# Request for IRB Determination of Exempt Status

IRB Number

# **Existing Data or Research Records**

|  |  |  |  |  |  |  |  |  |  |  |  |
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| Title of study: | | | |  | | | | | | | |
| Principal investigator: | | | |  | | | | | | | |
| Date requested: | | | | | Date study will begin: | | | | Anticipated ending date: | | |
| Click or tap to enter a date. | | | | | Click or tap to enter a date. | | | | Click or tap to enter a date. | | |
| **INITIAL CRITERIA** | | | | | | | | | | | |
| A. | Are all data in existence as of the date the application is submitted to the IRB? | | | | | | No  Yes | If **No**, **STOP**; study does not qualify for this type of exempt status. | | | |
| B. | Will any information from this project be submitted to the FDA? | | | | | | No  Yes | If **Yes**, **STOP**; study does not qualify for exempt status. | | | |
| C. | How will information be recorded in this study? (Check all that apply.) | | | | | | | | | | |
|  |  | Information is publically available. | | | | | | | | | |
|  |  | Information is recorded WITHOUT identifiers or linkage codes by the investigator. | | | | | | | | | |
|  |  | An independent individual, not associated with this research study, will de-identify data prior to providing it to the investigator and will not assign linkage codes. | | | | | | | | | |
|  |  | An independent individual or system, not associated with this research study, will de-identify data prior to providing it to the investigator and will assign linkage codes; but will not provide the investigator with access to students’ identities associated with those linkage codes: | | | | | | | | | |
|  | a. The following person or group, who is independent of the research team, has agreed  to serve in that capacity (fill in names below): | | | | | | | | |
|  | | | | | | | | |
|  | b. The following computerized system, to which the research team has no access, will electronically de-identified the data (fill in name of program or system below): | | | | | | | | |
|  | | | | | | | | |
|  |  | Other (describe) | | | | | | | | | |
|  |  |  | | | | | | | | | |
| **SUPPORTING INFORMATION** | | | | | | | | | | | |
| **1.** | **Records to be studied** | | | | | | | | | | |
| 1a. | Describe the records that will be accessed, including the source and/or the purpose for which they were originally collected. | | | | | | | | | | |
|  | | | | | | | | | | |
| 1b. | Are personal identifiers associated with the original data? Note: Unless data are publically available, investigators cannot record subject identifiers with data. If Yes, address the following questions: | | | | | | | | | | No  Yes |
|  | i. Who will access the records? | | | | | | | | | | |
|  |  | | | | | | | | | | |
|  | ii. What is their right to do so? (e.g., specify their right to access to the records; clarify that they will only have access to de-identified records, etc.) | | | | | | | | | | |
|  |  | | | | | | | | | | |
|  | iii. Describe the process of obtaining the data. | | | | | | | | | | |
|  |  | | | | | | | | | | |
|  | iv. Describe how data will be de-identified prior to being provided to the investigators (if applicable). | | | | | | | | | | |
|  |  | | | | | | | | | | |
| **2.** | **Methods** | | | | | | | | | | |
| **2a.** | Describe or list variables that will be extracted from records. | | | | | | | | | | |
|  | | | | | | | | | | |
| 2b. | If data are from a previous research study, attach copy of consent form. | | | | | | | | | | |
| **3.** | **Analysis** | | | | | | | | | | |
| How will results be analyzed to determine that study aims have been met? | | | | | | | | | | |
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| **4.** | **Additional Information, Clarification, or Comments for the IRB Reviewer** | | | | | | | | | | |
|  | | | | | | | | | | |
| **CERTIFICATIONS AND ASSURANCES** | | | | | | | | | | | |
| **Assurance of Individual Who is De-identifying Data to be Used in this Study** | | | | | | | | | | | |
| By signing below, I agree/certify the following:   * I have reviewed this project with the principal investigator and agree to de-identify and, if applicable, to maintain linkage code information for data that will subsequently be accessed by the research team. * I will, under no circumstance, provide the PI or any member of the research team with information that would permit the identification of research subjects. * I will not intervene or interact with identified human subjects during the conduct of this research project. * I will maintain the complete confidentiality of research subjects’ private information. | | | | | | | | | | | |
| Name: | | | | | | Signature: | | | | Date: | |
| Position: | | | | | | Email: | | | | Phone: | |
| **Assurance of Principal Investigator** | | | | | | | | | | | |
| I am responsible for the conduct of this research protocol, including the co-investigator(s) and other research staff. I have certified that all co-investigator(s) and other research staff have completed the training requirements. | | | | | | | | | | | |
| I hereby certify that   * The information contained in this document is accurate and correct. * I will carefully follow the approved research protocol and submit **all** major changes to the IRB for consideration **before** incorporating them into the study. * I will notify the IRB of any deviations from the approved research protocol taken in an emergency to protect the subject from harm; and any unanticipated problem, or serious, unusual, or unanticipated adverse event. | | | | | | | | | | | |
| I will protect the rights and welfare of each subject to the best of my ability. | | | | | | | | | | | |
| Signature: | | | | | | | | | | Date: | |