**IRB SUBMISSION FORM**

**Establishment of a Research Repository**

**Please ensure that all applicable materials listed below are submitted to the IRB office. The IRB will not put your research on an IRB meeting agenda until all applicable materials listed below are received. Forms are located on the Saint Luke’s IRB Website at:** <https://www.saintlukeshealthsystem.org/institutional-review-board>

**[ ]  Establishment of a Research Repository Form**

**[ ]  Repository Protocol*****detailing the repository policies and procedures for collection, storage, management, and***

 ***distribution of data/specimens.***

**[ ]  Proposed Informed Consent Document**

**[ ]  Proposed Parental Permission Document**

**[ ]  Proposed Assent Document**

**[ ]  Advertising and Recruitment Materials**

**[ ]  Scientific Merit Review form (Required for Investigator Initiated Studies)**

**[ ]  Data collection sheet**

**[ ]  DSMB or DMC charter or monitoring plan**

**[ ]  Nursing Research Council approval**

**[ ]  Informed Consent Waiver Request**

**[ ]  Informed Consent Documentation Waiver Request**

**[ ]  HIPAA Authorization Form or Waiver Request**

**[ ]  Surveys or other Instruments to be Used**

**[ ]  Signed Principal Investigator’s Agreement (located on the IRB website)**

**[ ]  Investigators’ CVs *(Please submit the most recent version of the CV at the time of initial submission for the Principal***

 ***Investigator and all Sub-Investigators)***

**[ ]  Proof of Completion of Required Training *(Please submit the certificate of completion for CITI training for each person***

 ***listed on the study)***

**IRB SUBMISSION FORM**

**Establishment of a Research Repository**

**Instructions:** *Submit this completed form to Saint Luke’s IRB Office when proposing the establishment of a research repository involving human specimens or data. This application must be accompanied by a* *repository protocol detailing the repository policies and procedures for collection, storage, management, and distribution of data/specimens.*

**NOTE:** Repository Investigators are responsible for ensuring that any necessary permissions and agreements (e.g., data use agreements, confidentiality agreements, materials transfer agreements) are in place when information or materials are shared or transferred outside of the holding organization.

|  |
| --- |
| **Protocol Title:**  |
| **Date:**  |

1. **PRINCIPAL INVESTIGATOR & RESEARCH TEAM**
2. Principal Investigator (PI)

|  |  |
| --- | --- |
| PI Name: | Department:  |
| Credentials (e.g., licenses, certifications):  |
| Address:  |
| Email:  | Phone Number:  |
|  |

1. Additional Personnel (insert additional rows if needed) **[ ]** NA

**NOTE:** *Other study personnel include all individuals with responsibilities related to the management or operations of the repository, including all personnel with access to identifiable specimens or data. All personnel must have current human subjects training certification.*

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Study Role(indicate if responsibilities include obtaining informed consent or not) | Department/Division/Unit (if applicable) | Email Address  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. How many protocols/studies is the PI currently responsible for?
2. Does the PI have protected or dedicated time available to supervise this repository?

**[ ]** Yes **[ ]** No

If No, explain how the PI will have adequate availability to supervise the repository:

1. Are any members of the research team or participating sites potentially under the jurisdiction of another IRB (check “yes” if UMKC or KUMC students, residents or fellows are listed as study personnel)?

**[ ]** Yes **[ ]** No

If Yes, please explain:

1. Has any member of the research team ever received a FDA 483, “Warning Letter”, Notice of Disqualification, or other warning or disciplinary action from an agency or licensing authority?

**[ ]** Yes **[ ]** No

If Yes, include a copy of the notice or report and related correspondence with your submission.

1. Has this repository protocol been disapproved or terminated by another IRB?

**[ ]** Yes **[ ]** No

If Yes, provide the basis for the disapproval or termination:

1. Please provide information concerning the funding sources for this repository.

**[ ]** NA (unfunded) **[ ]** Industry Sponsor

**[ ]**  Federal Government\* **[ ]** Other Government (State, Local)

**[ ]** Foundation **[ ]** Departmental/Unit Funds

**[ ]** Other:

Grantor/Sponsor Name:

Award/Contract Status:

Grant Title (if different from IRB submission title):

\*If Saint Luke’s Health System is the prime awardee of a federal grant that supports this repository, a copy of the grant must be included with your submission

1. Check all SLHS facilities where research repository activities will take place:

**[ ]** Saint Luke’s Hospital **[ ]** Saint Luke’s South Hospital

**[ ]** Saint Luke’s East Hospital **[ ]** SLCC/SLPS/SLMG physician practices

**[ ]** Saint Luke’s North Hospital **[ ]** SLCI Liberty

**[ ]** Other SLHS affiliated site **[ ]** Crittenton

**[ ]** Inpatient setting **[ ]** Outpatient setting

**[ ]** Non-SLHS affiliated site:

1. **ADDITIONAL REVIEWS/APPROVALS**
2. Has this protocol undergone Scientific Review? **[ ]** Yes **[ ]** No

If Yes, include a copy of the signed [scientific review evaluation](https://www.saintlukeshealthsystem.org/sites/default/files/files/Research/IRB%20Scientific%20Review%20Of%20Research%20Involving%20Human%20Subjects%20%28SYS-669%29.doc) form with your submission.

*Note: For all investigator initiated studies, it is Saint Luke’s policy that an individual who is not part of the study team must evaluate the scientific merit of the research before it is submitted to and reviewed by the IRB. Please submit the scientific review form to your department director to be completed before you submit to the IRB and include the completed form with your submission.*

1. Conflict of Interest

*Prior to IRB approval, all personnel listed on the study must complete a financial interest disclosure. This document will be reviewed to assess conflicts of interest. The questions below apply to this particular research. The questions below apply to all members of the study team.*

* 1. Do any members of the study team or their immediate family members have a financial interest in the sponsoring company? *(This includes honoraria, income, stock/stock options)*

**[ ]** Yes **[ ]** No

* 1. Do any members of the study team or their immediate family members have any consulting agreements, advisory positions or management responsibilities with the sponsoring company? *(this includes both paid and unpaid positions)*

**[ ]** Yes **[ ]** No

* 1. Do any members of the study team or their immediate family members receive gift funds, educational grants or any other remuneration from the sponsoring company?

**[ ]** Yes **[ ]** No

* 1. Do any members of the study team or their immediate family have any ownership or royalty interest in the intellectual property utilized in this study?

**[ ]** Yes **[ ]** No

* 1. Have any members of the study team or their immediate family been reimbursed by this company for travel?

**[ ]** Yes **[ ]** No

*If you answered yes to any of the questions above, Documentation of COI review and any conflict management plans must be provided to the IRB office prior to consideration of the submission.*

1. Is Radiation Safety review required? **[ ]** Yes **[ ]** No

If Yes, include documentation of the review and any requirements or recommendations with your submission.

1. Is Medicare Billing Analysis required? **[ ]** Yes **[ ]** No

If Yes, include documentation of the review with your submission.

1. **APPLICABLE REGULATIONS**

Select the regulations or oversight agencies that you believe are applicable to this repository protocol. This list is not all-inclusive (e.g., IATA isn’t included) but is intended to capture regulations or requirements relevant to the protection of human subjects that the IRB may have to consider. **Select all that apply**.

Regulatory oversight may be triggered by the following:

* Funding support
* Participation of agency employees in research activities as investigators or subjects
* By the use or study of regulated products or records
* By the subject population
* Other reasons

**[ ]** HHS ([Department of Health and Human Services](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html))

**[ ]** FDA ([Food and Drug Administration](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm))

**[ ]** HIPAA ([Health Insurance Portability and Accountability Act](http://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html))

**[ ]** CDC ([Centers for Disease Control](http://www.cdc.gov/od/science/integrity/hrpo/))

**[ ]** DOD ([Department of Defense](http://www.dtic.mil/biosys/hardte.html)); Branch:

**[ ]** DOE ([Department of Energy](http://humansubjects.energy.gov/regulations/))

**[ ]** DOJ ([Department of Justice](https://www.gpo.gov/fdsys/pkg/CFR-2003-title28-vol2/xml/CFR-2003-title28-vol2-part46.xml))

**[ ]** ED ([Department of Education](http://www2.ed.gov/about/offices/list/ocfo/humansub.html))

**[ ]** EPA ([Environmental Protection Agency](https://www.gpo.gov/fdsys/pkg/CFR-2010-title40-vol1/xml/CFR-2010-title40-vol1-part26.xml))

**[ ]** FERPA ([Family Educational Rights and Privacy Act](http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html))

**[ ]** ICH-GCP E6 ([International Conference on Harmonization – Good Clinical Practice E6](http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf))

**[ ]** NSF ([National Science Foundation](http://www.nsf.gov/bfa/dias/policy/human.jsp))

**[ ]** PPRA ([Protection of Pupil Rights Amendment](http://familypolicy.ed.gov/ppra?src=ferpa))

**[ ]** VA ([Department of Veterans Affairs](http://www1.va.gov/ORO/index.asp))

**[ ]** Other:

1. **REPOSITORY DESCRIPTION**
2. **Summary.** Briefly describe the proposed research repository in language that **can be understood by a non-scientist**. The abstract should summarize the objectives of the repository and how data/specimens will be used in the future. (**Maximum 250 words**)

1. **BENEFITS**
2. Describe the potential benefits to science and/or society which may occur as a result of this repository.

1. Are there any benefits which may accrue to the individual subjects in this repository? Compensation is not considered a benefit.

**[ ]** Yes **[ ]** No

If Yes, please explain:

1. **SUBJECT POPULATION**
2. The population of subjects whose data/specimens will be included in the repository includes the following (check all that apply):

**[ ]** Normal Adults/Healthy Volunteers

**[ ]** In-Patient Population

**[ ]** Out-Patient Population

**[ ]** Employees/Staff

**[ ]** Students of *(describe whose students)*

**[ ]** Residents/Fellows

**[ ]** Children

**[ ]** Prisoners

**[ ]** Pregnant Women, Fetuses, or Neonates

**[ ]** Adults with Impaired Decision-Making Capacity

**[ ]** Persons with [Limited English Proficiency](https://www.lep.gov/faqs/faqs.html#OneQ1), specify anticipated primary language(s):

1. Please indicate the total number of subjects whose data/specimens are expected to be included in the repository.*For the purposes of the IRB, a subject is enrolled once they have provided consent to participate, or for studies under waivers, once data/specimens have been collected on the subject.*

1. Provide the age range for the proposed subject population (e.g., 0-5 years old):
2. Specify the **inclusion and exclusion criteria** for subjects to be included in the repository or indicate the page(s) of the protocol where this information can be located.

1. If potential subjects will be excluded based on age, gender, race, ethnicity, national origin, primary language, pregnancy or childbearing potential, or disability, explain (a) the nature of the exclusion(s), and (b) the scientific basis or other justification for the exclusion(s) or indicate the page(s) of the protocol where this information can be located. **[ ]** NA

Nature of the exclusion(s):

Scientific basis or other justification:

1. **Secondary Subjects.** Is information being obtained about individuals other than the “target subjects” (e.g., family members)?

**[ ]** Yes **[ ]** No

If Yes, please explain:

1. **IDENTIFICATION/RECRUITMENT OF SUBJECTS**
2. Describe how subjects will be identified for recruitment into or inclusion in the repository.

1. Who will be responsible for determining whether potential subjects meet eligibility criteria and how will they do so? If the analysis of health information is necessary to determine eligibility, a medically-qualified person must be involved in the determination.

1. Will information from medical records, databases, or other data sources be used to identify and/or screen potential subjects prior to obtaining consent.

**[ ]** No, records will not be accessed prior to consent and authorization

**[ ]** No, records will not be utilized to identify potential subjects

**[ ]** Yes, records will be accessed prior to consent, complete the Request to Waive Informed Consent Form *(Note: If the records include PHI, also complete the Request to Waive HIPAA Authorization Form)*

If Yes, indicate whether screening information will be retained on persons who do not ultimately participate in the repository, and if so, what specific information will be retained and what identifiers, if any, it will include:

1. Will potential subjects be screened by asking questions of them prior to obtaining consent (e.g., phone interview, on-line questionnaire, etc.)?

**[ ]** Yes **[ ]** No

If Yes, answer the following and include a copy of the screening questions with your submission:

* 1. Describe the method of screening (e.g., phone interview, on-line questionnaire):

* 1. Indicate whether screening information will be retained on persons who do not ultimately participate in the repository, and if so, what specific information will be retained and what identifiers, if any, it will include:

1. If applicable, describe **how, where, and by whom** subjects will be recruited for participation in this repository. **[ ]** NA

1. If applicable, describe any steps that will be taken to protect potential subjects’ privacy during recruitment (e.g., bring to private room). **[ ]** NA

***NOTE:*** *Include copies of any proposed recruitment materials (e.g., brochures, posters, advertisements, social media, etc.) or scripts with your submission. All recruitment material must be approved by the IRB prior to use.*

1. **INFORMED CONSENT**

Unless waived by the IRB, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (LAR) or, for minors, parental permission.

Similarly, unless waived by the IRB, consent must be documented by the use of an IRB-approved written consent form signed by the subject or the subject's LAR. A copy of the consent form must be given to the person signing the form.

Assent may be required when subjects are unable to personally provide consent for reasons of age, mental state, legal status or other such reason.

1. Which of the following apply to this research repository?*(check all that apply)*

**[ ]** Informed consent will not be obtained. Submit a waiver of consent request.

**[ ]** Informed consent will be obtained and documented with a signed, written consent form.

**[ ]** Informed consent will be obtained, but won’t be documented by signature on a consent form. Submit a request for a waiver of documentation of consent. Include a copy of the oral script and/or information sheet with your submission.

**[ ]** Informed consent will be obtained, but the consent form (or script or information sheet) does not include all required elements of consent. (Please see the Informed Consent Checklist for the elements of consent.) Submit a request for an alteration of consent.

**[ ]** Surrogate consent will be obtained from Legally Authorized Representatives (LARs) for some or all adult subjects. Submit a request to include subjects with impaired decision-making capacity.

If the research includes more than one subject group, and the answers to the above differ based on the cohort, explain your plan for each group here:

1. **Consent Process**
	1. Describe the circumstances under which consent will be obtained including where the process will take place and any steps that will be taken to unsure the potential subject’s privacy.

* 1. Who will obtain consent? Describe their qualifications and experience in obtaining research consent.

*NOTE: If any of the persons obtaining consent are inexperienced, a plan to train and supervise them must be included.*

* 1. How will you ensure that subjects or Legally Authorized Representatives (LARs) have sufficient opportunity to consider whether to participate? *(Check all that apply)*

 **[ ]** Subjects will be provided the consent form to take home for consideration prior to signing.

 **[ ]** Subjects will be allowed a waiting period of at least  to consider their decision.

 **[ ]**  Other (describe):

* 1. How will the subjects’ or LARs’ understanding of the information presented be assessed? *(Check all that apply)*

 **[ ]** Subjects will be asked to “[Teach-Back](http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool5.html)”

 **[ ]** Subjects will be asked open-ended questions about the research (purpose, procedures, risks, alternatives, voluntary nature)

 **[ ]** A tool or post-test, such as ICEFT, DICCT, QuIC, or AHRQ Certification will be used.

 Specify:

 **[ ]** Other, describe:

* 1. Is recruitment/inclusion of subjects with [limited English proficiency](https://www.lep.gov/faqs/faqs.html#OneQ1) anticipated?

**[ ]** Yes **[ ]** No

If Yes, answer the following:

* + 1. What languages do you expect the subjects will be fluent in?

* + 1. How will you ensure that subjects understand the information provided to them and will be able to ask questions and communicate with the research team? (e.g., use of certified interpreters)

* + 1. Will consent forms and other subject materials be translated? *(Note: Cost alone is typically insufficient justification for not translating materials when recruitment of people with LEP is anticipated.)*

**[ ]** Yes

**[ ]** Some but not all, explain:

**[ ]** No, explain:

*NOTE: Once the English-version of the consent form and other materials are approved, translated documents and certificates of translation must be submitted to the IRB for approval prior to use.*

1. **Documentation of Consent:** *Signed, written consent forms are required unless waived by the IRB. Include copies of all proposed consent forms and materials to facilitate the consent process (handouts, videotapes, electronic tools, etc.) with your submission.*
	1. How will subjects’ informed consent be documented? *(check all that apply)*

**[ ]** NA, a waiver of consent or documentation of consent is being requested

**[ ]** Traditional signed written consent form

**[ ]**  Written note in medical and/or research record

**[ ]** By completion of a research survey or questionnaire

**[ ]** Consent will be administered via an electronic or web-based form

**[ ]** The consent process will be audio or video recorded

**[ ]** Use of the short form consent process *(The short form consent process should not be used when inclusion of subjects with LEP can be anticipated.)*

**[ ]** Other, describe:

* 1. If the enrollment of subjects who cannot read the consent form, due to visual impairment or other issues, is anticipated, how will consent be documented? Refer to [45 CFR 46.117(b)(2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117) or [21 CFR 50.27(b)(2)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.27) for information regarding the use of a short form.

**[ ]** NA

**[ ]** Short form *(Include copies of any proposed short forms with your submission)*

**[ ]** Other mechanism, describe:

1. **Ongoing Consent for continued use or collection of identifiable data/specimens**
	1. If this research involves children who may reach age of majority while their data/specimens are in the repository and available for distribution, explain your plans to obtain consent for ongoing participation. If you do not plan to obtain consent, please request a waiver of consent (and HIPAA authorization, if applicable) for these subjects.

**[ ]** NA because:

**[ ]** this repository does not include data/specimens from children

**[ ]** data/specimens from children will be destroyed prior age of majority

**[ ]** data/specimens from children will be de-identified by deleting all links between any individually identifiable data and the data/specimens.

* 1. If this research includes adults for whom consent was obtained from a legally authorized representative (LAR), and these adults may regain capacity to consent while their data/specimens are in the repository and available for distribution, explain your plans to obtain consent for ongoing participation. If you do not plan to obtain consent, please request a waiver of consent (and HIPAA authorization, if applicable) for these subjects.

**[ ]** NA – this repository does not include data/specimens from adults who did not originally provide consent themselves and may regain capacity to consent.

1. **PROTECTED HEALTH INFORMATION**

The Privacy Rule defines PHI as [individually identifiable](https://privacyruleandresearch.nih.gov/pr_08.asp#8a) health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium (including the individually identifiable health information of non-U.S. citizens). This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse. For purposes of the Privacy Rule, genetic information is considered health information. Generally, when specimens are labeled or associated with HIPAA identifiers, the specimens are considered identifiable under HIPAA.

1. Will **Protected Health Information** (PHI) be **[ ]**  accessed, **[ ]**  used, or **[ ]**  disclosed for or by the repository?

**[ ]** Yes **[ ]** No

If Yes, explain:

Indicate which of the following apply *(more than one may be selected*):

**[ ]** A partial waiver of the requirement for HIPAA Authorization is requested (e.g., for screening or for some subjects (e.g., retrospective cohort))

**[ ]** A full waiver of the requirement for HIPAA Authorization is requested

**[ ]** The PHI accessed or used for this research is a [Limited Data Set](https://privacyruleandresearch.nih.gov/pr_08.asp#8d) (LDS) and a Data Use Agreement (DUA) is or will be in place prior to accessing or obtaining the LDS.

**[ ]** HIPAA Authorization will be obtained

1. **OTHER PROTECTED/SENSITIVE RECORDS**
2. Will repository data include information that subjects or others might reasonably consider to be sensitive in nature (e.g., social security numbers, genetic test results, communicable disease status, substance abuse, mental health information, illegal behaviors, etc.)?

**[ ]** Yes **[ ]** No

If Yes, explain what sensitive information is included, why it is needed, and any additional safeguards that will be taken to protect it (beyond those described in “XI. Data/Specimens”)

1. Will repository data or permitted specimen use include or generate genomic or phenotypic data?

**[ ]** Yes **[ ]** No

If Yes, explain whether the data will or may be subject to the [NIH Genomic Data Sharing (GDS) policy](https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/), including consent requirements:

1. Will a [Certificate of Confidentiality](https://grants.nih.gov/grants/policy/coc/index.htm) (CoC) be obtained?

**[ ]** Yes **[ ]** No

1. **DATA/SPECIMENS**

**NOTE: If the requested information for any open-ended question in this section is fully addressed in the protocol, it is acceptable to respond with the page numbers where the information may be found.**

1. Describe the data/specimens that will be included in the repository and the general purpose (e.g., medical record data regarding oncology care, including relevant history, diagnosis, physical exams, procedure results, laboratory results, and outcome data will be included in the repository for future oncologic research including health care delivery, comparative effectiveness, …):

1. Describe the sources of the data/specimens, including whether the data/specimens are generated as a result of another primary activity (e.g., medical care, other research protocol(s), etc.) or specifically for this repository (e.g., from questionnaires or interviews with subjects, from exams or procedures performed to obtain data/specimens, etc.):

*Note: If subjects will be interviewed, complete questionnaires, diaries, or otherwise directly provide data for the repository, copies of all such materials must be included with your submission and the provisions to protect the privacy of subjects while providing data must be described in the protocol (e.g., confirmation of identity for phone interviews). If the data provided directly by subjects includes data that could be indicative of severe depression or suicidal ideation, plans for timely evaluation of such data and referral for support or evaluation must be included in the protocol.*

1. Are all of the data/specimen sources internally held?

**[ ]** Yes **[ ]** No

If No, describe the external sources, any needed permissions to access the data/specimens and the status of these permissions.

*Note: If data/specimens may be obtained from international sources, please contact the Compliance Office for information on export control and other laws that may impact data/specimen sharing.*

1. **Data/Specimen Input**
	1. Describe the procedures for receipt or input of data/specimens into the repository, including provisions to protect confidentiality:

* 1. Will the data/specimens accessed, obtained, or received by the repository be identifiable or will it be coded or de-identified?

**[ ]** Identifiable (includes direct identifiers or information such that subject identities could be ascertained)

**[ ]** Coded (direct identifiers are replaced by a unique code)

**[ ]** De-identified (all identifying elements have been removed or replaced, including dates, and the remaining information cannot readily be used to re-identify subjects)

**[ ]** Combination of the above, explain:

* 1. If the data/specimens that are accessed, obtained, or received by the repository are coded, answer the following:
		1. Describe the structure of the code (e.g., randomly generated number, sequential number plus initials, etc.):
		2. Will the repository PI or any repository personnel have access to the code or any other means to re-identify subjects? **[ ]** NA

**[ ]** Yes **[ ]** No **[ ]** Sometimes, explain:

* 1. If the data/specimens are provided by external sources, describe how consent and HIPAA authorization, if applicable, will be verified including whether the repository will receive copies of the forms:

*Note: Any consent forms and authorizations to be used by outside sources must be submitted to the Saint Luke’s IRB.*

1. **Data/Specimen Maintenance**
	1. Describe the types of records/specimens that will be maintained in the repository (e.g., frozen samples, paper worksheets, electronic files, audio recordings, video recordings, etc.):

* 1. Will the data/specimens maintained or stored by the repository be identifiable or will it be coded or de-identified?

**[ ]** Identifiable (includes direct identifiers or information such that subject identities could be ascertained)

**[ ]** Coded (direct identifiers are replaced by a unique code)

**[ ]** De-identified (all identifying elements have been removed or replaced and the remaining information cannot readily be used to re-identify subjects)

**[ ]** Combination of the above, explain:

* 1. If the data/specimens that are maintained or stored by the repository is coded, answer the following:
		1. Describe the structure of the code (e.g., randomly generated number, sequential number plus initials, etc.):
		2. Will the repository PI or any repository personnel hold or have access to the code or any other means to re-identify subjects? **[ ]** NA

**[ ]** Yes **[ ]** No **[ ]** Sometimes, explain:

* + 1. Describe where data/specimens will be held, who will have access, and the provisions to protect confidentiality:

* 1. If consent forms and/or HIPAA authorizations will be maintained, describe where they will be held, who will have access, and the provisions to protect confidentiality:

* 1. Describe how long data/specimens will be retained in the repository and available for research, include the process for destruction or de-identification of identifiable or coded data/specimens at the end of the retention period (as applicable):

1. **Data/Specimen Distribution**
	1. Describe the ‘rules’ and procedures for use of repository data/specimens for research, including:
		1. Who may request or use data/specimens from the repository for research and any restrictions (e.g., Saint Luke’s investigators only):

* + 1. Any restrictions on the types of research or testing that may be performed using data/specimens from the repository (e.g., cardiovascular research only, no whole genomic sequencing)

* + 1. The process to verify that the proposed research, and any proposed uses of data/specimens, are consistent with the IRB-approval for the repository:

* + 1. The process to verify that the proposed research has been IRB-approved or determined exempt or “not human subjects research”:

* + 1. The process to verify consent and authorization or waiver of the requirements, as applicable:

* + 1. Describe how repository data/specimens will be distributed to recipient investigators and the provisions to protect confidentiality:

* + 1. Describe the procedures for maintaining a central inventory of data/specimens and how releases will be tracked/logged:

* + 1. Explain how the repository will receive assurances that data/specimens will be used/managed in accordance with repository requirements, including any restrictions on re-identification (e.g., terms of use, data use agreement, confidentiality agreement, materials transfer agreement):

* 1. Will the data/specimens distributed by the repository be identifiable or will it be coded or de-identified?

**[ ]** Identifiable (includes direct identifiers or information such that subject identities could be ascertained)

**[ ]** Coded (direct identifiers are replaced by a unique code)

**[ ]** De-identified (all identifying elements have been removed or replaced, including dates, and the remaining information cannot readily be used to re-identify subjects)

**[ ]** Combination of the above or determined on a per-protocol basis, explain:

* 1. If the data/specimens that are distributed by the repository is coded, answer the following:

**[ ]** NA

* + 1. Describe the structure of the code (e.g., randomly generated number, sequential number plus initials, etc.):
		2. Will the recipient investigators hold or have access to the code or any other means to re-identify subjects?

**[ ]** Yes **[ ]** No **[ ]** Sometimes, explain:

1. **SUBJECT WITHDRAWAL**
2. If data/specimens maintained in the repository are identifiable, or coded and the repository operators hold or can access the code or otherwise re-identify subjects, explain the process for subjects to withdraw consent and request destruction of their data/specimens and any limitations on their ability to do so (e.g., when data/specimens have already been distributed). This information must be included in the consent form. **[ ]** NA

1. **PROVISION OF RESULTS**
2. Given the scope of research that data/specimens may be used for, describe the likelihood and nature of [incidental or secondary findings](http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf) and any repository rules regarding sharing such findings with subjects:

1. If the scope of research that specimens may be used for includes genetic testing, indicate any repository rules regarding sharing such findings with subjects:

**[ ]** NA – the repository does not include specimens or genetic testing will not be permitted

1. If the scope of research that specimens may be used for includes testing for communicable diseases, indicate any repository rules regarding sharing such findings with subjects and provisions for when findings must be reported to a state or federal agency:

**[ ]** NA – the repository does not include specimens or testing for communicable diseases will not be permitted

1. **COSTS [ ]** NA – No costs to subjects (Skip ahead to XV)
2. Describe the costs/potential costs that subjects may incur as a result of their participation (include travel, parking, etc.).

1. Will the subject, or the subject’s insurance, be responsible for any costs incurred as a result of participation?

**[ ]** Yes **[ ]** No

If Yes, describe each item that the subject, or the subject’s insurance, will be responsible for and the approximate cost of each:

1. Will subjects be reimbursed for any expenses related to their research participation?

**[ ]** Yes **[ ]** No

If Yes, indicate:

* 1. What subjects will or may be reimbursed for (e.g., travel, parking, public transportation, etc.) and explain any potential limitations or qualifiers:
	2. The type of reimbursement *(i.e., cash, check, cash card, etc.)*:
	3. The source(s) of funds to provide reimbursement:
	4. The timing of reimbursements
1. **COMPENSATION [ ]** NA – No compensation (Skip ahead to XVI)
2. If subjects will receive compensation for participating in this research, please describe*:*
	1. The amount and method of payment:
	2. The basis used to determine the amount of the payment:
	3. The distribution plan for the payment (one payment, pro-rated payment, etc.):
	4. The plan for payments in the event a subject withdraws before completing all visits, questionnaires, etc.:
3. If the repository includes data/specimens from children or adults unable to consent to participation, explain who will receive the compensation:

1. **NON-MONETARY GIFTS/TOKEN OF APPRECIATION [ ]** NA (Skip ahead)
2. If subjects will receive non-monetary gifts, incentives, or tokens of appreciation for participating in this research, please describe*:*
	1. The item(s)\* that will be provided:
	2. The approximate retail value of the item(s):
	3. The distribution plan (i.e., when subjects will receive the items):
	4. Any conditions or requirements that must be fulfilled for subjects to receive the item(s):

*\*Include a picture of the item(s) with your submission. The IRB may request a sample of the item(s) to review.*

1. If the research involves children or adults unable to consent to participation, explain who will receive the item(s):

**REQUIRED SIGNATURES**

Will any residents, fellows or students be involved in the research proposed in this application?

**[ ]** Yes **[ ]** No

If yes, you must obtain the signature of the Director of Medical Education. Please list the names of those individuals and whether they are residents, fellows or students.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Director of Medical Education Signature Date

**PRINCIPAL INVESTIGATOR CERTIFICATION**

By signing below, I certify that the information contained in this application, the protocol, and any associated materials accurately reflects how the research will be conducted. Any proposed changes to the research will be submitted for IRB review and approval prior to implementation (unless necessary to eliminate an apparent immediate risk of harm, in which case the issue and action taken will be reported to the IRB promptly).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department Director Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Department Director Signature Date