

## BPIC Data Request Procedures

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CTSI Best Practices Integrated Informatics Core

[bpic@umn.edu](mailto:bpic@umn.edu)

### BPIC Office Hours:

Tuesdays 1-3pm Walk-in

Thursdays 1-3pm by Appointment

*CRSC 330 Diehl Hall*

## 1 Purpose and Scope

The aim of this document is to define the key aspects utilized by CTSI BPIC resources in the handling of requests for clinical, genomic and biospecimen data. It is not the objective to specify a detailed working method, but to establish a framework for the standard procedures governed by the data request process.

## 2 Abbreviations

AHC-IE	: Academic Health Center-Information Exchange
BMT	: Bone Marrow Transplant
BPIC	: Best Practices Integrated Informatics Core
CDR	: Clinical Data Repository
CISS	: Clinical Informatics Shared Services
CTSI	: Clinical and Translational Science Institute
EHR	: Electronic Health Record
FRA	: Fairview Research Administration
FV	: Fairview Health Services
HST	: Health Sciences Technology (formerly AHC-IS)
HIPAA	: Health Information Portability and Accountability Act
IRB	: Institutional Review Board
LIMS	: Laboratory Information Management System
MCC	: Masonic Cancer Center
PHI	: Protected Health Information
PI	: Principal Investigator
SDE	: Secure Data Environment
UMP	: University of Minnesota Physicians

## 3 Informatics Infrastructure

The **Secure Data Environment (SDE)** is a robust and secure informatics infrastructure that supports clinical translational science research, healthcare operations, and quality of care improvement at the University of Minnesota and its clinical partners, Fairview and University of Minnesota Physicians. The SDE integrates and manages heterogeneous clinical, genomics and biospecimen data from disparate sources. It contains applications that support metadata and terminology management, provides data analysis tools, and follows best practices for data security, transfer, storage and sharing.

A primary component of the SDE is the **Clinical Data Repository (CDR)**. The CDR is a large data warehouse containing integrated data from various sources including research data systems managed by the Academic Health Center, public databases, and clinical data available through the Academic Health Center-Information Exchange.

The **Academic Health Center-Information Exchange (AHC-IE)** represents a collaboration agreement between the University of Minnesota Academic Health Center and Fairview Health Services and was created to support the joint mission of improving patient care and supporting healthcare research and education. Data from Fairview are loaded from source systems, enriched, standardized, and put into a Production Zone schema for easier access and retrievability.

Data are shared with users through the **Data Shelter**, a virtual workspace consisting of a combination of linux and windows servers that provides researchers a secure environment in which to access and work with their data. Inbound and outbound Internet traffic, installation privileges and network drives are disabled within the shelter to prevent unauthorized access and to ensure data is not extracted. Data are stored on encrypted drives and backed up daily to off-site locations.

Projects involving researcher-controlled data sets (i.e., data not originating from the AHC-IE) may utilize the **Secure Computing Environment (SCE)**, which is a HIPAA-compliant solution set up similar to the AHC-IE Data Shelter but that gives Researchers some control of extractions for data sets that they own (or for which they have a data use agreement with the data owner/broker).

## 4 Consultation Request Process

### 4.1 REQUEST SUBMISSION

To initiate a consultation, a researcher submits a request via the [BPIC website](https://z.umn.edu/requestdata): [z.umn.edu/requestdata](https://z.umn.edu/requestdata)

If the consultation request is received via email or the CTSI Portal, the Analyst fielding the request may fill out a request form on the researcher's behalf.

### 4.2 ACKNOWLEDGMENT

The Analyst who is assigned to the request will email the requestor within 2 business days to acknowledge receipt of the request and initiate the consultation process.

## 4.3 REVIEW

Requests associated with departments or centers that have collaboration agreements with BPIC will be brought before the relevant review committee prior to approval or prioritization.

- Department of Surgery: *SIREC Research Committee (SRC)* -- meets biweekly
- Masonic Cancer Center: *Cancer Research Translational Initiative (CRTI)* -- meets as needed

## 4.4 CONSULTATION

BPIC Analysts utilize a three-phase consultation process and will generate a consultation report that summarizes the project scope, necessary resources (including time and cost estimates), deliverables and milestones.

### ***Phase 1: Initial Consultation and Feasibility Analysis***

Free consultation during which a BPIC Informatics Consultant meets with the researcher(s) to discuss the proposed project and assess feasibility. This rapid appraisal reduces time delays, expands the scope of technical approaches that can benefit complex research, and reduces errors in the early stages of project design.

### ***Phase 2: Detailed Planning***

Detailed planning is a short and quick phase that outlines a technical plan, budget, timeline in a refined consultation report. Both BPIC and the researcher need to agree on the proposed scope before Phase 3.

### ***Phase 3: Execution/Implementation***

Project execution begins after BPIC and the researcher have an agreement on the scope of work. This is when the informatics work is done, including identifying exact data elements needed, informatics methods design, dataset creation, etc.

## 5 Data Request Types

Researchers are encouraged to visit the IRB Toolkit Library via the following link if they need help determining whether their request qualifies as Human Subjects Research: ([Human Research Determination Form](#))

APPROVALS REQUIRED	Prep-to-Research	Research	Operational	Quality
IRB		X		
UMP/FV Data Steward			X	X
MCC PI*	X	X	X	X
MCC Data Steward*	X	X	X	X

\* For Masonic Cancer Center requests only

### 5.1 RESEARCH

All requests that fall under the federal definition of human subjects research require IRB approval (<https://research.umn.edu/units/irb>).

- IRB submissions for studies utilizing Epic data must indicate the AHC-IE as a data source.
- Cancer-related projects needing scientific review may utilize the MCC Data & Biospecimen Utilization Committee (DBUC).

BPIC Analysts will review the IRB submission and verify IRB status, study personnel, and whether the study was

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approved to receive identifiers.

- If the PI has asked for someone to be given access to data who is not listed with the IRB, the PI needs to correct the application via a "modification" in ETHOS. [Job aids](#) for submitting modifications are available on the IRB website.
- If a cancer-related request needs data from another PI's study, CISS will obtain approval from the original study PI.

BPIC is responsible for verifying that the data extracted is the minimum necessary to accomplish the study goals and that the request for data falls within the scope of the IRB approved study.

Requestors are strongly encouraged to request de-identified data or limited datasets in order to minimize exposure to highly sensitive and confidential patient data.

## 5.2 PREPARATORY TO RESEARCH

Requests that are preparatory to research (e.g., feasibility analyses) do not require IRB approval; however, a Preparatory to Research Representation is required (see [Appendix A](#)).

Preparatory to research requests may include identifiers. Data will be delivered through a secure PHI-compliant data shelter and may not leave the controlled environment unless it is necessary to merge with external data sources (e.g., LIMS) in order to complete the feasibility assessment. Data cannot be used for publications, abstracts, presentation, or in any other manner other than to prepare for future research. For more information on the disclosure of PHI for activities preparatory to research, see the related [Administrative Policy](#).

## 5.3 OPERATIONAL

Data requests that are for operation purposes must be reviewed and approved by the appropriate Data steward. BPIC is responsible for securing this approval and will communicate back to the investigator any issues or concerns.

## 5.4 QUALITY OF CARE IMPROVEMENT

IRB approval is not required for quality of care projects; however, it is recommended that a Human Research Determination form be completed.

Quality requests must be reviewed and approved by the appropriate Data steward. BPIC is responsible for securing this approval and will communicate back to the investigator any issues or concerns.

## 6 Recruitment Requests

### 6.1 FEASIBILITY ANALYSIS

Researchers are encouraged to use self-service tools for simple feasibility analyses. For more complex queries researchers may submit a consultation request to BPIC.

i2b2: [i2b2.ahc.umn.edu](https://i2b2.ahc.umn.edu)

- Sign up on the site with your x500

TriNetX: [live.trinetx.com](https://live.trinetx.com)

- Contact [bpic@umn.edu](mailto:bpic@umn.edu) for access

## 6.2 IRB SUBMISSION

When utilizing BPIC services for recruitment, answer YES to the question, “Are you utilizing data from the Academic Health Center – Information Exchange (AHC-IE)?”. Fairview Research Administration (FRA) will be assigned ancillary reviewers and will review and approve the recruitment plan.

## 6.3 NOTIFY FRA and BPIC

For recruitment plans that include mailings, submit a request to BPIC and notify FRA that you intend to recruit patients via mail. Providers with a treating relationship may receive IRB approval to directly contact their patients, therefore bypassing the FRA process described below. See [Appendix D](#) for detailed information about the recruitment process.

### FRA Guidelines

FRA has the following [recruitment guidelines](#) - Patients must be:

- Alive and have not opted-out of research
- < 80 years old
- Seen in a Fairview facility within the past two years

### Mailing Process

1. The PI writes the recruitment letter and shares it with FRA
2. BPIC shares patients contact information with FRA via Box (the study team never receives contact info)
3. FRA coordinates with the UMN Office of Address and Mailing to print and send letters
  - FRA prints letters on Fairview letterhead (\$)
  - UMN A&M sends the letters (\$)

## 7 User Authorization

BPIC receives requests for and manages the provision of access to the SDE and its data. Access to SDE will be granted to Authorized Users who meet the criteria established by the AHC-IE Executive Committee.

### 7.1 UNIVERSITY OF MINNESOTA, FAIRVIEW and UMP EMPLOYEES

#### Affiliation

At least one member of the study team needs to have an active University, UMP or Fairview affiliation, and be a student or employee of good standing. An employee of an AHC-IE partner institution will be authorized by their respective employer.

*\*Note: BPIC services are available to external collaborators (industry) who are subject to the applicable legal agreements (MTA, BAA, DUA, etc.) in lieu of the affiliation requirement. For more information on external collaborators see below.*

#### HIPAA training

- HIPAA training is now available on the University's [Training Hub](#)

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- A record of all training completed while at the University is available online through the Training History link at the [MyU website](#)
- Questions about meeting the training requirements may be addressed to the Health Information Privacy and Compliance Office ([privacy@umn.edu](mailto:privacy@umn.edu))

## AHC-IE Attestation form

When utilizing data from the AHC-IE users must sign the [Attestation Form for Individuals Accessing the AHC-IE](#) (see [Appendix B](#)). This attestation sets forth certain rights and responsibilities of individuals who wish to access Fairview data through the AHC-IE and is valid for one year.

## 7.2 PERIODIC USER REVIEW

Each project will have a designated User Reviewer (e.g., the PI or delegate) who is responsible for reviewing all users associated with the project every 180 days. The User Reviewer will receive automated email notifications reminding them of the required review and reauthorization to ensure that continued access is appropriate.

1. The system will send an automated email to the User Reviewer prompting them to log in to [Portunus](#) and review all users associated with the project. Notifications are delivered 150, 170, and 179 days since the last review, giving the User Reviewer several reminders to reauthorize individuals on the project.
2. The User Reviewer follows the link to log in to Portunus and access the project page.
3. The User Reviewer removes access for users who should no longer be authorized.
4. The User Reviewer clicks on the "Mark Reviewed" button to reauthorize users.
5. If the User Reviewer fails to log in to Portunus and click on the "Mark Reviewed" button after 180 days since the last review, the system disables access for everyone on the project and notifies the User Reviewer of the action.

## 7.3 AUTOMATIC DEPROVISIONING

When a user has a student or employment status change (e.g., termination of employment or graduation) the change is detected through an HST system (I5) and the user's AD account will be automatically disabled. As an AD account is necessary to access to the Data Shelter and Secure Computing Environment, the user will no longer have access to these environments. In such cases where there is a new status that continues to meet the AHC-IE user authorization requirements, and continued access is still appropriate, the user should contact BPIC to be reauthorized and for information on how to reactivate their AD account.

## 7.4 EXTERNAL COLLABORATORS

External collaborators cannot request data themselves, but qualified University-affiliated individuals can be granted access in some cases. To do so, a University member must secure a sponsored guest x500 account for their external collaborator. This is a free service that can be [requested via the Office of Information Technology](#). Collaborators will also be asked to provide evidence of recent HIPAA training and will sign the AHC-IE Attestation form.

## 7.5 DOMAIN-SPECIFIC REGISTRIES

For domain specific registries/databases such as BMT and LIMS, CISS will provide authorized users access to the full registry to perform data quality checks and identify data enrichment and transformation tasks. Authorized users or Subject Matter Experts (SMEs) will not have the ability to extract and deliver data.



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- Data that is added to enhance domain specific projects (from chart review; research laboratory analyses or other) will be integrated, if possible, with the CISS record for storage and future analysis. Any data that are supplemented for research purposes need to be approved by IRB.

## 8 Data Preparation

BPIC will work with the study team to identify requirements, inclusion/exclusion criteria and all codes required for the project. Custom queries will be built to extract data from the source (e.g., Clinical Data Repository (CDR), BMT database, LIMS, OnCore, etc.). If multiple sources are necessary the data will be fully integrated.

BPIC is responsible for fully [de-identifying](#) or providing [limited datasets](#) in accordance with the HIPAA Privacy Rule, if required.

## 9 Data Delivery

Data will be delivered to study team members through the data shelter or via a PHI Compliant tool approved by the [Center of Excellence for HIPAA Data](#). The delivery method will be recommended by BPIC after considering applicable policies and the needs of the project.

PIs, their staff and study team members will all have shared access to the data shelter or other PHI Compliant tool. BPIC will provision access and provide instructions on accessing the data.

BPIC will periodically review user access and confirm if access is still needed and/or appropriate.

### Delivery Methods:

#### DATA SHELTER

Data will be delivered by default via the data shelter. All study team members, including biostatisticians, will access and analyze data within the shelter. The [Data Shelter User Guide](#) contains instructions for setting up access to the shelter.

- In some cases, data may be extracted from the shelter if certain criteria are met (*refer to [Section 11: Data Extraction Policies](#) below*).
- Traffic in and out of the shelter is disabled. Researchers wishing to transfer files must use our secure file transfer application (*refer to [Section 12: Data Shelter File Transfers](#) below*).

#### BOX

This is the preferred method when sharing data externally with a sponsor or an affiliate site. BPIC will release data only upon completion of all legal work between the University and the affiliate site or sponsor.

- Cancer researchers may consult the DBUC administrator for help with the legal process

#### ACTIVE DIRECTORY NETWORK FOLDERS

*Restricted:* This pertains only to automated operational reports, which do not include Fairview data, and are used by MCC CTO, BMT, Lab and Data Solution teams. HST has approved specific AD paths as being PHI compliant.

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## EMAIL

**Restricted:** Only for aggregate reports, graphs, or protocol level data. The University discourages the transmission of PHI via email (see [Appendix to Policy E-mail and Protected Health Information](#)). It is BPIC policy that all PHI and individual level data must not be emailed.

## Other Scenarios:

- There may be special circumstances where approval is obtained (e.g., from the IRB, Office of Compliance, partner Data Stewards, Center of Excellence for HIPAA Data, the AHC-IE Executive Leadership Committee) to deliver and store data outside of the default methods listed above. In these situations, BPIC may facilitate the approval process but will not approve such requests.
- When a PI leaves or joins the University research data may be transferred subject to the Transferring Research Data policy: <https://policy.umn.edu/research/researchdata-proc01>

## 10 CTSA Grant Acknowledgment

When presenting or publishing results based on this data, please acknowledge that the research was supported in part by a grant from the National Center for Advancing Translational Sciences of the National Institutes of Health and that the data was provided by the University of Minnesota's Clinical and Translational Science Institute, Best Practices Integrated Informatics Core. See [Appendix E](#) for detailed information about the citation requirement.

## 11 Rates

Consultations	:	<i>Free of charge</i>
Grant proposal preparation	:	<i>Free of charge</i>
Other services	:	<i>Directly supported by the appropriate funding sources</i>

### Costs for services are recovered through:

- % effort of personnel (grant or departmental agreement)
- Internal Service Organization (ISO) model: \$120/hr\*
- For Masonic Cancer Center Members (internal rate): \$95/hr

## 12 Data Extraction Policies

Requests to deliver AHC-IE data outside of the approved methods described above may only be granted if all criteria are met in the applicable data extraction policy. If individual level data are approved to be removed from the secure data environment, BPIC will transfer the data to the target destination via a PHI compliant mechanism, typically Box or via sftp.

### 12.1 DE-IDENTIFIED DATA

#### Extraction of De-Identifiable Data Policy

The data are fully de-identified by BPIC; and

- a. The data are required by law to be submitted to another entity such as an oversight agency, regulatory authority or data registry; or
- b. The data are required for IRB approved research or health care operations and 1) need to be analyzed using tools or computing power not available in the environments described in [Section 3](#), or 2) integrated with other data sources not available in the environments described in [Section 3](#).



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## 12.2 IDENTIFIABLE DATA

### Extraction of Identifiable Data Policy

- a. The data are required by law to be submitted to another entity such as an oversight agency, regulatory authority or data registry; or
- b. The data are required for IRB approved research or health care operations and 1) need to be analyzed using tools or computing power not available in the environments described in [Section 3](#), or 2) integrated with other data sources not available in the environments described in [Section 3](#); and
  - o The data are stored on a UMN device that is supported by HST and is up to date with encryption; or
  - o If the data are sent to a third party, a Data Use Agreement as approved by the [Health Information Privacy & Compliance Office](#) is entered into with the third party

## 13 Data Shelter File Transfers

To import and export files to and from the data shelter use the Data Shelter File Transfer application. Documents may be imported from your personal computer using the site <https://portunus.ahc.umn.edu/>. To retrieve uploaded documents or export documents from the shelter, the same website will be accessed from a browser within the shelter. Please note that all exports will be reviewed by an analyst and approved if they meet the above-referenced data extraction policies.

For instructions on using the file transfer application visit-  
<https://confluence.ahc.umn.edu/display/POR/File+Transfers>

Version number	1.2	Author	Gretchen Sieger
Superseded version	1.1	Reviewer(s)	Steve Johnson
Effective	7/1/2018	Amended	7/1/2020

## Appendix A

### AHC-IE Preparatory to Research Representation

#### Project: SiegerG-Test00001

Required representations for reviews preparatory to research.

**First name:**

Gretchen

**Last name:**

Sieger

**Email**

sieger022@umn.edu

**Internet Id**

sieger022

The approval of your review of patient data for this purpose is contingent on your agreement with the following representations. Please check each box below to indicate that you acknowledge and agree that:

- ☐ Patient data will only be used or disclosed as necessary to prepare a research hypothesis, assess whether a sufficient and appropriate number of individuals would meet the eligibility criteria, or other similar purposes preparatory to research;
- ☐ Patient data used or disclosed during this review will not be removed from the secure data shelter in any form, including in abstract;
- ☐ The use or disclosure of the requested patient data is necessary for the research.

By clicking the button below you indicate that you agree to all the above terms.

Submit

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## Appendix B

### Attestation Form for Individuals Accessing the AHC Information Exchange

This document sets forth certain rights and responsibilities of individuals who wish to access data and systems within the AHC IE. This attestation must be renewed on an annual basis in order for you to maintain your status as an authorized user and continue access to the system.

**Please acknowledge your agreement to the terms below by checking each box.**

#### Access and Use Obligations

- ☐ **Access.** I will only access and use AHC IE data for the purposes specified in the original AHC IE Data Request Form.
- ☐ **Restricted Use for Patient Contact.** I will not use AHC IE data identifiers to contact patients unless I am a) the patient's treating physician, b) part of the treating physician's practice, or c) engaged in authorized fundraising through the University of Minnesota Foundation.
- ☐ **Restricted Use Outside Data Shelter.** I will only use AHC IE data within the secure data shelter provided by the Academic Health Center and will not export data from the data shelter. If my work requires that I export data from the data shelter, I will request permission to do so. After receiving such permission, I will store any exported data on AHC-maintained hardware or using other methodology approved through my request for permission.

#### Confidentiality Obligations and Acknowledgements

- ☐ **Limits on Disclosure.** I will not disclose AHC IE data to any individual who has not been granted access to the data on the original AHC IE Data Request Form or otherwise approved to receive this information.
- ☐ **Confidentiality of Images.** I will not generate any images for export from the secure data shelter that include individually identifiable health information.
- ☐ **Compliance with Policy and Law.** I will protect the privacy, confidentiality, and security of AHC IE data. Specifically, I will abide by all policies and procedures of the organization I am affiliated with (University of Minnesota/UMP/Fairview) related to security and privacy as well as state and federal laws applicable to health information.
- ☐ **Reporting Violations.** I will report any security incident involving the improper use or disclosure of health information stored in or derived from information in the AHC IE to [abuse@umn.edu](mailto:abuse@umn.edu) or the University's Chief Health Information Compliance Officer.
- ☐ **Data Destruction Requirements.** To the extent I have exported data and stored it outside the data shelter with the required permission as outlined above, I will destroy the data at the end of use in accordance with applicable technology standards so as to render PHI, including a limited data set, unusable, unreadable, and undecipherable, and will attest to the data's destruction at the end of use.
- ☐ **Penalties.** I acknowledge that violation of confidentiality or of my organization's policies and procedures related to health information may result in revocation of AHC IE access rights as well as disciplinary action up to and including termination.

#### Acknowledgement of Intellectual Property (IP) Terms

**Please check each box below to acknowledge that you understand the intellectual property terms between Fairview and the University**

- ☐ **Fairview Created IP.** I understand that Fairview has granted the University a limited right to use Fairview's patented inventions, copyrighted works and other intellectual property solely in connection with the University's research and educational purposes, and that Fairview's intellectual property may not be shared with anyone outside of the University unless Fairview had granted its prior written consent.
- ☐ **University Created IP.** I understand that the University, under its Board of Regents Policy: [Commercialization of Intellectual Property Rights](#), claims ownership of inventions I create using data provided by Fairview; that the University has granted Fairview a limited non-exclusive license to use such University IP when that IP relates to Fairview's health care services, healthcare operations and/or strategies; but that Fairview's license does not extend to intellectual property I create that relates to the development, manufacture or sale of medical devices or pharmaceuticals, or to other IP unrelated to Fairview's health care services, operations and/or strategies.
- ☐ **Jointly Created IP.** I understand that Fairview and the University jointly own any inventions that a Fairview employee, agent or contractor and I jointly create using data provided by Fairview; and that the University has granted Fairview an exclusive license to its rights to any such invention in the fields of (i) the development and/or maturation of TIDE; (ii) data and other analytic processes and methods; or (iii) models and/or approaches to care model innovation, health management and/or population health/accountable care including, but not limited to, clinical care pathways or protocols, disease management and/or care coordination, and technology/telehealth models and/or application.

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## Appendix C

### Helpful Links

CTSI Services	
<a href="#">BPIC</a>	CTSI Best Practices Informatics Consulting website
<a href="#">CISS</a>	MCC Clinical Informatics Shared Services website
<a href="#">CTSI</a>	ctsi.umn.edu
Request Forms	
<a href="#">BPIC Consultation Request</a>	Request an informatics consultation
<a href="#">CTSI Portal</a>	Request CTSI services
Self-service Tools	
<a href="#">i2b2</a>	Cohort discovery tool for the CTSI Clinical Data Repository (CDR)
<a href="#">TriNetX</a>	Cohort discovery tool for the CDR and TriNetX network
<a href="#">SHRINE</a>	Cohort discovery tool for the Accrual to Clinical Trials (ACT) network
SDE User Guides	
<a href="#">Data Shelter User Guide</a>	AHC-IE Data Shelter User Guide
<a href="#">Working with SQL Server</a>	Tips on working with a SQL Server datamart
<a href="#">Data Shelter File Transfer</a>	Instructions for using the data shelter file transfer application
<a href="#">Data Shelter Troubleshooting</a>	Troubleshooting guide for accessing the data shelter
Applications	
<a href="#">Fairview Secure Gateway</a>	Access to Epic and other Fairview applications
<a href="#">Data Shelter File Transfer</a>	Application to allow secure transfer of files in/out of the shelter
<a href="#">Box</a>	UMN Box Secure Storage
<a href="#">REDCap</a>	REDCap application for building online surveys and databases
<a href="#">Duo</a>	Enroll in Duo two-factor authentication
<a href="#">UMN VPN</a>	Connect to the UMN network remotely via VPN
<a href="https://nlppier.ahc.umn.edu/">https://nlppier.ahc.umn.edu/</a>	NLP – Patient Information Extraction for Research <i>*must be accessed from within the data shelter</i>
Training and Authorization	
<a href="#">AHC-IE Attestation Form</a>	Attestation form for individuals accessing the AHC-IE
<a href="#">HIPAA Training</a>	Information about HIPAA training and requirements
Reference	
<a href="#">Sherlook</a>	Look-up tool for CDR codes (e.g., diagnoses, locations, orders, etc.)

## Appendix D

### BPIC Services for Participant Recruitment

*Using Clinical Data Obtained via CTSI's Best Practices Informatics Consulting (BPIC) Service for Participant Recruitment*

BPIC works in partnership with Fairview Research Administration (FRA) to facilitate recruitment mailings for IRB approved studies.

BPIC analysts can assist by:

- providing cohort feasibility estimates (please visit [z.umn.edu/i2b2](http://z.umn.edu/i2b2) to learn more)
- identifying potential participants based on inclusion and exclusion criteria
- supplying the clinical information necessary to screen eligible participants
- ensuring potential participants are alive and have not opted out of research
- verifying patients meet FRA's eligibility guidelines
- securely delivering patient contact information to FRA

FRA will send recruitment letters on your behalf, provided that you have IRB approval and your study will occur at Fairview or MHealth. For more information on the FRA Recruitment Mailing process, please see [these guidelines](#). You are advised to contact FRA at [research@fairview.org](mailto:research@fairview.org) as early as possible with questions about developing a recruitment plan or carrying out a mailing.

### Process

To initiate a BPIC request, please fill out an informatics consultation request form at: [z.umn.edu/requestdata](http://z.umn.edu/requestdata).

As with all patient data that we deliver to researchers, we will provide you access to your dataset within a secure data shelter. If it is necessary to further screen potential participants, you will also be able to access Epic from within the shelter.

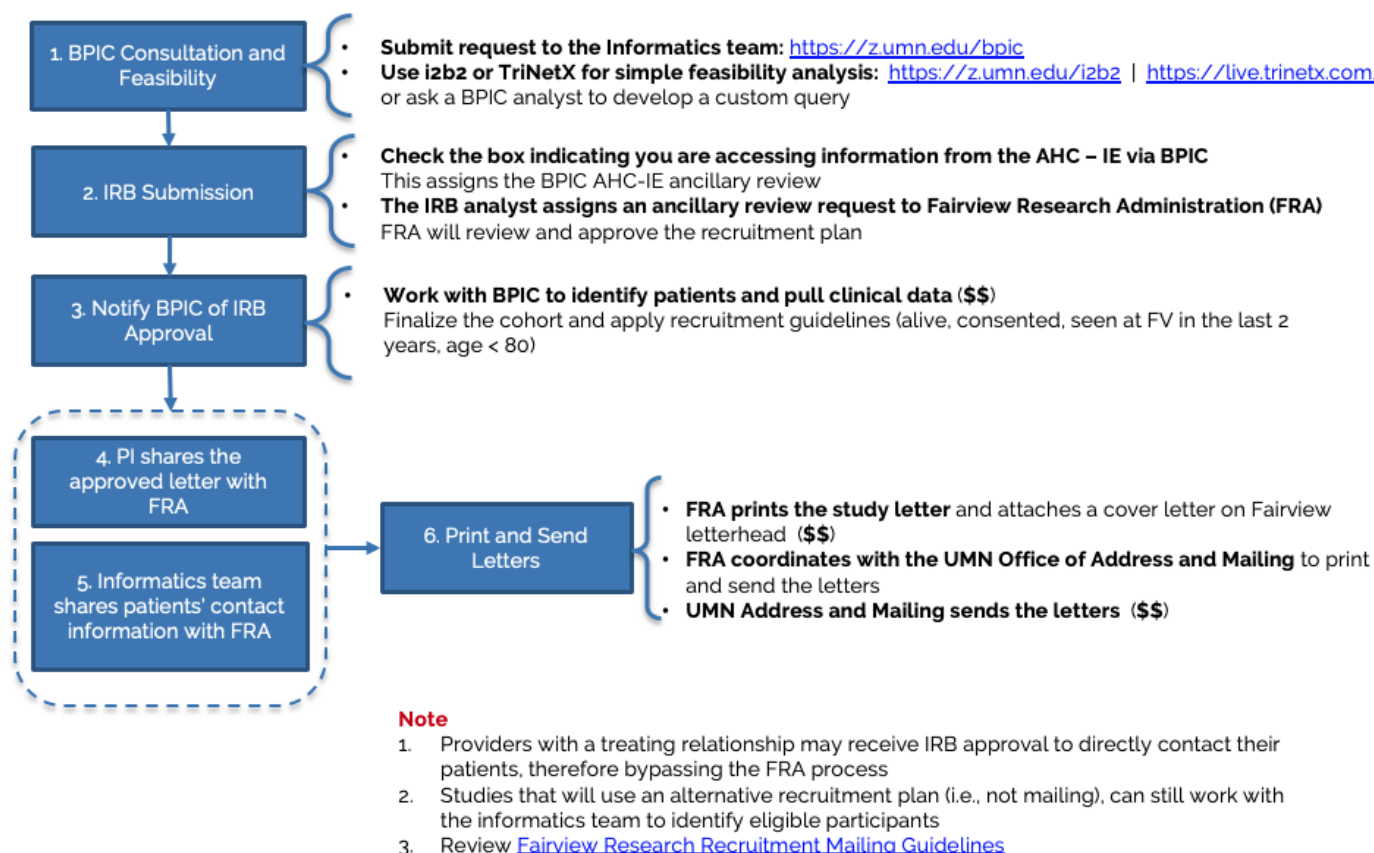
Once you have settled on the patients to whom you would like to send a recruitment letter, you will let BPIC know that the MRN list is ready in your project folder. BPIC will ensure the final list continues to meet all recruitment requirements and will then send the patients' mailing addresses to FRA for handling.

Unless specifically approved by FRA, researchers will not have direct access to patient contact information. Please remember that you are never allowed to directly contact patients who are not under your care or the care of other providers within your clinic or department.



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## Process Diagram



## Requirements

BPIC will work with the study team to ensure the following requirements are met:

- PI engagement and oversight of the recruitment process
- Identification of sensitive populations and an assessment, from the patient's perspective, of who should not receive an invitation to participate
- The study team will manually screen for any important inclusion or exclusion that cannot be accounted for by a data pull before determining the final list of patients to whom letters will be sent

## Alternatives

If recruitment letters are not appropriate for your study population or do not suit the recruitment plan you have designed, you may want to work with CTSI and FRA to discuss alternative [recruitment strategies](#).



## Appendix E

### Citation Requirement

When presenting or publishing results based on this data, please acknowledge that the research was supported in part by a grant from the National Center for Advancing Translational Sciences of the National Institutes of Health and that the data was provided by the University of Minnesota's Clinical and Translational Science Institute, Best Practices Integrated Informatics Core.

#### When to acknowledge CTSA support

Please note that assistance is not limited to monetary support (e.g., pilot grant funds), but also includes use of CTSI space, consultation with CTSI faculty or staff, and use of any CTSI Internal Service Organization services (Biostatistical support, Informatics support, Biospeciman support, and Regulatory assistance such as IND/IDE support, clinical trial monitoring, or ClinicalTrials.gov support), or tools and software such as StudyFinder, REDCap, and OnCore.

#### How to acknowledge CTSA support

All publications resulting from the use of CTSI resources are required to credit CTSA by using the following text:

***This research was supported by the National Institutes of Health's National Center for Advancing Translational Sciences, grant UL1TR002494. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health's National Center for Advancing Translational Sciences.***

#### Complying with the NIH Public Access Policy

The NIH requires that the publications that arise from NIH-funded research be compliant with the mandatory NIH Public Access Policy, including obtaining a PMCID. To ensure your research is publicly available, and to enable us to demonstrate the value of CTSI as a resource for the University of Minnesota, review NIH instructions on obtaining a PMCID and having the full article made available to the public on [PubMed Central](https://pubmed.ncbi.nlm.nih.gov/).

#### Help

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