Conducting Research at Banner Facilities for College of Nursing Faculty and Students

For College of Nursing faculty and students planning to conduct research studies at Banner facilities, there are processes that need to be followed. These guidelines will facilitate the review and approval process. *Please follow the procedures below (not procedures listed elsewhere)*.

Planning/Proposal Development

- 1. Prior to submitting a proposal for funding or developing a research protocol that will include a Banner facility, contact Karen Johnson, PhD, RN, FAAN, Director of Banner Nursing Research (Karen.Johnson2@bannerhealth.com) who will function as the Research Navigator for the College of Nursing. It is recommended that you contact Dr. Johnson as early in the brainstorming process as possible so she can connect you with potential collaborators at Banner with similar interests to form a team.
 - Include in the email key specifics about the planned study:
 - o PI name
 - Co-I name(s)
 - $\circ \quad \text{Study title} \\$
 - \circ Aims
 - \circ Overview of methods
 - o Recruitment plans
 - Key study personnel
 - Specific requests for use of Banner resources specific site(s)/clinics for study where access is needed for study procedures, including badge access and access to electronic health records and/or use of Banner WiFi or equipment.
 - This will help facilitate early protocol planning and reduce potential barriers such as access to PHI, nursing staff time, and recruitment barriers due to overlap with other studies.
 - Dr. Johnson will reach out on behalf of the PI to Banner unit directors, and/or other support entities within Banner with this information. This will also expedite obtaining the letters of support needed for the University of Arizona IRB submission process.
- 2. After gaining tentative support from Banner, the PI should create a letter of support for the facility/clinic director of the study site.
 - Send an email with the draft letter of support attached to Dr. Johnson for the specific Banner service unit(s).
 - Send the letter of support to the facility/clinic director(s), reminding them of your initial contacts in which they supported the project going forward. Ask them to put the letter of support on Banner stationary, sign, and return to you.
 - Keep Dr. Johnson aware of any delays in the letter being returned so that she can follow up on delayed responses.

Once You Receive Your Just-in-Time and/or Are Ready to Begin Your Study

 Once you are ready to begin a study that will include a Banner facility (i.e., have received a Just-In-Time request or you are conducting an intramurally-funded or nonfunded study), contact Karen Johnson, PhD, RN, FAAN, Director of Banner Nursing Research (<u>Karen.Johnson2@bannerhealth.com</u>) who will function as the Research Navigator for the College of Nursing.

Obtaining IRB Approval

- Submit the University of Arizona IRB Protocol form and supporting documents to Alice Pasvogel, Office of Research & Scholarship (<u>apasv@arizona.edu</u>) for review. Obtain College of Nursing attestations.
- Submit your study through the Research Administration Portal (RAP) (<u>https://comhub.medicine.arizona.edu/groups/RAP</u>).
- Once you submit your study through the Research Administration Portal (RAP). it will be routed to Dr. Karen Johnson at Banner for feasibility review.
- Immediately following submission into RAP, please notify by email Dr. Karen Johnson (<u>Karen.Johnson2@bannerhealth.com</u>) letting her know that the documents have been submitted in RAP. This notification will eliminate possible delays in feasibility review.
- Include in the email key specifics about the planned study:
 - o PI name
 - o Study title
 - o Aims
 - Overview of methods
 - o Recruitment plans
 - Key study personnel
 - Specific requests for use of Banner resources <u>specific site(s)/clinics for study</u> where access is needed (not just BUMC-T or BUMC-S addresses) for study procedures, including badge access and access to electronic health records and/or use of Banner WiFi or equipment.
- Dr. Johnson will review the forms for feasibility review and approval. Your feasibility review determination will come to you via email, and you can also see the feasibility review determination in RAP.
- Once you receive Banner approval, submit documents to University of Arizona IRB through eIRB for approval.
- <u>Please Note</u>: If you intend to use the Banner Clinical Research Data Warehouse (CRDW), please note this on the RAP application. This is the only mechanism to request an Honest Broker submission to the CRDW.

IRB Approval and Study Activation

Send the IRB approval letter, the protocol number, and PI/site Co-I information to Dr. Karen Johnson. She will notify the study site(s) that your study has IRB approval and is ready to commence with study procedures and recruitment activities.

CERNER Training & Access

CERNER is the electronic health records (EHR) system used by Banner Health. If you will be accessing Banner Health EHR, research staff must receive training to obtain access. It is highly recommended that this training be done as soon as possible – even before IRB approval. Request forms for CERNER training and access is located at: <u>https://cats.med.arizona.edu/content/banner-umc</u>

Upon completion of training, IT tickets will be submitted on your behalf.

<u>Please Note</u>: CERNER access expires one year after it is granted. CERNER may not notify you when your access will expire so track your expiration date to prevent a lapse in access.

Badge Access

Request forms for badge access are located at: <u>https://cats.med.arizona.edu/content/banner-umc</u>. Please remember to specify the exact locations where you plan to conduct your study. Submit a separate submission for each research staff member requiring a new badge and/or badge change.

<u>Please Note</u>: Security badge access expires one year after it is granted.

Adding/Changing Study Personnel

Please remember to email Dr. Karen Johnson (<u>Karen.Johnson2@bannerhealth.com</u>) whenever you make changes to study personnel via RAP and request CERNER and/or badge access. In the email, please include PI name, study title and name(s) of personnel being added to or removed from your study and need CERNER and/or badge access/change.

Honest Broker Process for Requesting CERNER Data from Banner

To access data from CERNER (September 19, 2017 – present date):

- Complete the Banner Clinical Research Data Warehouse (CRDW) request form. The form can be found at https://research.uahs.arizona.edu/clinical-trials/cerner
- Submit either the IRB Protocol for Human Research/IRB Protocol for Human Research Retrospective Data Review (if obtaining identifiable data) or the IRB Protocol for Determination of Human Research (if obtaining de-identified data) to Alice Pasvogel, Office of Research & Scholarship (apasv@arizona.edu) for review. Obtain College of Nursing attestations, as applicable.

- Submit the IRB Protocol form through the Research Administration Portal (RAP) (<u>https://comhub.medicine.arizona.edu/groups/RAP</u>) and include the CRDW request form. Immediately following submission into RAP, please notify by email Dr. Karen Johnson (<u>Karen.Johnson2@bannerhealth.com</u>) letting her know that the documents have been submitted in RAP. Please include the PI name and study title in the email.
- If the data requested is for all Banner facilities or includes Banner UA and other Banner facilities, a Data Sharing Agreement must be approved through the University of Arizona and Banner Contracts offices and Banner IRB.
- Submit documents to the University of Arizona IRB through the eIRB system for approval/determination.
- Upon receiving approval/determination from the IRB, please forward the IRB approval/determination to <u>BHHonestBrokerDataRequest@bannerhealth.com</u>. Include a copy of the IRB approval document, the CRDW request form, and the IRB Protocol form.

UA Clinical Data Warehouse (CDW)

To access data from EPIC (November 1, 2013 - September 18, 2017):

- Submit either the IRB Protocol for Human Subjects Research Retrospective Data Review (if obtaining identifiable data) or the IRB Protocol for Determination of Human Research (if obtaining de-identified data) to Alice Pasvogel, Office of Research & Scholarship (apasv@arizona.edu) for review. Obtain College of Nursing attestations, as applicable.
- Submit documents to the University of Arizona IRB through the eIRB system.
- Once IRB approval/determination is obtained, submit a data request to the CDW.

<u>Please Note</u>: If you need data from Banner Health facilities outside Tucson and data from Tucson between or overlapping November 1, 2013 and September 18, 2017, complete a CDW request for the Tucson data and submit the IRB Protocol form through Research Administration Portal (RAP) (<u>https://comhub.medicine.arizona.edu/groups/RAP</u>) and email Dr. Karen Johnson and include the PI name, study title, and CRDW request form for the data from Banner facilities outside Tucson.