

**Request for Access to Protected Health Information for a Research Purpose without Subject’s Authorization**

**Instructions:** Research is defined in the HIPAA Privacy Rule as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” In order to comply with HIPAA and HITECH laws and regulations governing covered entities, individuals engaged in Research at Baylor St. Luke’s Medical Center (BSLMC) must document their requests to use Protected Health Information (PHI) for research purposes without a patient’s authorization. Researchers must complete and maintain a copy of this form for all such requests. A copy of the form must also be provided to the office providing access (such as Health Information Management), as applicable. Questions regarding this form or related regulations you should contact BSLMC\_Research@bcm.edu

**Principal Investigator (PI) Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PI Primary Institution/Employer:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PI email/phone:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Administrative contact name/email/phone:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Research Project Title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. I hereby request to review individually identifiable health records for the named research project for which the Individual’s authorization is not available. I represent that the PHI to which access is sought is necessary to the research and will be used solely for the named research project. My request is based upon the following authorization/justification. I have attached the required documents as indicated.

[ ]  Subject’s written authorization WAIVED by IRB (full or partial waiver)

1. Copy of IRB-approved waiver of consent
2. Copy of IRB approval letter

[ ]  Decedents’ health Information only.

1. I agree that, upon request, I will provide documentation of the death of the individuals whose health information I will review.
2. Brief description of research purpose and health information requested
3. Copy of IRB approval letter

[ ]  Information is preparatory to research only. No PHI will be recorded or removed from the area of review.

1. I agree that no PHI will be emailed or stored on a flash drive, laptop, or otherwise recorded or removed from BSLMC (the “covered entity”. I agree that health information will only be recorded in a manner such that the subject cannot be identified (identifiers include name, MRN, dates, etc.) I agree that if I want to record any identifiers including dates (of birth, service, etc.), then either a HIPAA waiver or subject authorization must be obtained. I understand that failure to abide by these conditions will result in automatic termination of access to PHI for research purposes.
2. Brief description of research purpose and health information requested
3. Type of health information to which access is requested

[ ]  Electronic records. Database to be queried: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Paper records: Describe source/location

[ ]  Imaging

[ ]  Other: Describe

1. List all individuals who will have access to the requested PHI and their roles (i.e., co-investigator, study coordinator): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Please check one of the following:

[ ]  I have attached a list of records that I am requesting from Health Information Management. (The list must include the project title and PI name, full legal name of patient, patient’s date of birth or SSN and medical record number when available).

[ ]  I am requesting that a list of records be generated for me by Health Information Management. I have attached a description of records I am looking for (include project title and PI name)

[ ]  I and/or the individuals listed above will directly access PHI under preexisting EPIC authorization and do not require assistance by Health Information Management.

***I agree that the information I have requested will only be used for the research purpose as stated in this form and its accompanying documentation. I will protect the confidentiality and security of this information while it is in my possession and will destroy identifiers if required by accompanying documentation.***

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Signature of Principal Investigator\*

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Date

For HIM support, the completed form should be sent to Nanette Moreno, Systems Administrator, Health Information Management (nmoreno@stlukeshealth.org). No information can be released without IRB approval.

*\* Electronic or typed signatures are acceptable if form is sent from Principal Investigator’s email address.*