# Request for IRB Determination of Exempt Status

IRB Number

# **Existing Data or Research Records**

|  |  |
| --- | --- |
| 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.) |
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|  | 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? |
|  |
| **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.
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| 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: |