Training & Refresher Resources

Please visit our website for a wide variety of guidance documents. (Net ID Login required)

### 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.

### Next Steps

- Implementation of the eRegulatory Management System (eReg) has been completed. The official launch will begin in mid-April 2022. Please contact regulatory@email.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@email.arizona.edu with questions, or for additional help.

### OnCore Technical Support

Technical support for OnCore is now handled by COMHelp. Requests for assistance should be submitted through the COMHelp ticketing system. This will require you to login with your UA NetID. Service requests include:

- Technical support
- Password resets
- User account troubleshooting
- Requests for reports

Please do not include PHI information with your ticket. If your ticket is regarding help with subject management, COMHelp will contact you regarding a secure method to transmit PHI or screenshots (i.e. secure email, UA BoxHealth, or HIPAA Zoom). Tickets that include PHI will be purged from the system and you will need to resubmit your ticket.

Technical support requests sent to OnCoreSupport@email.arizona.edu will be referred to COMHelp.
Banner Hospital billing for the months of May 2018 – February 2022 have been reviewed and sent out to the corresponding UA Departments via UABox Health. March 2022 invoices will be distributed by the second week of May.

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 in your department’s UABox Health. If there are any discrepancies, please email ctfinance@email.arizona.edu for assistance. Discrepancies need to be reported within 2 weeks of the receipt of invoices. Insurance carriers have deadlines for filing and BH has a limited window for reversing charges back to insurance carriers (as applicable).

- When submitting backup to FSO, please only redact the patient’s 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)

<table>
<thead>
<tr>
<th>Entity Code</th>
<th>Medical Records #</th>
<th>Act #</th>
<th>Patient Name</th>
<th>DOS</th>
<th>Charge #</th>
<th>CPT4 Code</th>
<th>CPT4-Code Description</th>
<th>Change Amount</th>
<th>Adjustment</th>
<th>Balance Due</th>
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<tr>
<td>483</td>
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<td>486222</td>
<td>0308</td>
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<td>$2,750.80</td>
<td>$1,571.82</td>
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<td></td>
<td></td>
</tr>
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<td>2019-05-01</td>
<td>486225</td>
<td>0308</td>
<td>ECHOCARDIOGRAPHY, ECHO, CMP, W/O CNT</td>
<td>$2,750.80</td>
<td>$1,571.82</td>
<td>$878.98</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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.

- 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.

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 have questions, please contact our office at ctfinance@email.arizona.edu or 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."

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 vphscro@email.arizona.edu.

CRP meetings will now be held every other month.

The next scheduled meeting is Wednesday, May 18, 2022, 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:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Time</th>
</tr>
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<tbody>
<tr>
<td>Thursday, Jul 21, 2022</td>
<td>Zoom</td>
<td>3:00 pm - 4:30 pm</td>
</tr>
<tr>
<td>Wednesday, Sep 21, 2022</td>
<td>Zoom</td>
<td>12:00 pm – 1:30 pm</td>
</tr>
<tr>
<td>Thursday, Nov 17, 2022</td>
<td>Zoom</td>
<td>3:00 pm - 4:30 pm</td>
</tr>
<tr>
<td>Friday, Dec 16, 2022</td>
<td>Kiewit</td>
<td>11:00 pm – 1:00 pm</td>
</tr>
</tbody>
</table>
GENERAL INFORMATION AND RESOURCES

UAHS Research Administration provides guidance and assistance with the following:

- Our website: [https://research.uahs.arizona.edu/](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: UAHSCntacts@email.arizona.edu
- Regulatory contact regulatory@email.arizona.edu or schedule 1:1 session
- Post-Award Clinical Trial Accounting and Auditing: contact CTFinance@email.arizona.edu

UAHS Project Status Report: [https://research.uahs.arizona.edu/facilities-and-resources](https://research.uahs.arizona.edu/facilities-and-resources) (UA NetID Login required)

Research Intake Application (RIA):
Applications and required documentation should be emailed to ResearchApp@email.arizona.edu. Instructions and the application forms can be found here. If you have questions, email Research Administration at crc@email.arizona.edu.

OnCore UAHS Support: OnCoreSupport@email.arizona.edu or [https://research.uahs.arizona.edu/oncore](https://research.uahs.arizona.edu/oncore) or schedule 1:1 session (calendar validations, subject management, regulatory)

OnCore Technical Support: [https://comhelp.arizona.edu/](https://comhelp.arizona.edu/) Net ID Login required (password resets, user account creation, requests for reports)

ClinicalTrials.gov Assistance:
- Non-cancer studies: Kirsten Anderson, regulatory@email.arizona.edu or (520) 621-6417
- Cancer studies: UACC-NCTN@uacc.arizona.edu

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

UAHS Global HIPAA Procedures: [https://research.uahs.arizona.edu/facilities-and-resources/uahs-hipaa-sop’s](https://research.uahs.arizona.edu/facilities-and-resources/uahs-hipaa-sop’s) (Net ID Login required)

IRB Training Opportunities
Upcoming sessions are located on the IRB website with instructions for registering through UAccess Edge Learning.

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

Data Warehouse Information: [https://research.uahs.arizona.edu/cClinical-trials/resources#data](https://research.uahs.arizona.edu/cClinical-trials/resources#data)

UA Clinical and Translational Science (CATS) Research Center:
[http://cats.med.arizona.edu](http://cats.med.arizona.edu)

Coordinator Corner: [https://cats.med.arizona.edu/content/coordinator-corner](https://cats.med.arizona.edu/content/coordinator-corner)

COM-P Clinical Research website: [https://phoenixmed.arizona.edu/research/clinical-research/investigators](https://phoenixmed.arizona.edu/research/clinical-research/investigators)

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 your department’s assigned Banner Health Clinical Trial Senior Manager. [https://research.uahs.arizona.edu/c clinical-trials/ cerner](https://research.uahs.arizona.edu/cClinical-trials/ cerner)

Sonora Quest Laboratories Account Set-up and/or Care360 User Request: email request to cffinance@email.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).


SQL Care360 Training: Contact the Customer System Team at (602) 685-5465 or SQLCustomerSystems@SonoraQuest.com to schedule training. Please be sure to include your SQL departmental account number when requesting training.
The eDisclosure Project-Based Investigator Status dashboard provides Conflict of Interest information such as Determination Status and Training Certification Date for Investigators associated with a specific project.

This dashboard can be searched using the following categories:

- Investigator ID
- Investigator Name
- Department ID
- Department Name
- Proposal ID
- Award ID
- IRB ID
- Certification Type

You can also toggle this dashboard to include all Investigators, only Active Investigators or only Inactive Investigators. The default is only Active Investigators.

**Status Key:** The Determination Status column* reflects where the Research Certification is in the Financial Conflict of Interest review process. (Information about this review process can be found on OROI’s [COC & COI Review Processes](#) webpage.)

**Complete COI Statuses**
- No Review Required
- Review Complete
- Under Management/Mitigation Plan

**Incomplete COI Statuses**
- Administrative Review (awaiting review by OROI)
- Administrative Review: Response Pending (awaiting a response from the Investigator)
- Discloser Review of Plan (awaiting Investigator’s review of management/mitigation plan)
- Draft (awaiting submission from Investigator)
- Meeting Complete: Response Pending (awaiting a response from the Investigator)
- Review Completed: Preparing Correspondence (OROI drafting correspondence to Investigator)
- Scheduled for Meeting (Research Certification on agenda for a committee meeting)
- Withdrawn (Investigator requested removal from project or project not funded)

*Please allow 1 business day for updated information in eDisclosure to be reflected in this column.
The eDisclosure Proposal Development Status dashboard provides Conflict of Interest compliance status information for Investigators associated with a specific proposal in UAccess Research. Proposals will be viewable in this dashboard 1 business day after the proposal development document is saved in UAccess Research.

Reminder: Pursuant to federal regulations, Investigators must have an up-to-date disclosure at the time of proposal submission to a federal funding agency.

This dashboard can be searched using the following categories:

- Proposal Development Number
- Proposal Development Document
- Lead Investigator Name
- Lead Unit
- Investigator Name
- Investigator NETID
- Conflict of Interest Status

Status Key: The Disclosure Status column reflects whether an Investigator has an up-to-date disclosure certification.

Up-to-Date Disclosure Certification Status

- OK to Submit (The individual has submitted a certification in eDisclosure in the past 364 days.)

Incomplete Disclosure Certification Statuses

- Incomplete (The individual needs to submit a certification in eDisclosure.)
- Not Started (The individual needs to contact the Office for Responsible Outside Interests to request that an Annual Disclosure Certification be created for them.)
- Expired (The individual’s last certification was submitted more than 364 days ago.)

*Please allow 1 business day for updated information in eDisclosure to be reflected in this column.
eDisclosure Requirement Status Dashboard User Guide

The eDisclosure Requirement Status dashboard provides individual-specific Conflict of Interest status information.

An individual’s “COI Requirement Status” will be Complete when they have completed the following:

1. Completed the Conflict of Interest Required Disclosure Training after July 1, 2021, and
2. Submitted a certification in the last 364 days. The certification can be an Annual Disclosure Certification or Research Certification.

This dashboard can be searched using the following categories:

- College ID
- College Name
- Department ID
- Department Name
- Employee ID
- Investigator Name
- NETID
- COI Requirement Status

Status Key: The COI Requirement Status column* reflects whether an Investigator is up-to-date on their COI requirements.

- Complete = The individual has completed their COI training and disclosure requirements.
- Incomplete = The individual needs to complete the Conflict of Interest Required Disclosure Training in EDGE Learning, submit a certification in eDisclosure or both.

*Please allow 1 business day for updated information in eDisclosure to be reflected in this column.
In alignment with CDC guidance, below are our current masking practices that keep you safe.

NOTE: Always follow the precautions listed on isolation and procedure rooms. The masking guidance below is secondary to these precautions.

Safe Masking Practices
- **DO** choose the right mask for the right task
- **ALWAYS** wear your mask properly, covering your nose and mouth
- **DO** remove your mask completely from your face for taking sips of drinks
- **DON'T** double mask or wear masks incorrectly
- Masks/N95s may be worn continuously for more than one patient in some circumstances. Please refer to COVID-19 Toolkit for detailed PPE use guidance
- **DON'T** store and reuse procedure or N95 masks. If removed from your face for more than a short drink, discard the mask and obtain a new one.

Mask Use and Choices

**Cloth Face Coverings**
- Can be used continuously in non-patient care locations only (e.g. corporate offices, other non-patient care business locations); must be worn continuously
- Can be used to enter and exit patient care locations when reporting to or leaving work. Must be changed to a procedure mask upon arrival to department

**Procedure Mask**
- Continuous mask for ALL staff in patient care locations
- Worn during all routine patient care unless other PPE is required according to isolation sign on patient door
- Must be discarded and replaced if removed from face for longer than a short sip/drink, or when the mask becomes moist or soiled
  *Reminder, If the mask is worn in a droplet, droplet/contact or enhanced precautions room it must be discarded*

**N95 Respirator Mask**
- **N95 and Face Shield Required:**
  - All team members entering a COVID suspect/positive patient room (enhanced precautions) *Reminder, limit personnel present during an AGP to prevent risk to team members*
  - Team members in higher risk locations, such as an emergency department or dedicated COVID unit may opt to wear an N95 continuously, with the required use of a face shield to protect the mask from contamination
    *Reminder, If the N95 mask is removed at any time it must be discarded*

**Personally Owned Medical Grade Masks**
- Team members who purchase their own medical grade masks may use them as their continuous mask if they meet at least the minimum requirements of protection listed above, and are responsible for their proper fit, maintenance, and cleaning
- Team members are **REQUIRED** to change into a Banner approved/provided procedure mask or N95 when entering isolation rooms

As we continue to respond to this very challenging situation, we’re committed to keeping you safe and saving as many lives as possible.
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)

<table>
<thead>
<tr>
<th>Study status</th>
<th>Plan</th>
<th>Mitigation strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not open, not recruiting</td>
<td>May open and begin new recruitment</td>
<td>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. 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.</td>
</tr>
<tr>
<td>Open, not recruiting</td>
<td>May begin new recruitment when appropriate. Continue monitoring as required by regulatory procedures.</td>
<td>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. 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.</td>
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<td>Open and recruiting</td>
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