# IRB Determination

*“Not Human Subjects Research” determination: In order for the IRB to make the determination that a project is not human subjects research, it must not meet the definition of human subjects.*

*Human subject means a living individual about whom an investigator (whether professional or student) conducting research:*

*(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or*

*(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.*

**Please complete this application as thoroughly as possible.**

Additional information and templates are available at [Office of Research Integrity and Compliance](http://www.cmu.edu/research-compliance/human-subjects-research/)

\*Note that incomplete applications will result in delays.

**Protocol Number:**

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**Study Title:**

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**PI Name:**

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| 1. Study Scope |

1. **What is the purpose of this research?**

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1. **What are the goals of this research?**
2. **Describe the research:**
3. **Indicate why this project is not human subjects research/does not meet the definition of human subjects found above:**

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| 7. Data Security and Confidentiality  |

1. **If datasets are used indicate who is providing them (your source):**
2. **Describe the contents of the dataset. What are the data elements?**
3. **Describe how the data will be provided to you (***secure password protected file, encrypted USB hard drive, etc.)* or **:**
4. **Describe how the identifiers will be removed from the data before you receive it. (Note that researchers who are part of this project cannot do the de-identification. It must be done by someone who normally has access to the information, who is not part of the research team, and the de-identification must occur before the researchers receive it.)**

**OR**

**Describe how the information to be used in this research is identifiable but not private**

1. **Indicate how you will keep the data secure:**
2. **In addition to the individuals listed on the study personnel page, who will have access to research? Indicate if information might or will be shared outside the research team and/or CMU.**