INSTRUCTIONS: This document contains embedded comments that can be used to submit a new medical record review application. Some questions are completed to show adaptive branching logic depending on your specific research study that may not be required for all studies. Please ensure text is reviewed and adheres to your specific research needs. This form corresponds to the January 2022 IRB application, however suggested text may apply to subsequent iterations of the Insight application.

To submit a new application, please visit www.insight4.partners.org and select 'Humans' and 'Create Protocol' to start the process.

Mass General Brigham

Title: Research Study Name (Test)
Sponsor Name: None
PI Name: **Protocol #:** **Type:** Initial Review (IR)
Date Received:

Non Study Staff Added

Name	Degree	Organization
Mueller, Ariel	MA	MGH > Anesthesia

InitialReview

Title:

Research Study Name (Test)

The Mass General Brigham Institutional Review Board has created several forms for review of human subjects research. This questionnaire includes a series of questions to identify the form (s) you need to complete for your research project.

1. Intervention/Interaction
2. Health / Medical Information
3. Excess Human Material and Related Health / Medical Information
4. Secondary Use of Research Samples and/or Data (samples/data from another research study)
5. Research Data Repository (collecting and storing health/medical information for future research)
6. Tissue or Sample Repository
7. Coordinating Center / Core Labs
8. Emergency / Single Patient Use of Investigational Products

1. Intervention and/or Interaction

Does your research involve an **intervention** and/or **interaction** with subjects for the collection of specimens or biological material or data (including health or clinical data, surveys, focus groups or observation or behavior)?

NOTE: Do not answer YES if this protocol is to establish a Research Data Repository or Sample/Tissue Repository. There are separate forms for Data and Tissue Repositories.

- ○ Yes
- ◉ No

2. Health / Medical Information

Is your research limited to the use of health / medical information?

- ◉ Yes
- ○ No

COVID-19/SARS-CoV-2

Is this research related in any way to the novel coronavirus, COVID-19, SARS-CoV-2 or, any impact or consequences related to the outbreak and pandemic?

- ○ Yes
- ◉ No

Sponsor Funding: None

Select the source of funding that will be used to support the proposed research:

- ○ Government / Foundation / Other Non-Profit
- ○ Corporate
- ○ Institutional Award
- ○ Department Funds
- ◉ None

Is this the primary source of funding?

- ○ Yes
- ○ No
- ◉ Not applicable

Health / Medical Records

The Health/Medical Records specialized form is to be used for studies that are limited in scope to review of health or medical information from medical records or other sources, including use of datasets that were not collected for research purposes, e.g., CMS or other third party insurer datasets.

Do not use the health/medical records form for research that involves contacting subjects, e.g., a follow-up phone call for patient status.

More detailed descriptions of specific questions/categories below can be found in the Research Navigator "Specialized Forms" section. See Research Navigator.

1. Purpose

Briefly describe the purpose of the research:

Data resulting from this research will be used for the following.

Check all that apply.

- ☐ Publication
- ☐ Oral Presentation
- ☐ Other

Will data resulting from this research ever be submitted to the FDA?

- ○ Yes
- ○ No

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2. Study Population

Check all that apply.

- ☐ Patients
- ☐ Healthcare Providers

NOTE: Healthcare providers may be considered subjects if you are studying provider behavior or performance, or analyzing patient outcomes based on provider. In such cases, you must consider the privacy risks and privacy rights of providers and address these in the waiver of consent / authorization section.

- ☐ Other

Age

Check all that apply.

- ☐ Children (less than 18 years of age)
- ☐ Adults (18 years and older)
- ☐ Unknown

Gender

Check all that apply.

- ☐ Male
- ☐ Female
- ☐ Unknown

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3. Source of Health / Medical Information

Indicate:

- ☑ Mass General Brigham Sites

Mass General Brigham Sites

Check all that apply.

- ☐ BWH
- ☐ BWFH
- ☐ MEE
- ☐ MGH
- ☐ McLean
- ☐ NWH
- ☐ NSMC
- ☐ PCHI
- ☐ SERI

☐ SRH
☐ Other Mass General Brigham Site

☐ Non-Mass General Brigham Sites
☐ NeuroNext or Stride Network

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4. Data To Be Collected / Obtained

Check all that apply.

Administrative:
- ☐ Billing data
- ☐ Coded encounter data (diagnoses, procedures, dates)
- ☐ Demographic data (age, gender, vital status)

Health / Medical:
- ☐ Allergies
- ☐ Discharge Summary
- ☐ Doctors Orders
- ☐ History / Physical
- ☐ Immunizations
- ☐ Medication List
- ☐ Office / Clinic Notes
- ☐ Operative / Procedure Notes (e.g. endoscopy)
- ☐ Pharmacy
- ☐ Problem List

Health/Medical Reports/Results:
- ☐ Blood Bank
- ☐ Laboratory
- ☐ Pathology reports (reports only). Complete the Excess Human Material form for use of tissue/slides instead of this form.
- ☐ Radiology
- ☐ Clinical Genetic Data

Sensitive/Personal Information:
- ☐ HIV Status
- ☐ Mental Health
- ☐ Reproductive History (e.g., abortions)
- ☐ Sexual Behavior / Sexually Transmitted Diseases
- ☐ Substance Abuse (e.g., drug or alcohol abuse)
- ☑ Other potentially stigmatizing behaviors (such as illegal activities) or information

Specify:

Will any sensitive/personal information listed above be collected?

- ◉ Yes

○ No

Explain why the sensitive/personal data checked above is needed to achieve the goals of the study:

Other Health/Medical Information:

☐ Other

Note: The HIPAA Privacy Rule requires Mass General Brigham and its affiliated hospitals and providers to make all reasonable efforts to use or release only the "minimum necessary" identifiable health care information to achieve the intended purpose. The minimum necessary standard applies to research limited to health/medical information collected with a waiver of authorization.

Have you created a data collection form or other tool for data collection?

○ Yes
◉ No

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5. Data To Be Requested From The Following Time Period (Encounter Dates)

Indicate the time period of interest for your study, e.g. 01/01/2000 - 01/01/2024. Prospective reviews are allowed for most studies limited to health/medical information, usually limited to 5-7 years in the future. The end date can be extended by amendment.

From (mm/yyyy):

To (mm/yyyy):
For future data, use anticipated project end date.

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6. Protected (Identifiable) Health Information

PHI refers to health/medical information that is accompanied by any of the listed 18 HIPAA identifiers or by a code where the key to the code that links to the identifiers is accessible to investigators. Note that if any part of an identifier, e.g. patient initials, is included in a code number, the code number itself is then considered an identifier under HIPAA. DE-IDENTIFIED DATA (without any identifiers or codes that link back to individuals) are not considered PHI, and are not subject to HIPAA regulations.

- Names, including initials
- Social security numbers
- Medical record numbers
- Addresses by street location
- Addresses by city, county, precinct, zip code
- All elements of dates (except year) related directly to individuals including, but not limited to, dates of birth, death, admission, discharge, or any service
- All ages over 89 and all elements of dates (including year) indicative of such age
- Telephone numbers
- FAX numbers
- Electronic email addresses
- Web URLs
- Internet protocol (IP) addresses
- Account numbers

- Certificate/license numbers
- Vehicle identification numbers and serial numbers including license plates
- Medical device identifiers and serial numbers
- Biometric identifiers, including finger and voice prints
- Full face photographs and any other comparable images
- Any other unique identifying numbers, characteristics or codes including, but not limited to, globally unique identifiers (GUID) and universally unique identifiers (UUID) or equivalent

Will you be recording any of the identifiers listed above with the data or using a code to link the data to any of the identifiers? If yes, under the HIPAA Privacy Rule provisions the data cannot be considered de-identified and authorization from the subject or a waiver of authorization must be granted by the IRB. When answering this question, consider the need for recording dates or retaining direct identifiers, such as name and/or medical record number, to link data from multiple sources, to avoid duplicating records, or for QA purposes.

NOTE: If you are recording medical record number or other identifiers, even if temporarily for QA purposes or to avoid duplicating records, then answer "Yes".

◉ Yes
○ No

Check the identifiers that will be recorded with or linked by code to the data.

- ☐ Name, including initials
- ☐ Social Security Number
- ☐ Medical record number
- ☐ Address by street location
- ☐ Address by city, county, precinct, zip code
- ☐ All elements of dates (except year) related directly to individuals, including, but not limited to, dates of birth, death, admission, discharge, or any service
- ☐ All ages over 89 and all elements of dates (including year) indicative of such age [Note: Consider substituting range, e.g., 89+, for actual age.]
- ☐ Telephone number
- ☐ Fax number
- ☐ Electronic email address
- ☐ Web URLs
- ☐ Internet protocol (IP) address
- ☐ Health plan beneficiary number
- ☐ Account number
- ☐ Certificate / license number
- ☐ Vehicle identification number and serial number, including license plate number
- ☐ Medical device identifiers and serial numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full face photographic images and any other comparable images
- ☐ Any other unique identifying number, characteristic, or code (e.g., Pathology Accession #, Code #), including, but not limited to, globally unique identifier (GUID) and universally unique identifier (UUID) or equivalent

Will identifiers be removed from the data and destroyed after all of the data has been collected, the study has been completed, or all regulatory and sponsor obligations have been met? **Note:** Federal regulations mandate that, under a Waiver of Consent/Authorization, identifiers be destroyed as early as possible. De-Identified datasets may be retained indefinitely.

For guidance, see the MGB IRB Recordkeeping and Record Retention Requirements.

- ◉ Yes
- ○ No

6A. Waiver of Informed Consent / Authorization

Explain why it would be impossible to conduct the research without access to and use of identifiable health / medical information. For example, the data cannot be obtained from electronic health / medical records or databases without access to identifiers or identifiers are needed for prospective data collection.

Explain why the risk to subjects, specifically the risk to privacy, is no more than minimal risk. When addressing this question, describe the measures you have put in place to protect the privacy of subjects and confidentiality of the data; for example: (1) identifiable health information will be stored on a computer on the Mass General Brigham network with password protections enabled and anti-virus software or an encrypted laptop and access to identifiable data will be limited to study staff by use of password protected files or restricted shared file areas; (2) name and/or medical record number will be replaced with a study ID or code and the key to the code stored in a password protected file; (3) direct identifiers, such as name and medical record number, will be removed once all of the data is collected and analysis performed on de-identified data.

Explain why the research could not practicably be carried out without the waiver of consent / authorization. When addressing this question, consider the difficulty in locating individuals who may have moved, the number of subjects and cost and use of limited resources of locating individuals and sending letters and consent forms, and the impact on the scientific validity of the study if you could use only data of individuals from whom you were able to obtain informed consent.

NOTE: "Only in a few research studies would it be impossible to obtain informed consent; however in many studies the financial cost would be prohibitive and a potentially poor use of limited research resources." ***Ensuring Voluntary Informed Consent and Protecting Privacy and Confidentiality, National Bioethics Advisory Commission.***

Explain why the rights and welfare of the subjects will not be adversely affected by the waiver of consent / authorization. When addressing this question, consider the individual's right to privacy and the measures you have put in place to protect the privacy of subjects and confidentiality of any data and any health/medical implications for subjects; for example: (1) identifiable data will be stored securely with access limited to study staff; (2) information resulting from this study will not have any important health/medical implications for subjects.

NOTE: If the research uncovers information about the subjects that has important health / medical implications for them, contact the MGB IRB to discuss the appropriate process for providing subjects with additional pertinent information.

Are healthcare providers also subjects of the research?

- ◉ Yes
- ○ No

Explain why it would be impossible to conduct the research without access to and use of

identifiable health / medical information. For example, the data cannot be obtained from electronic health / medical records or databases without access to identifiers or identifiers are needed for prospective data collection.

Explain why the risk to subjects, specifically the risk to privacy, is no more than minimal risk. When addressing this question, describe the measures you have put in place to protect the privacy of subjects and confidentiality of the data; for example: (1) identifiable health information will be stored on a computer on the Mass General Brigham network with password protections enabled and anti-virus software or an encrypted laptop and access to identifiable data will be limited to study staff by use of password protected files or restricted shared file areas; (2) name and/or medical record number will be replaced with a study ID or code and the key to the code stored in a password protected file; (3) direct identifiers, such as name and medical record number, will be removed once all of the data is collected and analysis performed on de-identified data.

Explain why the research could not practicably be carried out without the waiver of consent / authorization. When addressing this question, consider the difficulty in locating individuals who may have moved, the number of subjects and cost and use of limited resources of locating individuals and sending letters and consent forms, and the impact on the scientific validity of the study if you could use only data of individuals from whom you were able to obtain informed consent.

Explain why the rights and welfare of the subjects will not be adversely affected by the waiver of consent / authorization. When addressing this question, consider the individual's right to privacy and the measures you have put in place to protect the privacy of subjects and confidentiality of any data and any health/medical implications for subjects; for example: (1) identifiable data will be stored securely with access limited to study staff; (2) information resulting from this study will not have any important health/medical implications for subjects.

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7. Research Data

How will research data be recorded and stored?

☑ Electronically

Electronic Research Data

What type of device will the research data be accessed and stored on?

Check all that apply.

- ☐ Cloud (e.g., OneDrive, Dropbox, Amazon S3, Azure, etc.)
- ☐ Desktop computer
- ☐ Portable device i.e., Laptop, Netbook, Tablet, iPod computer, Cell/Smart phone
- ☐ USB Flash/Thumb, External Hard Drive
- ☐ Other device

Portable devices can include cell phone/smart phones, laptops, iPad/tablet computers, iPods or any other electronic device that can communicate wirelessly. For information on portable device security, refer to the Mass General Brigham Portable Device Security Handbook (MGB Internal only link)

Where is the primary storage location of the device(s)? For example, the desktop computer is located in the PI's locked office on White 1; the laptop is stored in office 123 of White 1 and is secured to a desk with a laptop lock; the hard drive is stored in a locked cabinet in office 123 on White 1 and access is limited to study staff only, etc.

Who will have access to the electronic research data stored at MGB? For example, PI, MGB study staff, non-MGB research collaborators who will access data onsite or remotely. There are both IRB and institutional policies regarding how non-MGB collaborators can access MGB electronic systems, whether clinical or research. Describe in detail if requesting non-MGB, research collaborator access to electronic data stored on MGB systems.

Note: For more information, see MGB IRB guidance regarding Non-BWH/Non-MGH Employees as Co-Investigators/Study Staff and Collaborators.

NOTE:

- **All computers and portable devices must have password protections enabled;**
- **All computers must have active anti-virus software;**
- **Laptops, tablet, netbook computers, and USB Flash/Thumb drives must be full disk encrypted;**
- **If data will be transmitted outside the Mass General Brigham firewall, data must be encrypted during transit with the use of SSL/https.**

Will data be uploaded to a website/server?

◉ Yes
○ No

Will the data be uploaded using a wireless network?

○ Yes
○ No

Will the data be uploaded outside of the Mass General Brigham Firewall/computer network? If sending identifiable sensitive/confidential information, please contact Research Information Security.

○ Yes
○ No

Will the website/server be located in a Mass General Brigham facility and maintained by Mass General Brigham IS?

○ Yes
○ No

☐ Paper

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8. Sending Health / Medical Information to Collaborators Outside Mass General Brigham

Will any health / medical information be sent to collaborators outside Mass General Brigham?

◉ Yes
○ No

NOTE: Please be aware that as a data set is being sent to external collaborators, a Data Use Agreement (DUA) must be executed between Mass General Brigham and the entity receiving the data. Please make sure to initiate the DUA following the directions on this page in the Research Navigator: https://partnershealthcare.sharepoint.com/sites/phrmlnitiate/imcdc/Pages/Data-Use-Agreements-(DUAs).aspx

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HIPAA and Limited Data Sets/Tracking Disclosures of Identifiable Health Information (PHI)

1. Tracking is NOT required for disclosure of LIMITED DATA SETS under a DATA USE AGREEMENT. For more information about LIMITED DATA SETS and DATA USE AGREEMENTS, refer to Mass General Brigham policy "Limited Data Sets Policy/Data Use Agreements" (MGB Intranet link).

2. Disclosures of PHI to persons or entities outside Mass General Brigham without the written authorization of the subject must be tracked in accordance with Mass General Brigham policy "Accounting of Disclosures" (MGB Intranet link). You may use the HIPAA Tracking Tool. NOTE: A code derived from the subject's name is considered identifiable, for example, a code that contains subject initials.

NOTE: Mass General Brigham (MGB) is the HIPAA covered entity. MGB includes BWH, BWFH, MEE, MGH, NWH, NSMC, McLean, PCHI and SRH, among others. MGB does not include other Harvard affiliated hospitals, such as BIDMC, DFCI, HSPH, or CHB. Therefore, when MGB investigators send identifiable information to investigators at BIDMC, DFCI, HSPH, CHB or any other institution outside Mass General Brigham, it is considered a disclosure of protected health information.