DELETE All INSTRUCTIONS AND COMMENTS

Read these instructions carefully before starting

As you are finishing this document, **remove these instructions**, delete all the template language (in dark orange) so that they are not contained in the final version of your protocol.

Delete sections that do not apply to your study. **If removing sections of this protocol**, update the table of contents by right-clicking on it and selecting “update field”.

* **What template should I use?**
	+ This template is for research studies involving the use of data or biospecimens that have been already collected.
	+ For studies involving solely a review of medical charts, please see the “[Retrospective Chart Review Protocol](http://irb.emory.edu/forms/Study%20Submission.html)” template instead.
	+ If unsure whether IRB review is required for your project, please start by [using our website tool](http://irb.emory.edu/forms/review/index.html) under “Does My Project Need IRB Review?”
	+ For studies involving interviews, surveys, focus groups, or behavioral interventions, please use the [Sociobehavioral](http://irb.emory.edu/forms/Study%20Submission.html) template instead.
	+ For studies involving secondary data analysis only, please use the “[Secondary Analysis Protocol](http://irb.emory.edu/forms/Study%20Submission.html)**”** templateinstead**.**
* **You must complete below** the [Secondary Data/Biospecimen Analyst Checklist](#_Protocol_Checklist) to  with your protocol, to attest that you have considered all the required sections in this template.
* Grant applications normally **may** **not** be submitted to the IRB instead of a protocol document
* When you write this document, keep an electronic copy. You will need to modify this copy when making changes. You should **upload** the modified copy of your protocol instead of **adding a new version**.

**PROTOCOL TITLE**: Include the full protocol title. (Add your text)

**EXTERNAL (NON-EMORY) COLLABORATORS**

Name, Title(s), Institution, and Department of External Collaborators

(For each entry, please indicate whether that institution’s IRB will review (or has already reviewed) that individual’s engagement in human participants research activities)

(Add your text)

**PRINCIPAL INVESTIGATOR:**

Name (Add your text)

Department (Add your text)

Telephone Number (Add your text)

Email Address (Add your text)

**VERSION**: **ADD** (Add your text)

**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. (Add your text)

**REVISION HISTORY**

No need to review this section if this is the first version of the protocol you are submitting to the IRB

|  |  |  |
| --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Table of Contents

[1. Study Summary 5](#_Toc125722817)

[2. Objectives 5](#_Toc125722818)

[3. Background 5](#_Toc125722819)

[4. Study Design 6](#_Toc125722820)

[5. Procedures 7](#_Toc125722821)

[6. Data Analysis 7](#_Toc125722822)

[7. Population 7](#_Toc125722823)

[8. Informed Consent 8](#_Toc125722824)

[9. HIPAA 9](#_Toc125722825)

[10. Risk to Participation 9](#_Toc125722826)

[11. Benefits to future subjects 9](#_Toc125722827)

[12. Confidentiality 9](#_Toc125722828)

[13. References 10](#_Toc125722829)

[14. Protocol Checklist 10](#_Toc125722830)

# Study Summary

|  |  |
| --- | --- |
| **Study Title** |  |
| **Study Design** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Research Intervention(s)/Interactions** |  |
| **Study Population** |  |
| **Sample Size** |  |
| **Study Duration for individual participants** |  |
| **Study Specific Abbreviations/ Definitions**  |  |
| **Funding Source (if any)** |  |

# Objectives

Describe the purpose, specific aims, or objectives and state the hypotheses to be tested.

The following must be addressed when study involves developing/evaluating an algorithm/clinical decision tool/artificial intelligence/machine learning tool(s)):

* Whether data will or may be submitted to FDA
* Whether there is a plan to test the model clinically (i.e., providing any output to healthcare provider(s) or patients at this stage) in the current submission. If there are no plans to test the model clinically in this protocol, note that a new IRB submission will be required if it will be tested clinically in the future.
* Whether the Algorithm/Product/Software is intended to become proprietary, and can/will it be commercialized outside of Emory?

(Add your text)

# 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. What is ultimate intended purpose and audience(s) for the results of the study?

(Add your text)

# Study Design

Sample: provide some information about the data set that the research team will be analyzing.

The following questions should be answered:

* The source of the data: from whom? From where? Who “owns” it?
	+ If data is obtained via a third party organization (e.g. via a web portal), provide the forms/application that must be submitted to access the data (or a link thereto) and any assurances you are asked to provide (e.g. a data use agreement).
	+ Is a person outside Emory going to be collaborating on this study in any way? Is their IRB going to review their study participation? List external collaborators on the first page of this protocol including whether external collaborators are seeking IRB approval from Emory IRB or their own IRBs. If there are any external collaborators seeking approval from Emory IRB, please reach out to the reliance team at irb.reliance@emory.edu. Please see our [collaborative page](https://www.irb.emory.edu/guidance/research-types/collaborative.html) for more information.

Are there any identifiers associated with the data or specimens? A list can be found [here](http://www.irb.emory.edu/documents/phi_identifiers.pdf).

If the data/specimens have identifiers associated with them now, but all of the above identifiers will be removed prior to starting your analysis: who did or will de-identify the data or specimens?

Are the data or specimens linked to an individual by a code number? If yes, will anyone on the research team have access to the key linking the study ID to individuals?

Why were the data or specimens originally collected? Were they collected as part of clinical care? If for a research study, provide Emory IRB number(s) if applicable, and the informed consent/HIPAA authorizations signed by the subjects (so that the IRB can determine if the new proposed use of the data/specimens is within the scope of the original consent/authorization - required)

Inclusion and Exclusion criteria for data/biospecimen collection.

(Add your text)

# Procedures

What will you do with the data/specimens?

Are there plans to store any data/specimens long-term? For what purpose? (May require a repository-specific IRB submission)

Detail whether any of the following are brought to an Emory research laboratory for further experimentation: microorganisms or infectious materials; nanomaterials; genetically modified primary cells or cell lines; genetically modified live or live-attenuated microbes (e.g., bacteria, fungi, virus, etc.); arthropods; plant products; toxins; environmental samples; human cells, cell lines, stool samples, or other human source materials; and human blood, blood products or tissue. (Note: If yes, then EHSO Biosafety ancillary review is required.)

(Add your text)

# Data Analysis

Describe the data analysis plan, including any statistical procedures or power analysis.

Describe the steps that will be taken to secure the data or 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 quality control of collected data.

Describe how data or specimens will be handled study-wide:

* What information will be included in that data or associated with the specimens?
* Where and how data or specimens will be stored?
* How long the data or specimens will be stored?
* Who will have access to the data or specimens?
* Who is responsible for receipt or transmission of the data or specimens?
* How data or specimens will be transported?

(Add your text)

# Population

Indicate specifically whether you will include or exclude any of the following special populations: (You may not include members of these populations as participants in your research unless you include them in the description of your subject population.)

* Adults unable to consent
* Individuals who are not yet adults (infants, children, teenagers)
* Pregnant women
* Prisoners
* Cognitively impaired or Individuals with Impaired Decision-Making Capacity
* Individuals who are not able to clearly understand English(If you indicated you will exclude, please provide reasoning.)

Community Participation (if applicable)

For studies aimed at addressing issues that affect a certain community or group, how, if at all, will this study involve people from the target community in the design of the study? Conduct of the study? How will the results of the research be shared with the participants and/or the target community(ies)?

If your research questions involve race and/or ethnicity, please clarify the following:

(1) Describe the definition you are using for “Race” and/or “Ethnicity” in this study (examples here (link to [JAMA](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fjamanetwork.com%2Fjournals%2Fjama%2Ffullarticle%2F2776936&data=04%7C01%7Crebecca.rousselle%40emory.edu%7C98fd1abfb9004c48e8fb08d9a583cf9f%7Ce004fb9cb0a4424fbcd0322606d5df38%7C0%7C0%7C637722807820672228%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=lEegCWT0%2Byid8HZ%2FBk%2FuP1rTaABQlAiGQW%2FIyoKBawU%3D&reserved=0), [JHM](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.journalofhospitalmedicine.com%2Fjhospmed%2Farticle%2F235223%2Fhospital-medicine%2Fnew-author-guidelines-addressing-race-and-racism-journal&data=04%7C01%7Crebecca.rousselle%40emory.edu%7C98fd1abfb9004c48e8fb08d9a583cf9f%7Ce004fb9cb0a4424fbcd0322606d5df38%7C0%7C0%7C637722807820682221%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=aCTdniEe5lj%2F8cHWWhNKweykajcbqk7kUYjxZi4wf2s%3D&reserved=0), [AHA](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ahajournals.org%2Fdisparities-research-guidelines&data=04%7C01%7Crebecca.rousselle%40emory.edu%7C98fd1abfb9004c48e8fb08d9a583cf9f%7Ce004fb9cb0a4424fbcd0322606d5df38%7C0%7C0%7C637722807820682221%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=SFwpaswIRrcefX0z3eE0vj5GUo4shR60EIiTiQUCl90%3D&reserved=0), and [Health Affairs](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.healthaffairs.org%2Fdo%2F10.1377%2Fhblog20200630.939347%2Ffull%2F&data=04%7C01%7Crebecca.rousselle%40emory.edu%7C98fd1abfb9004c48e8fb08d9a583cf9f%7Ce004fb9cb0a4424fbcd0322606d5df38%7C0%7C0%7C637722807820692211%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=UIPb8XoHu6Xj1hKNSfb2XBBzcw3BnaExQvOKCooG06Q%3D&reserved=0) guidance). (2) State whether you are using racial and ethnic classification of patients for descriptive statistics or within an explanatory model (as a covariate). (3) If you are using race and/or ethnicity as a variable to explain differences between patients (as a covariate), please describe the proposed mechanism of action (what is race being used as a proxy for?).

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.

(Add your text)

# Informed Consent

Do you wish to request a waiver of informed consent for this research? Please address how your request meets the following criteria:

* The research involves no more than minimal risk to the subjects.
* The waiver or alteration will not adversely affect the rights and welfare of the subjects.
* The research could not practicably be carried out without the waiver or alteration (impracticability normally requires justification beyond inconvenience or cost)
* Whenever appropriate, the subjects will be provided with additional information about their participation in the research (often not necessary).

(Add your text)

# HIPAA

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 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.

(Add your text)

# Risk to Participation

Include breach of confidentiality if any identifiers remain on the data/samples

Consider risks related to genetic information, if applicable

Do not state that there are no risks.

(Add your text)

# Benefits to future subjects

Describe

(Add your text)

# Confidentiality

Plan to protect 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 stripped off first?
* What are plans for protecting the data or disposing of it once the study is completed.
* Will any data be shared with an external entity or non-Emory collaborator? If so, clarify what identifiers will be included with the data.
* Will any identifiable data be shared via a platform/software/eConsent/app? If not a [vetted option](https://it.emory.edu/security/protecting-data/software_for_research.html), please note [Emory OIT security review](https://emory.service-now.com/sp?id=kb_article&sys_id=e5c2cd88f5cdf1c055c77bd8604896c2) may be required.

(Add your text)

# References

Add references.

(Add your text)

# Protocol Checklist

**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.**

|  |  |
| --- | --- |
| **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** |
| **Objectives*\**:** Describe the purpose, specific aims, or objectives and state the hypotheses to be tested | [ ]  **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. What is the ultimate intended purpose and audience(s) for the results of the study? | [ ]  **Yes** |
| **Study Design\*:** Provide some information about the data set that the research team will be analyzing. The following questions should be answered:* The source of the data: from whom? From where? Who “owns” it?
	+ If data is obtained via a third-party organization (e.g. via a web portal), provide the forms/application that must be submitted to access the data (or a link thereto) and any assurances you are asked to provide (e.g. a data use agreement).
	+ Is a person outside Emory going to be collaborating on this study in any way? Is their IRB going to review their study participation?
 | [ ]  **Yes** |
| **Data/Biospecimens\***: If the data/specimens have identifiers associated with them now, but all of the above identifiers will be removed before starting your analysis: who did or will de-identify the data or specimens? If the data is already de-identified, when was it de-identified?Are the data or specimens linked to an individual by a code number? If yes, will anyone on the research team have access to the key linking the study ID to individuals?Why were the data or specimens originally collected? Were they collected as part of clinical care? If for a research study, provide Emory IRB number(s) if applicable, and the informed consent/HIPAA authorizations signed by the subjects (so that the IRB can determine if the new proposed use of the data/specimens is within the scope of the original consent/authorization - required)Inclusion and Exclusion criteria for data/biospecimen collection. | [ ]  **Yes** |
| **Research with pregnant women, fetuses, or neonates:** review [this checklist](http://irb.emory.edu/documents/Emory%20Subpart%20B%20Worksheet.doc) to verify you have provided enough information to ensure the safety and well-being of this population. | [ ]  **Yes**  |
| **Research with neonates of uncertain viability:** review [this checklist](http://irb.emory.edu/documents/Emory%20Subpart%20B%20Worksheet.doc) to verify you have provided enough information to ensure the safety and well-being of this population. | [ ]  **Yes**  |
| **Research involving prisoners:** review [this checklist](http://irb.emory.edu/documents/Emory%20Subpart%20C%20Worksheet.doc) to verify you have provided enough information to ensure the safety and well-being of this population. | [ ]  **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**  |
| **Procedures\*:** What will you do with the data/specimens?Are there plans to store any data/specimens long-term? For what purpose? (May require a repository-specific IRB submission) | [ ]  **Yes**  |
| **Data analysis*\****: Describe the data analysis plan, including any statistical procedures or power analysis.Describe the steps that will be taken to secure the data or 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 or specimens will be handled study-wide:* What information will be included in that data or associated with the specimens?
* Where and how data or specimens will be stored?
* How long the data or specimens will be stored?
* Who will have access to the data or specimens?
* Who is responsible for receipt or transmission of the data or specimens?
* How data or specimens will be transported?
 | [ ]  **Yes**  |
| **Informed Consent*\**:** Do you wish to request a waiver of informed consent for this research? Please address how your request meets the following criteria:* The research involves no more than minimal risk to the subjects.
* The waiver or alteration will not adversely affect the rights and welfare of the subjects.
* The research could not practicably be carried out without the waiver or alteration (impracticability normally requires justification beyond inconvenience or cost)
* Whenever appropriate, the subjects will be provided with additional information about their participation in the research (often not necessary).
 | [ ]  **Yes**  |
| **HIPAA*\****: 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 Participation\*:** Include breach of confidentiality if any identifiers remain on the data/samples. Consider risks related to genetic information, if applicable. Do not state that there are no risks.Indicate if there is no direct benefit. Do not include benefits to society or others. Describe areas of knowledge that would be strengthened. Compensation should NOT be stated as a benefit. | [ ]  **Yes** |
| **Benefit to future subjects or science\*:** Describe in the protocol. | [ ]  **Yes** |
| **Confidentiality*\**:** 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 stripped off first?
* What are plans for protecting the data or disposing of it once the study is completed?
 | [ ]  **Yes** |