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| Submit typed, hard copy of this form with **original signatures** for review. **\*\*Keep a copy for your files\*\*** | | |
| TITLE OF STUDY: | | |
| **INVESTIGATOR(S)**  Name: | Division/Department: | Program: |
| Address (Room Number): | Telephone: | Fax/email: |
| **Person(s) who will carry out the chart review (include as many persons as necessary)** | | |
| Name: | Division/Department: | Program: |
| Address(Room Number): | Telephone: | Fax/Email: |
| **Time Frame** | Proposed  Start Date:  dd/mmm/yyyy | Termination  Date:  dd/mmm/yyy |
| **FUNDING:** How will the study be funded?  Grant – Specify funding source:  Industry – Sponsor Name & full billing address including a contact’s name & email address:  Internal – Specify funding source:  No Funding Required | | |
| **DIVISION/DEPARTMENT APPROVAL (**I have reviewed this proposal and approve this request)    Division/Dept. Head Print Name Signature Date (dd/mmm/yyy) | | |
| CONFIDENTIALITY AGREEMENT*Investigator* I, the undersigned, agree to adhere to the **MSH Policy on Information and Data Security (Policy #I-H-5)** and understand that a breach of this policy will be just cause for termination of my employment and/or affiliation with the hospital. I agree that all health information, which I may have access to, is to be dealt with in keeping with the policies and procedures of Mount Sinai Hospital with respect to confidentiality. If identifying information is collected, the information will be kept secure and identifiers removed at the completion of collection. I also accept full responsibility for protection of information that has been collected by a delegate on my behalf.    Print Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_ | | |

Please address the following ethical concerns regarding access to confidential medical information. The response to these issues should be sufficiently detailed and complete to allow the REB to determine the merit of the investigation and that sufficient protection is in place to protect the confidentiality and security of the information. Incomplete applications will be returned.

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| **Section 1** | **Project Summary** | | | | |
| 1. Primary Objective for the study (**include the rationale for the study**) |  | | | | |
| 1. Specific Hypotheses or Questions to be addressed |  | | | | |
| 1. Provide study summary and outline analyses |  | | | | |
| 1. Specify the data to be collected or attach data collection form |  | | | | |
| 1. Data source: Identify all sources of data   In Patient  Day Surgery  Emergency | | | | | |
| 1. Proposed number of research subjects/charts: | | | | | |
| 1. Time period of requested data (i.e.,01/01/1970 to 01/01/1980): | | | **From** | | **To** |
| **Section 2** | | **Information Protection: Patient Identifying Data** | | | | |
| 1. If personal health information is collected, used or disclosed, without consent from individuals to whom the information relates, explain why obtaining explicit consent would be impractical. | |  | | | | |
| 1. How will relevant patient charts be identified? | |  | | | | |
| 1. Have you already developed a list of specific patients? | | YES  NO  **If Yes, please indicate how patients were identified:** | | | | |
| 1. Will any identifying information be recorded? 🞏 YES 🞏 NO | | YES  NO | | | | |
| **If YES,**  i) Specify the identifying information and justify the necessity for its collection. | | ii) Will individual identifiers be removed once the relevant data is collected? If not, please justify. | | |
| 1. Will this data be transferred outside of MSH? | | YES  NO  **If yes, where:**  **Is there a Data Sharing Agreement:**  YES  NO  Pending  **How will the confidentiality be protected?** | | | | |
| 1. Multicenter Study? | | YES  NO  **If yes, please identify the other sites and indicate the REB approval status**: | | | | |
| 1. Is there any anticipated linkage of the data to be collected with other data? | | YES  NO  **If yes, how will the linkage information be treated?** | | | | |
| 1. Will this data be reported publicly? (e.g. publication) | | YES  NO | | | | |
| 1. Will this data being collected be used now or in the future for commercial purposes? | | YES  NO  **If yes, please provide details:** | | | | |
| 1. How will security and confidentiality of the data be protected, maintained and retained? | |  | | | | |