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
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).

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)

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)

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<td>MCC Data Steward*</td>
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* 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 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
- Sign up on the site with your x500
- TriNetX: live.trinetx.com
- Contact 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.

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
- 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)

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 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.

7.3 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.
- 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.

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 Rates
Consultations : Free of charge
Grant proposal preparation : Free of charge
Other services : Directly supported by the appropriate funding sources

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
11 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.

11.1 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.

11.2 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.

12 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
AHC-IE Preparatory to Research Representation

Project: SiegerG-Test00001

Required representations for reviews preparatory to research.

First name:
Gretchen

Last name:
Sieger

Email
siege022@umn.edu

Internet Id
siege022

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
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/UMF/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 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 indecipherable, 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.
### Appendix C

**Helpful Links**

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