

## **Clinical Research Data Warehouse (CRDW)**

#### **Request Process**

To support the use of Banner 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 take in requests for data, assess the feasibility of the requests, and ultimately fulfill the requests. Requests are initiated using the Research Intake Form: <u>https://research.uahs.arizona.edu/clinical-trials/research-intake-form.</u> A high-level overview of the process is given below:

# CRDW Data Request Process

Investigator Submits Research Intake Form with Clinical Research Data Request Form Banner Research Operations Receives Proposal and forwards on to Honest Broker Staff for feasibility assessment

Honest Broker Staff reviews proposal and provides a feasibility assessment Once IRB and Contracting have completed, Honest Broker Staff begin working on project

Honest Broker Staff meet with Investigator to review data and make revisions based on feedback Investigator contacts HIPAA Privacy/Security Officer to ensure they are properly securing the data

In our experience, having a well formed and complete data request to start with helps make the process move more smoothly. On the following page we have attempted to make a streamlined form that captures the necessary elements for a complete request. If you have any questions about the process or would like assistance on your data request, please feel free to contact us at: <u>BHHonestBrokerDataRequest@bannerhealth.com</u>.

# Frequently Asked Questions (FAQ)

**How long will a data request take?** This is highly dependent on the scope of the request and the Honest Broker staff will provide an estimate as part of the feasibility review. Most frequently, the process generally takes 4 – 8 weeks until the data is extracted to the investigator's satisfaction. Often there are other steps in the process such as contracting which can impact the overall time, so we ask that you submit your request as early as possible.

After 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 <u>PrivacyOffice@email.arizona.edu</u> 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: <u>https://rgw.arizona.edu/compliance/hipaa-privacy-program</u>

What is involved in the contracting process? There will need to be a signed Data Sharing Agreement (DSA) between Banner and UA. Banner is working with UA to make this a Master Agreement with each project being an addendum, but until this is complete, a DSA will need to be executed for each request. The turnaround time for the DSA alone is estimated at three weeks.

How can I determine the status of my request? For status updates, please email:

<u>BHHonestBrokerDataRequest@bannerhealth.com</u> and include PI Name and Project Title. At some point in the future a dashboard may be put in place.

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#### Clinical Research Data Warehouse (CRDW)

#### **Request Form**

Please complete <u>all</u> 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 Phoenix Campus. Any visit receiving a medication

order (prescription or inpatient medication order) between the dates of 1/1/2018-6/30/2018) 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
- Ethnic Group
- Patient Race



- Randomized MRN
- Randomized Visit Number
- Diagnosis Entry Date
- Diagnosis Description
- 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 (Med Only, Med Form Strength, etc).
- RXNORM CODE- 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. ANTIEMETIC/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 but 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 dose was weight based, this field shows the calculated amount (5).
- RX MIXTURE CALCULATED AMOUNT UNIT- If dose was weight based, this field contains the calculated dose 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 date 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 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- High 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 if visit is an inpatient or outpatient

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

### 1/1/2018-6/30/2018

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

Banner University Medical Center Phoenix Campus