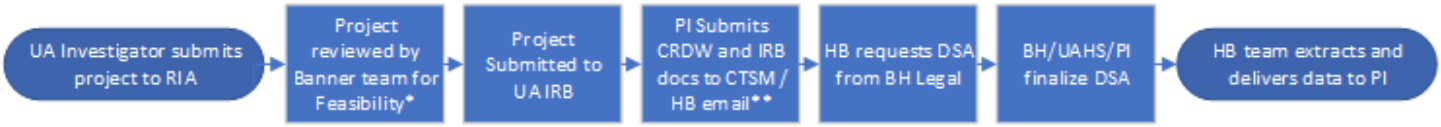
Clinical Research Data Warehouse (CRDW)

Request Process

To support the use of Banner Health clinical data for research purposes, a protocol entitled "Clinical Research Data Warehouse and Associated Honest Broker Processes" has been approved by the Banner IRB. The protocol details how Honest Broker staff, who are neutral intermediaries between the researcher and the EHR data, will process requests for data, assess the feasibility, and ultimately fulfill the data requests. Requests are initiated by using the Research Intake Application (RIA): https://research.uahs.arizona.edu/clinical-trials/research-intake-form.

PROCESS OVERVIEW



Abbreviations
CTSM: Clinical Trial Senior Manager
HB: Honest Broker
IRB: Institutional Review Board
UAHS: University of Arizona Health Sciences
DSA: Data Sharing Agreement

* Banner team is CTSM + HB

**email is:
BHHonestBrokerDataRequest@bannerhealth.com
Documents required:
CRDW Data Request Form
UA IRB Approval letter
F200/Application for Human Subjects Research

A well-formed and complete data request will help the process proceed in a timely fashion. The CRDW form provides guidance to capture the necessary elements for a complete request. If you have questions about the process or would like assistance on your data request, please contact: BHHonestBrokerDataRequest@bannerhealth.com.

IMPORTANT: UPON RECEIVING APPROVAL FROM THE IRB, PLEASE FORWARD THE IRB DOCUMENTS TO: BHHonestBrokerDataRequest@bannerhealth.com

Frequently Asked Questions (FAQ)

How long will a data request take? This is highly dependent on the scope of the request and the backlog of requests. The Honest Broker staff will provide an estimate as part of the feasibility review. Other steps in the process, such as contracting or IRB approval, can impact the overall timeline. It is important that requests be submitted as early as possible.

How can I determine the status of my request? For status updates, please send an email to BHHonestBrokerDataRequest@bannerhealth.com. Please include PI Name and Project Title for project reference.

What is involved in the contracting process? A Data Sharing Agreement (DSA) between Banner and UA will need to be in place. This is handled by the Banner and UAHS contract offices (UAHSContracts@email.arizona.edu)

What do I do when I receive IRB approval? Send an email to BHHonestBrokerDataRequest@bannerhealth.com, include a copy of the IRB approval document, the CRDW form and the F200 Application for Human Subjects Research

Prior to receiving data, who do I contact about properly securing the data? Properly securing the data is of the upmost importance. Please contact the University of Arizona (UA) HIPAA Privacy Program at PrivacyOffice@email.arizona.edu for assistance in coordinating with your departmental IT staff to ensure that the data is properly secured. Additional information is available at the HIPAA Privacy Program's website: https://rgw.arizona.edu/compliance/hipaa-privacy-program.

Version 2020-02-12

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Please complete **all** sections below and provide specific details when specifying inclusion/exclusion criteria and data points. Please also specify the facilities from which you are requesting data as well as the care settings (inpatient/outpatient/ED/ICU etc.) and the timeframes for the data. ***Incomplete forms may cause a delay in the project approval.***

If diagnoses are used for inclusion/exclusion criteria, please specify the ICD codes; if lab tests are used, please specify the lab names and any ranges that may include/exclude; if medications are used, please specify the medications rather than a class such as "anti-coagulants" and include both generic and brand name.

Principal Investigator Name & Contact Information (Name, email and phone):

Pat Jones, MD
patjones@email.arizona.edu or patjones@bannerhealth.com
520-626-1111

Project Title:

Review lab outcomes for drug interactions

Inclusion Criteria:

Ages 18 - 75
Inpatient and Outpatient visits at BUMC-Tucson Campus.
Any visit receiving a medication order (prescription or inpatient medication order) between the dates of 1/1/19-12/31/19 should be included.

Exclusion Criteria:

Ages 0 - 17

Data Points Requested (*Be specific and include ICD/CPT codes*):

Requesting 4 different files.

See page 4-5 for complete list.

Start and End Dates for requested data:

1/1/2019-12/31/2019

Facilities & Care Settings Utilized for Data Collection (e.g. BUMCT, South, BUMCP, inpatient/outpatient/ED/ICU, etc.):

BUMC-T, BUMC-South, inpatient & outpatient

Intent of request/Funding:

☐ In support of a funded project

☒ In support of an application for funding

☐ Prep to research

☐ Intend to publish results

☐ Clinical Trial

☐ Other

Other Explanation:

Data Points Requested:

1. **Patient Data File**
   - Randomized MRN
   - Date of birth
   - Sex
   - Ethnic Background
   - Patient Race

2. **Diagnosis Data File**
   - Randomized MRN
   - Randomized Visit Number
   - Diagnosis Entry Date
   - Diagnosis Visit Number
   - ICD9 Code- Comma delimited list if multiple
   - ICD10 Code- Comma delimited list if multiple

3. **Order/Prescription Data File**
   - Randomized Order ID
   - Randomized MRN
   - Randomized Visit Number
   - Patient's Nursing Unit/Location
   - AUTHORIZING PROVIDER RECORD NAME
   - Medication Description (product description) (i.e. Ondansetron HCl (PF) 4mg/2ml Injection Solution)
   - NDC- National Drug Code
   - RXNORM CODE LEVEL- Comma delimited list if multiple
   - RXNORM TERM TYPE- Comma delimited list if multiple (Ingredient, Precise Ingredient, Semantic Clinical Drug, etc.)
   - NDC CODE
   - AHFS CODE- (i.e. 56:22.20)
   - THERAPEUTIC CLASS (i.e. GASTROINTESTINAL)
   - PHARM. CLASS (i.e. ANTIMETIC/ANTIVERTIGO AGENTS)
   - Medication Description (product description) (i.e. Ondansetron HCl (PF) 4mg/2ml Injection Solution)
   - RX MIXTURE – MED ID- When an order has multiple components, the RX Mixture fields will contain information about each component. All components will have the same order number for each row will contain unique information about individual components. Med ID is the internal unique number for the medication.
   - RX MIXTURE – MED ID RECORD NAME- Internal unique name for each medication.
   - RX MIXTURE – INGREDIENT TYPE- Description of the ingredient (i.e. medication, additive, base).
   - RX MIXTURE – DOSE AMOUNT- Dose of the ingredient (i.e. 100, 10, etc.)
   - RX MIXTURE – AMOUNT UNIT- Dosing unit of the ingredient (i.e. mg, ml, mg/kg, etc.)
   - RX MIXTURE – CALCUATED DOSE AMOUNT- If does was weight based, this field shows the calculated does unit (mg).
   - MEDICATION ROUTE- Route (i.e. IV, Oral, etc.).
   - Dose- Include weight-based dose (mg/kg) if available in one column and total dose (mg) in another column.
   - FREQUENCY RECORD NAME- Frequency of the order (daily, bid, continuous, etc.).
   - MEDICATION START DATE- Start date of the order.
   - START TIME- Start time of the order.
   - MEDICATION END DATE- End time of the order.
   - MEDICATION END TIME- End time of the order.
   - Flag if inpatient order or outpatient prescription

- If outpatient prescription, include columns for days supply and quantity dispensed.
- Randomized OrderID
- Randomized MRN
- Randomized Visit Number
- DeptName- Location of the patient when the specimen was drawn (5WICU, ED, PACU etc.).
- SpecType- Type of specimen (i.e. blood, urine).
- SpecDate- Date specimen was drawn.
- SpecTime- Time specimen was drawn.
- ResultDate- Date of the result.
- ResultTime- Time of the result.
- ComponentName- Lab component name (i.e. Potassium-Blood, Creatinine-Blood, etc.).
- CommonName- Common lab name (i.e. Potassium, Creatinine, etc.).
- ExternalName- Lab name shared with external locations (i.e. Potassium, Blood)
- LOINC- LOINC valude of the lab name (i.e. 2823-3)
- ResultValue- Lab result (i.e. 4.5)
- ResultUnit- Lab result unit (mMol/L)
- RefLow- Low reference value (3.5)
- RefHigh- Higher reference value (5.1)
- ProcID- Internal ID of the lab procedure.
- ProcName- Name of the lab procedure (i.e. Comprehensive Metabolic Panel)

4. **Visit Data File**
    - Randomized MRN
    - Randomized Visit Number
    - Admit Date
    - Admit Time
    - Discharge Date
    - Discharge Time
    - Flag is visit is an inpatient or outpatient