

**2018 Exempt Category 4
Secondary Use of Identifiable Data or Specimens**
[Exempt Research: 45CFR46.104 (d) (4)]

START
Meets the definition of research.*

↓ YES

Will you be using IDENTIFIABLE, PRIVATE data or biospecimens for secondary research?
Use of de-identified data/biospecimens for research does not require an application to the IRB.

↓ YES

Were the data/biospecimens originally collected for a different primary purpose?

NO

Does not qualify for Exempt Category 4
Submit a Non-Exempt Application

↓ YES

Are the data/biospecimens covered by HIPAA?

YES

Special concerns apply.
Contact [hsirb@davidson.edu](mailto:hsirb@ davidson.edu).

↓ NO

Are the data/biospecimens publicly available?

YES

Qualifies for Exempt Category 4
Submit application for Exempt Research Designation

↓ NO

Is the information recorded in a way that there is no possible way to link the data to the subjects' identities?

YES

↓ NO

Does the researcher plan to have contact with the subjects or re-identify the data?

NO

YES

*"Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.