**Study Number:**

**Study Title:**

**PI’s Name:**

Please note that protocol **sections with an asterisk (\*)should always be included in the protocol;** if the section does not have an asterisk, and you have not included the section in the protocol, the IRB will consider it your attestation that the section does not apply to your study.

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| --- | --- |
| **Protocol Section** | **Added to the protocol?** |
| **External Collaborators**- if applicable, add each external collaborator information and indicate whether that institution’s IRB will review (or has already reviewed) that individual’s engagement in human participants research activities)  | [ ]  **Yes** |
| **Funding Source*\****: Include the information for the funding entity for this study. Please explain if this study is covered by a sub-award or other pertinent information. Say “department” if you do not have any other funding. | [ ]  **Yes** |
| **Background*\**:** Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data. Provide the scientific or scholarly background for, the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. | [ ]  **Yes** |
| **Objectives*\**:** State the specific details surrounding the objectives in creating your registry/repository/ database; broad objectives are acceptable – try to predict all possible future uses. For example:• “This protocol aims to develop a biobank of lung tissue to be used in future research on biomarkers for patients with cystic fibrosis and other complications caused by this diseaseInformation here should align with language in the consent form, if applicable.Objectives should not include specific research aims and analyses. Studies using data or biospecimens collected from this protocol will require a separate IRB submission.  | [ ]  **Yes** |
| **Project Design\*:** Describe and explain the study design in more detail. Describe all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or to minimize risks. Source of data (be specific). How will the data for the registry/repository/database be obtained? Will it be obtained by direct interaction with participants from a clinical or hospital site, via chart review or Clinical Data Warehouse (CDW) query of data? Be sure to note if the biospecimen includes any vulnerable populations (pregnant women, minors, or prisoners)* If data obtained from chart review or CDW, include date range (in MM/DD/YYYY-MM/DD/YYYY format) from which chart data will be reviewed, if applicable.
	+ Inclusion criteria, including age range
	+ Exclusion Criteria
	+ Please do not include the estimated number of charts to be reviewed (to avoid unnecessary violations of HIPAA via reviewing too many charts); though the estimated minimum number of charts may be included in the Data Analysis section below.
* Source of biospecimens: If biospecimens are collected from direct interaction with participants or from another existing clinical archive and whether any initial analysis is completed as part of the repository:
	+ Detail any assays/analyses being done as part of the repository, independent of specific research aims.
	+ Explain whether there will or will not be any variability to the analyses or types of biospecimens collected based on the specific needs of downstream researchers.
	+ If your study involves blood draws, describe the following:
		- Quantity of blood collected
		- Notes: For your study to be considered for expedited review, the quantity of blood drawn is limited as follows:
			* “(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550mL in an 8-week period and collection may not occur more frequently than 2 times per week; or
			* “(b) from other adults and children [2], considering age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50mL or 3mL per kg in an 8-week period and collection may not occur more frequently than 2 times per week.”
		- Biospecimen storage details
		- Biospecimen collection setting/transportation details/qualifications of phlebotomist.
	+ Collection of Follow-up Data and or specimens:
		- Describe the purpose and how you intend to collect follow-up data from your participants including but not limited to:
			* Data from routine, the standard of care visits
			* Additional blood draws for project purposes only
			* Follow-up phone calls/questionnaires
 | [ ]  **Yes** |
| **Vulnerable Populations:** If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.If the research involves pregnant women, human fetuses, or neonates of uncertain viability or non-viable neonates review the “[Pregnant Women, Fetuses, and Neonates Checklist”](http://irb.emory.edu/documents/Emory%20Subpart%20B%20Worksheet.doc) to ensure that you have provided enough information.If the research involves prisoners, review the “[Prisoner Subjects Checklist”](http://irb.emory.edu/documents/Emory%20Subpart%20C%20Worksheet.doc) to ensure that you have provided enough information.If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the “[Minor/Children Subjects Checklist](http://irb.emory.edu/documents/Emory%20Subpart%20D%20Worksheet.doc)” to ensure that you have provided enough information.If the research involves cognitively impaired adults, review the “[Cognitively Impaired Checklist”](http://irb.emory.edu/documents/CHECKLIST-Cognitively_Impaired_Adults.docx) to ensure that you have provided enough information. | [ ]  **Yes** |
| **Recruitment Methods\*:**Describe when, where, and how potential participants will be recruited, who will make initial contact and how, and if physicians or staff refer participants.Describe the source of participants.Describe the methods that will be used to identify potential participants.Describe materials that will be used to recruit participants. (Attach copies of these documents in Smartform on the “Study-Related Documents” page under “Recruitment material templates.” with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/videotape. You may submit the wording of the advertisement before taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/videotape.)How will eligibility be determined? Provide a detailed description of any eligibility screening done before enrolling the subject (including whether any identifiers will be recorded – note that IP address is an identifier)If recruiting online, describe how potential participants would be directed to your recruitment information and study description. | [ ]  **Yes** |
| **Provisions to Monitor the Data to Ensure the Safety of Participants\*:** Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe.  | [ ]  **Yes** |
| **Data/Biospecimens Management\*:** Describe the data/biospecimens management plan. Describe the steps that will be taken to secure the data and specimens (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. Describe any procedures that will be used for the quality control of collected data.Describe how data/biospecimens will be handled study-wide:* What information will be included in the data/biospecimens?
* Where and how will the data/biospecimens be stored?
* How long will the data/biospecimens be stored?
* Who, in general, will have access to the data/biospecimens?
* Who is responsible for receipt or transmission of the data/biospecimens?
* How will data/biospecimens be transported?
* Explain what would take place if a participant declines participation. For example: “If a participant declines to participate in all portions of the study, the participant will not be assigned a study ID number and the study coordinators/data collects will refrain from collecting any data on the participant. If the participant agrees to participate in some portions of the study by not others, the participant will be assigned a study ID number and the study coordinators/data collectors will be instructed to collect data only on those aspects of the study to which the participant has agreed to participate. These procedures will help prevent unauthorized inclusion of the patient’s data in the database.”
 | [ ]  **Yes** |
| **Informed consent\*:** In general, informed consent cannot be waived for these protocols. Indicate whether you will be obtaining informed consent and if so, describe:* Where will the consent process take place?
* Will there be any waiting period between informing the prospective participant and obtaining the consent?
* Will there be a process to ensure ongoing consent?
* Please describe:
	+ The role of the individuals listed in the application as being involved in the consent process.
	+ The time that will be devoted to the consent discussion.
	+ Steps that will be taken to minimize the possibility of coercion or undue influence.
	+ Steps that will be taken to ensure the participants’ understanding.

Note: If you are planning to obtain consent via electronic signature, please review [this document](http://www.irb.emory.edu/documents/guidance-eICF_use.pdf). Additional guidance on consent documentation and process can be found at <http://www.irb.emory.edu/forms/consent_toolkit/guidance.html> Indicate whether you will be obtaining consent and if so describe:* Where will the consent process take place?
* Any waiting period available between informing the prospective subject and obtaining the consent.
* Any process to ensure ongoing consent.
* Please describe:
* The role of the individuals listed in the application as being involved in the consent process.
* The time that will be devoted to the consent discussion.
* Steps that will be taken to minimize the possibility of coercion or undue influence.
* Steps that will be taken to ensure the participants’ understanding.

Note: If you are planning to obtain consent via electronic signature, please review [this document](http://www.irb.emory.edu/documents/guidance-eICF_use.pdf). Additional guidance on consent documentation and process can be found on our website, under the [consent toolkit](http://www.irb.emory.edu/forms/consent_toolkit/guidance.html).  | [ ]  **Yes** |
| **Research with non-English speaking participants*** Indicate what language(s) other than English are understood by prospective participants or representatives.
* If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent.
* If you checked N/A, please provide reasoning of why subjects with limited English proficiency are excluded.

Note: if you stated that subjects with LEP will be enrolled, you are approved for the use of the Emory IRB short forms. Please read the guidance about the use of short forms here. | [ ]  **Yes** |
| **Research involving children:** review [this checklist](http://irb.emory.edu/documents/Emory%20Subpart%20D%20Worksheet.doc) to verify you have provided enough information to ensure the safety and well-being of this population. | [ ]  **Yes** |
| **Research involving cognitively impaired adults:** review [this checklist](http://irb.emory.edu/documents/CHECKLIST-Cognitively_Impaired_Adults.docx) to verify you have provided enough information to ensure the safety and well-being of this population. | [ ]  **Yes** |
| **Adults unable to consent*** List the individuals from whom permission will be obtained in the order of priority. (E.g., durable power of attorney for health care, a court-appointed guardian for health care decisions, spouse, and adult child.)
* For research conducted in the state, review Chapter 46 LEGALLY AUTHORIZED REPRESENTATIVES AND SURROGATE CONSENT to be aware of which individuals in the state meet the definition of “legally authorized representative.”
* For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research.

Describe the process for the assent of the participants. Indicate whether:* Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to provide assent and which will not.
* If assent will not be obtained from some or all participants, an explanation of why not.
* Describe whether the assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents.
 | [ ]  **Yes** |
| **Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception):** * Review the [Emory IRB waiver document](http://www.irb.emory.edu/documents/Combined_Waiver_Consent_HIPAA_Elements.docx) to ensure you have provided sufficient information for the IRB to make these determinations.
* If the research involves a waiver of the consent process for planned emergency research, please review the Emory P&Ps, Chapter 48, WAIVERS OF, AND EXCEPTIONS FROM, INFORMED CONSENT FOR PLANNED EMERGENCY RESEARCH to ensure you have provided sufficient information for the IRB to make these determinations.
 | [ ]  **Yes** |
| **HIPAA\*:** Will you be recording identifiers from charts? A list of HIPAA identifiers can be found here. If you are recording identifiers from subjects who are still living, and it is not practicable to obtain their HIPAA authorization for your study, you will need to request a HIPAA waiver. Please address how your request meets the following criteria:* The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
* An adequate plan to protect the identifiers from improper use and disclosure;
* An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
* Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by this subpart.
* The research could not practicably be conducted without the waiver or alteration.
* The research could not practicably be conducted without access to and use of the protected health information.
 | [ ]  **Yes** |
| **Risk to Participants\*:** * Do not state that there are no risks.
* List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related to the participant's participation in the project.
* Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks.
* Consider physical, psychological, social, legal, and economic risks. Include risks of loss of privacy or breach of confidentiality.
* If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable.
* If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
* If applicable, describe risks to others who are not participants.
 | [ ]  **Yes** |
| **Benefits to Future subjects or science:** * Describe the potential benefits that individual participants may experience
* Indicate if there is no direct benefit.
* Do not include benefits to society or others.
* Describe areas of knowledge that would be strengthened.
* Do not include compensation as a benefit.
 | [ ]  **Yes** |
| **Compensation to Participants\*: If data and biospecimen biospecimens will not be obtained via direct interaction with human participants, delete this section.*** Describe participant compensation if applicable.
* Describe if/how subjects will be compensated for participation in this study.
	+ Indicate what method compensation will be delivered (e.g. cash, gift card, school credit).
	+ Describe the amount and timing of any payments to participants.
	+ Describe if tax information is required. (if so, must be reflected in the informed consent form).
	+ Describe if payments will be pro-rated if a participant withdraws early.
* If using contests or raffles as an incentive, you must offer entry to all potential participants, not just those who enroll in the study/complete study-related procedures, per Georgia State Law
 | [ ]  **Yes** |
| **Confidentiality\*:** Include a statement reflecting compliance with Emory’s Data Security Policy. All sensitive data and data that contains HIPAA identifiers, when electronic, must be stored on a hard drive, disk, or thumb drive that is encrypted – not solely password-protected or kept in a locked office. Plan to protect the privacy of subjects and confidentiality of data and/or specimens. The plan needs to answer the following questions: * What identifiers will be kept with the data?
* If codes, where will the key linking the codes to identifiers be kept? Will other parties help create and/or host the database? How will data be securely stored?
* Will other parties help with statistical analysis, and if so, will identifiers be removed first?
* What are plans for protecting the data or disposing of it once the study is completed?
 | [ ]  **Yes** |
| **Incidental Findings\*:** * Review this [useful primer](https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/Researcher%20Primer%20Incidental%20Findings%2010.30.16.pdf) for researchers about incidental findings.
* Based on the nature of the research expected to be done with the data/specimens, determine if any expected or incidental findings should ever be shared with participants.
* Keep in mind that when a registry/repository will be used broadly for many types of future research, it will be hard to predict what kinds of findings might result.
* Return of results should be based on at least the following factors:
	+ Whether data/specimens will be shared with any identifiers (if not, including no study ID, then sharing results will be impossible)
	+ Whether findings could be medically actionable
	+ Whether findings can be reproducible via CLIA lab tests
* Include information about how findings will be shared in the informed consent form, if applicable.
 | [ ]  **Yes** |
| **Withdrawal of Participants\*:** Describe anticipated circumstances under which participants will be withdrawn from the research without their consent. Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection. | [ ]  **Yes** |
| **Potential Recontact for Future Study Enrollment\*:** State whether you will ask participants if they consent to be re-contacted for future research studies for which they might be eligible; should align with the informed consent form. | [ ]  **Yes** |
| **Access to Registry/Repository/Database\*:** This section should explain who will be given access to biospecimens and/or data and how.* Describe who may be granted use of data/biospecimens (e.g. within the institution, outside of the institution).
* IRB Approval Documentation, if recipient researchers will be given data/biospecimens with any HIPAA identifiers attached
* Describe how identifiers will be handled.
* Research team members who will evaluate requests for use of data/biospecimens. For example:
	+ “The information in the database will be shared with Emory and non-Emory investigators to help them study [Insert aims of registry/database]. These studies will require authorization by the Principal Investigator. Any approved study run by an investigator at any institution must be approved by an Institutional Review Board. Studies that might be approved to use the information in the database will be those…The research investigators involved in this study and in future studies and any other individual who may have access to the biospecimens and/or data, and its derivatives, are not authorized to and are forever prohibited from using this material for any attempt at cloning a human being. Information that may be released to researchers may include but is not limited to [Insert potential info]. Identifiers, like names, addresses, and social security numbers will not be released, except if patients need to be contacted again for specific purposes in new studies. All efforts will be made to keep true identities confidential.”
	+ “Access to this database will be restricted by a database manager and will be password protected. The only individuals who will be able to see patient identifiers like name, address, and social security number will be the Principal Investigator, research coordinators, recruiters, and database managers. Other investigators will have different passwords that will provide restricted access to the database. Those with restricted access will be able to query the database for scientific information/variables but will not be able to view information on patient identifiers such as name, address, and social security number. If investigators with restricted access want to conduct studies that require them to obtain patient identifiers so that patients can be contacted for follow-up information/follow-up visits, these investigators will have to submit a separate protocol to IRB to get permission to obtain patient identifiers and contact patients.”
 | [ ]  **Yes** |
| **Future Studies\*:** When this study is approved, approval will not extend beyond the creation of the database. If any identifiers will be provided to other researchers, those studies will need a separate IRB approval. If the data/biospecimens are provided to others [without any HIPAA identifiers](http://irb.emory.edu/documents/phi_identifiers.pdf), or without codes that the recipients could use to link identifiers, an IRB approval will not be needed | [ ]  **Yes** |