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](https://research.uahs.arizona.edu/clinical-trials/research-intake-form).

**PROCESS OVERVIEW**

- **Investigator**: submits RIA application with CRDW Request Form
- **Banner Research Operations**: receives proposal and forwards on to Honest Broker staff for feasibility assessment
- **Honest Broker staff**: reviews proposal and requests clarifications as needed
- **Honest Broker staff**: begins working on the project once IRB approval & a fully executed contract are received
- **Honest Broker staff**: meet with investigator to review data and make revisions based on feedback
- **Investigator**: contacts UA HIPAA Privacy Security Officer to ensure data will be properly secured

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. The Honest Broker staff will provide an estimate as part of the feasibility review. The process generally takes 4 – 8 weeks until the data is extracted to the investigator’s satisfaction. 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. Banner Health Legal will send the initial DSA agreement, RIA application, and CRDW request form to UAHS contracting at [UAHSContracts@email.arizona.edu](mailto:UAHSContracts@email.arizona.edu) to initiate formal negotiations. UAHS contracting will send a copy of the fully executed contract to study team, Banner Health Legal, and the Honest Broker staff.

- **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.

- **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](https://rgw.arizona.edu/compliance/hipaa-privacy-program).

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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:**

PI Name pi@email.arizona.edu or pi@bannerhealth.com

**Project Title:**

Individualized Drug Interaction Alerts

**Inclusion Criteria:**

Inpatient and Outpatient visits at Banner University Medical Center Tucson Campus. Any visit receiving a medication order (prescription or inpatient medication order) between the dates of 1/1/19-6/30/19 should be included.

**Exclusion Criteria:**

Click or tap here to enter text.

**Data Points Requested (Be specific):**

Requesting 5 different files

Patient Data File

- Randomized MRN
- Date of birth
- Sex
- Ethnic Background
- Patient Race

Diagnosis Data File

- Randomized MRN
- Randomized Visit Number

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• Diagnosis Entry Date
• Diagnosis Visit Number
• ICD9 Code- Comma delimited list if multiple
• ICD10 Code- Comma delimited list if multiple

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 RxMixture 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 – CALCULATED 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).

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• 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 value 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)

Visit Data File

• Randomized MRN
• Randomized Visit Number
• Admit Date
• Admit Time
• Discharge Date
• Discharge Time
• Flag is visit is an inpatient or outpatient

Timeframe to Collect Data (start date/finish date):

1/1/2019-6/30/2019

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

Banner University Medical Center Tucson Campus