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”.

**CHOA chart reviews:** If your study involves only the review and analysis of CHOA medical records, please instead submit your study to the CHOA IRB.

* **What template should I use?**
	+ **This template is** for studies that solely involve the collection/analysis of medical record data that was generated from non-research activities (i.e. medical care).
	+ For studies involving secondary data analysis from sources other than medical records, please use the “[Secondary Analysis Protocol template](http://irb.emory.edu/forms/Study%20Submission.html)” instead.
	+ For studies involving the creation of a data or biospecimen registry/repository/database, please use the “Registry/Database/Repository Protocol template” instead.
* You must also complete below the [Chart Review Checklist](#_Protocol_Checklist) with your protocol, to attest that you have considered all the required sections in this template.
* If unsure whether IRB review is required for your project, please start by using our website tool under “[Does My Project Need IRB Review](http://irb.emory.edu/forms/review/request.html)?”
* Grant applications may not be submitted to the IRB instead of a protocol document.
* When you write a protocol, keep an electronic copy in your records. 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)

**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. Site Summary 5](#_Toc125967319)

[2. Background 5](#_Toc125967320)

[3. Study Design 5](#_Toc125967321)

[4. Source of records 6](#_Toc125967322)

[5. Date range 6](#_Toc125967323)

[6. Inclusion criteria, including age range 6](#_Toc125967324)

[7. Exclusion Criteria 6](#_Toc125967325)

[8. Population 6](#_Toc125967326)

[9. Procedures 7](#_Toc125967327)

[10. Data Analysis 7](#_Toc125967328)

[11. Informed Consent 8](#_Toc125967329)

[12. HIPAA 8](#_Toc125967330)

[13. Risk to Participation 9](#_Toc125967331)

[14. Benefits to future subjects or science 9](#_Toc125967332)

[15. Confidentiality 9](#_Toc125967333)

[16. Reference/Bibliography 10](#_Toc125967334)

[17. Protocol Checklist 10](#_Toc125967335)

# Site Summary

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

# 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.

(Add your text)

# Study Design

Note: 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.

|  |
| --- |
| Select one of the following (do not delete this table; see margin comment for definitions): |
| [ ]  Retrospective chart review |
| [ ]  Prospective chart review |
| [ ]  Both: retrospective and prospective chart review |

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)

# Source of records

Please, be specific.

(Add your text)

# Date range

Add this information in MM/DD/YYYY to MM/DD/YYYY format from which chart data will be reviewed (start and end dates)

(Add your text)

# Inclusion criteria, including age range

(Add your text)

# Exclusion Criteria

(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?).

(Add your text)

* If the research involves individuals who are vulnerable to coercion or undue influence, state this.
* 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.
* Otherwise, just note whether the dataset will include data from minors, employees, or cognitively impaired individuals

(Add your text)

# Procedures

Procedures for medical record data collection, what is the data to be collected, and how will the data be obtained (if other than directly accessing the electronic record).

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 (may include the minimum number of charts needed, but avoid giving an exact number to be used, to avoid HIPAA issues).

Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, Data Use Agreements, 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 will be handled study-wide:

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

(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 or feasible).
* If the data includes that of minors, note if you are also requesting a waiver of assent and parental permission.
* If this study is being conducted at the VA: a waiver of informed consent is not required for VA records review studies.

If your study does not meet the criteria for waiver of informed consent (more likely for prospective chart reviews), explain how and when consent will be obtained.

(Add your text)

# HIPAA

List the specific HIPAA identifiers you will record in your research files. A list of HIPAA identifiers can be found [here](http://www.irb.emory.edu/documents/phi_identifiers.pdf).

**HIPAA waiver**: If you are recording identifiers from subjects who are still living, and it is **not practicable** to obtain their HIPAA authorization for your study, state that you are requesting a HIPAA waiver. Also, you must address how your request meets the following criteria for a waiver, with protocol-specific details:

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.

(Add your text)

# Risk to Participation

Include the risk of breach of confidentiality if any identifiers remain on the data/samples. Do not state that there are no risks.

(Add your text)

# Benefits to future subjects or science

Described benefits if any

(Add your text)

# Confidentiality

Include a statement reflecting compliance with [Emory’s Data Security Policy](http://it.emory.edu/security/security_awareness/encrypt.html). 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 stripped off first?
* What are plans for protecting the data or disposing of it once the study is completed?

(Add your text)

# Reference/Bibliography

(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** | **Included in 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). 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.  | [ ]  **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** |
| **Study Design\*:** 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. | [ ]  **Yes** |
| ***Source of Records*\*:** Please, be specific. | [ ]  **Yes** |
| **Date Range\*:** Add this information in MM/DD/YYYY to MM/DD/YYYY format from which chart data will be reviewed (start and end dates) | [ ]  **Yes** |
| **Inclusion Criteria\*:** Added in the protocol | [ ]  **Yes** |
| **Exclusion Criteria\*:** Added in the protocol | [ ]  **Yes** |
| **Research with individuals who are vulnerable to coercion or undue influence:** provide details if applicable | [ ]  **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** |
| **Other populations:** note whether the dataset will include data from minors, employees, or cognitively impaired individuals | [ ]  **Yes** |
| **Procedures\*:** Procedures for medical data collection, data to be collected and how will the data be obtained (if other than EeMR) | [ ]  **Yes** |
| **Data analysis*\****: (may include a minimum number of charts needed, but avoid giving an exact number to be used, to avoid HIPAA issues).Describe the steps that will be taken to secure the data (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 will be handled study-wide:* What information will be included in that data?
* Where and how data will be stored?
* How long the data will be stored?
* Who will have access to the data?
* Who is responsible for the receipt or transmission of the data?
* How data 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).
* If the data includes that of minors, note if you are also requesting a waiver of assent and parental permission.
* If this study is being conducted at the VA: a waiver of informed consent is not required for VA records review studies

If your study does not meet the criteria for waiver of informed consent (more likely for prospective chart reviews), explain how and when consent will be obtained. | [ ]  **Yes** |
| **HIPAA*\****: List the specific HIPAA identifiers you will record in your research files. A list of HIPAA identifiers can be found [here](http://www.irb.emory.edu/documents/phi_identifiers.pdf).**HIPAA waiver**: If you are recording identifiers from subjects who are still living, and it is **not practicable** to obtain their HIPAA authorization for your study, state that you are requesting a HIPAA waiver. Also, you must address how your request meets the following criteria for a waiver, with protocol-specific details: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. Do not state that there are no risks. | [ ]  **Yes** |
| **Benefit to future subjects or science\*:** Describe in the protocol. | [ ]  **Yes** |
| **Confidentiality*\**:** Include a statement reflecting compliance with [Emory’s Data Security Policy](http://it.emory.edu/security/security_awareness/encrypt.html). 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 stripped off first?
* What are plans for protecting the data or disposing of it once the study is completed?
 | [ ]  **Yes** |