

**Human Research Protection Program
Protocol for Previously Collected Data or Specimens**

# STUDY TEAM INFORMATION

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| **Project Title** |  |
| **Investigator Name** |  |
| **Faculty Supervisor (Students Only)** |  |

This form must be used to submit an application through [eCompliance system](http://ecompliance.ku.edu/). **No other methods of submission will be accepted.**

**Students and faculty supervisors:** Faculty supervisors must complete an ancillary review in eCompliance to document faculty supervisor approval. [Please see the guidance on ancillary reviews for more information](http://research.ku.edu/sites/research.ku.edu/files/docs/Faculty%20-%20Ancillary%20Review%20Instructions.pdf).

For faster processing, ensure all study staff have completed the required human research training available on the [IRB website](http://research.ku.edu/human_research_protection_program).

**This protocol should only be used for retrospective analysis of existing data or specimens. The IRB staff may ask you to complete the full IRB protocol if your project includes procedures outside of retrospective analysis.**

Contact irb@ku.edu with questions!

# 1. PROJECT INFORMATION

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| **1.1 Expected Project Time Period**  |

**From:** Click here to enter text.

**To:** Click here to enter text.

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| **1.2 Explain how many data records or specimens you expect to analyze.** |

Click here to enter text.

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| **1.3 Do you currently have funding or expect to obtain funding in the future?** |

Choose an item.

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| **1.4 Select Type of Funding** |

Choose an item.

**Select your award’s current status.**

Choose an item.

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| **1.5 Study Purpose: Describe the purpose of the research. Explain what is intended to be discovered; include goals, aims, and objectives and/or state the hypothesis to be tested.** |

Click here to enter text.

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| **1.6 Background: Provide a brief scientific or scholarly background for the research activities, address gaps in current knowledge that may be filled by this research project.** |

Click here to enter text.

# 2. RISK & BENEFITS

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| **2.1 Does this study involve any of the following? (Check all that apply)** |

[ ]  Genetic information

[ ]  Biological specimens

[ ]  Information pertaining to illegal activity

[ ]  Information pertaining to substance abuse

[ ]  Information relating to sexual attitudes, orientation, or practice

[ ]  Private identifiable information

[ ]  Personal or sensitive information

[ ]  Information pertaining to disability status

[ ]  Private records (academic, medical, etc.)

[ ]  Information that if released could damage an individual's financial standing, employability, reputation, or cause social stigmatization or discrimination

[ ]  Information that if released could cause stigmatization or discrimination within a specific community

[ ]  Other

[ ]  None of these

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| **2.2 Describe the nature and degree of the risk or harm checked above. Describe if the number of samples/records you are receiving affects the degree of risk.** |

Click here to enter text.

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| **2.3 What steps will be taken to minimize the risks or harm and protect the subjects' welfare (when risk is greater than minimal)?** |

Click here to enter text.

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| **2.4 Describe the anticipated benefits of the research for the individuals, society, or science. Explain how the benefits outweigh the risks.** |

Click here to enter text.

# 3. DATA INFORMATION

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| **3.1 Data Storage and Transfer Information****a. Summarize the original procedures for collection of the data/specimens, including the original investigators/owners of data, and the original intent for collection of the data/specimens.****b. Describe where the data/specimens are currently being stored and, if specimens, whether they are currently held in a tissue/specimen bank (or other facility).****c. Explain who will give the KU investigators access to the data/specimens for this project.** |

Click here to enter text.

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| **3.2 What type of data will you be analyzing? *(Check all that apply)*** |

[ ]  De-identified data (no direct/indirect identifiers)

[ ]  Identifiable data

[ ]  PHI (Protected Health Information)

[ ]  Academic Records

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| **3.2a If the data are de-identified, will you have access to a key or code that could link the data to identifiable private information (e.g., a person’s name, email)?**  |

[ ]  Yes – The PI or study team will have access to a master key

[ ]  No – The PI and study team will not have access to a master key

[ ]  Unsure – I do not know if I will have access to a master key

*\*If unsure, contact the source who originally collected the data to confirm if they will send a key to identifiable information.*

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| **3.3 Check the types of identifiers present in the data set you are analyzing: *(Check all that apply)*** |

[ ]  Names

[ ]  Geographic subdivisions smaller than a state (street address, city, county, zip code)

[ ]  Birth dates, date of death, admission/discharge dates

[ ]  Age (without birth dates)

[ ]  Student/employee IDs

[ ]  Ethnicity/Race

[ ]  Telephone or fax numbers

[ ]  Electronic mail address (e- mail)

[ ]  Social security numbers

[ ]  Social media or Website Usernames

[ ]  Medical or mental health records

[ ]  Account numbers

[ ]  Health plan beneficiary numbers

[ ]  Certificate or license numbers

[ ]  Vehicle identifiers and serial numbers

[ ]  Device identifiers and serial numbers

[ ]  Web Universal Resource Locators (URLs)

[ ]  Internet Protocol (IP) address numbers

[ ]  Biometric identifiers, including finger/voice prints

[ ]  Other unique identifiers

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| **3.4 Explain what type of data will be included in your analysis. Explain why it is necessary to obtain or store identifiers. Describe the size of the data set or the number of specimens that will be analyzed.** |

Click here to enter text.

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| **3.5a Explain how the data was originally collected. Explain if the data was originally approved for research or non-research purposes, and if the project was approved by an IRB.** |

Choose an item.

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| **3.5b Will participants be contacted or compensated for use of their data?** |

Choose an item.

**If other, please explain.**

Click here to enter text.

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| **3.6 Informed Consent Information****a. Explain how you will obtain consent from participants for use of this data, or why you do not plan to obtain consent.** **b. Describe the process of obtaining consent. Include names of individuals on the research team who will be obtaining consent, where/when the process will take place and how you will ensure the subjects' understanding.** **c. For educational records or Protected Health Information (PHI), explain how you will satisfy the requirements for an authorization to use this data for research purposes under HIPAA and FERPA regulations.** |

Click here to enter text.

# 4. DATA SECURITY

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| **4.1 Do you have any of the following agreements for this project? *(Check all that apply)*** ***\*\*If yes, please upload the agreements with this protocol in eCompliance.*** |

[ ]  Data Use Agreement (DUA)

[ ]  Contract

[ ]  Memorandum of Understanding (MOU)

[ ]  Other agreement

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| **4.2 Data Security Plan****a. Outline your data security plan, including protocol for personnel handling data, physical security safeguards, and electronic security safeguards.** **b. Describe the steps that will be taken to secure the data during storage, use, and transmission.** **c. Provide details such as where and how the data will be stored, for how long it will be kept, how it will be disposed/destroyed. Explain if the data will be returned to the original owner.** |

Click here to enter text.

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| **4.3 By checking this box, you verify that you are aware of the KU IT data security policies/procedures, and that you will be following and abiding by these policies to ensure security of the data related to this project.** |

[ ]  Yes, I verify I understand and will comply with [KU IT data security policies/procedures.](http://policy.ku.edu/IT/data-classification-handling-procedures)