

Examples of Research Involving Coded Private Information and Secondary Analysis of De-Identified Data/ Samples:

Below are some examples of projects involving coded private information or secondary analysis of de-identified samples, some of which were deemed to be Not Human Subject Research at Tufts Medical Center/ Tufts University and some of which were not.

The list below is not intended to be exhaustive, but rather to help give some concrete examples as researchers consider whether their own project might be considered Not Human Subject Research at Tufts.

As a reminder, for research involving coded private information to be considered Not Human Subjects Research at Tufts, the following conditions must be met:

- Neither you or any member of your research team is [engaged](#) in the research through which information or specimens were collected; **and**
- Tufts investigators cannot readily ascertain the identity of the individuals to whom information or specimens belong.

Examples in which Tufts IS engaged in Human Subject Research:

1. A research team at Tufts would like to study the effect of sunlight on mood. They ask colleagues at institution X to conduct a study which they have designed. Tufts researchers will never interact with study subjects nor know the identity of study subjects. However, in this example, they would still be considered to be engaged in research as the research activities were designed by Tufts University.
2. Tufts University and institution X are collaborating on another study to look at the effect of sunlight on mood, which they will do in California. The team on the ground in California consists of both Tufts University researchers and institution X researchers. All data will be de-identified before being sent back to Tufts for analyses. However, in this

example, because some Tufts researchers were present for the collection of samples, Tufts would be considered to be engaged in human subject research.

3. A researcher at Tufts Medical Center wants to do further studies on the effect of sunlight on mood. They know that a researcher at institution Y already has serum samples from an earlier and related study that they are willing to share with Tufts. The samples will be coded but the Tufts researcher will also have access to the study code. In this example, Tufts would be considered to be engaged in human subject research as Tufts can readily ascertain the identity of the individuals to whom the samples belong.

Examples in which Tufts IS NOT engaged in Human Subject Research:

1. A research team at institution Y is studying the effects of consuming daily protein on overall health. Blood samples are taken from subjects as part of study participation. Institution Y has asked one of Tufts University's labs to process these blood samples. They will be coded numerically when they are given to Tufts and no other information will come attached to the samples. Institution Y's research team holds the code and attests that they will not share it with Tufts researchers. The principal investigator at Tufts attests that he and his study team will not attempt to ascertain the identity of individuals. After analysis, results will be presented back to the research team at institution Y. In this example, Tufts would not be considered to be engaged in human subject research.
2. Institution Y is conducting another study in which they require additional help with statistical analyses. They will provide their body of data to a research team at Tufts, stripped of any individually identifiable information. Tufts will then aid in the data analysis and provide the information back to institution Y. In this example, Tufts would not be considered to be involved in human subject research.
3. An investigator at Tufts is interested in studying a particular type of cancer. They happen to know that someone at institution Y specializes in this type of cancer and has banked tissues with this particular disease. Institution Y agrees to provide coded tissue samples to the Tufts researcher for the purposes of this research. The samples will be coded numerically and the investigator at institution Y holds the code. The investigator at institution Y attests that she will not share this code with anyone at Tufts, and the investigator at Tufts attests that neither he nor anyone on his research team will attempt to ascertain the identity of the individuals to whom the samples belong. In this example, Tufts would not be considered to be involved in human subject research.