**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** | **Included in 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, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. | **Yes** |
| **Study Design\*:** Source of records (be specific). Be sure to note if the sample includes any vulnerable populations (pregnant women, minors, or prisoners)  Date range (in MM/DD/YYYY-MM/DD/YYYY format) from which chart data will be reviewed  Inclusion criteria, including age range  Exclusion Criteria  Please do not include estimated number of charts to be reviewed (to avoid unnecessary violations of HIPAA via reviewing too many charts); though estimated minimum number of charts may be included in the Data Analysis section below | **Yes** |
| **Research with pregnant human, 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** |
| **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 minimum number of charts needed, but avoid giving 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 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 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 this study is being conducted at the VA, a waiver of informed consent is not required for VA records review studies. | **Yes** |
| **HIPAA*\****: Will you be recording identifiers from charts? A list of HIPAA identifiers can be found here: <http://www.irb.emory.edu/documents/phi_identifiers.pdf>.  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. | **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 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** |