Is Your Human Subjects Research Eligible for Exemption?

Start: You are conducting Human Subjects Research

(See Decision Chart Tree 1)

Are prisoners the intended and targeted subject population?

Yes

No

No, but some prisoners might be included in the population.

Does Study involve collecting data or biomaterials for research via interaction or intervention?

Yes

No

Does Study involve the use of secondary data collected for a different primary purpose?

Yes

No

Is study being conducted by a Federal agency, and will it evaluate or improve public services?

Yes

No

See Category 4

Begin with Category 1 Chart
May be exempt under 1, 2, or 3

Go to Category 4 Chart

Go to Category 7 and 8 Charts

Research may not meet the definition of Human Subjects. Please contact the IRB office at trammellj@sou.edu

See Category 5

Not eligible for exemption.
Fill out application for Non-Exempt Research

NOTE:

1. A IRB Request for Review application must be submitted to the IRB office regardless of exempt self-determination.
2. Researchers may not make self-determination of exemption from IRB review. All research involving human subjects must be reviewed by SOU’s IRB office, and granted either an Exemption or Approval before study procedures may begin.
3. In order for the research to be eligible for exemption, the only involvement of human participants in the research must fall into one or more of the exemption categories.
4. Definitions and other resources are on the IRB website www.sou.edu/irb

Updated January 7, 2019
Educational Practices: Does Exemption Category 1 Apply to Your Research?

45 CFR 46.104(d)(1)

1. **Research involves collecting data or biomaterials**

   - **Research will be conducted in established or commonly accepted educational settings?**
     - Yes
     - No
     - **Research examines normal educational practices?**
       - Yes
       - No
     - **Are prisoners the intended and targeted study population?**
       - Yes
       - No*
     - **Could research adversely affect student learning of educational content?**
       - Yes
       - No
     - **Could research adversely affect the assessment of educators who provide instruction?**
       - Yes
       - No

*Note: Prisoners may be included in the study population as long as they are not the targeted population.

2. **Exempt under Category 1**

   - Fill out Exempt Application

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Not exempt under Category 1. But may be exempt under 2, 3, 5, or 6
Surveys, Tests, or Observations: Does Exemption 2 Apply to Your Research?

45 CFR 46.104(d)(2)

Research involves collecting data or biomaterials, but is not Exempt under Category 1

Yes → Are prisoners the intended and targeted subject population?

Yes → Not Exempt under Category 2

Fill out non-Exempt Application

*Note: Prisoners may be included in the sample population as long as they are not the targeted population.

No → Are researchers participating in the observed activities?

Yes → Are minors enrolled in the study?

Yes → Not Exempt under Category 2

Fill out non-Exempt Application

No → Is researcher engaging in the observation of public behavior?

Yes → Does research involve educational tests?

Yes → Will personal identifiers be collected?

No → Limited IRB review is required.

Fill out Exempt Application

No → Does research involve survey or interview procedures?

Yes → Are minors enrolled in the study?

Yes → Not Exempt under Category 2

Fill out non-Exempt Application

No → IRB determines there are adequate provision in place to protect the privacy of subjects and to maintain the confidentiality of data

Yes → Exempt under Category 2

Updated January 7, 2019
Benign Interventions: Does Exemption 3 Apply to Your Research?

45 CFR 46.104(d)(3)

Research involves collecting information, but is not eligible for exemption under Categories 1 or 2.

Are prisoners the intended and targeted study population?

Yes  

Not Exempt under Category 3  
Fill out non-Exempt Application

No

Are minors enrolled in the study?

Yes

Exempt under Category 3

No

Does research involve behavioral interventions?

Yes

Will personal identifiers be recorded?

Yes

Limited IRB review is required.
Fill out Exempt Application

No

Could disclosure of identifiers reasonably place participants at risk?

Yes

IRB determines there are adequate provision in place to protect the privacy of subjects and to maintain the confidentiality of data

No

Are the interventions benign?

Yes

Did participants agree to the intervention in advance?

Yes

Is full purpose of the study disclosed in consent?

Yes

Not Exempt under Category 3. Check other categories or fill out non-Exempt Application

No

No

No

No

Are participants informed that they will be unaware of or misled regarding research purpose?

Yes

Exempt under Category 3

No

*Note: Prisoners may be included in the sample population as long as they are not the targeted population.

Updated January 7, 2019
Research uses IDENTIFIABLE, PRIVATE data or biospecimens for secondary research*

Data/biospecimens were originally collected for a different primary purpose?

Yes

Are data/biospecimens covered by HIPAA regulations?

Yes

Are data/biospecimens publicly available?

Yes

Is information recorded in such a way that subjects’ identity is not readily ascertained?

Yes

Will participants be re-identified or will they be contacted?

Yes

Is research being conducted for, or on behalf of a federal department or agency?

Yes

Will information be maintained in compliance with federal privacy laws?

Yes

Exempt under Category 4

No

Or

Will information be generated or obtained by the government for non-research purposes?

Yes

Exempt under Category 4

No

Special concerns apply. Contact the IRB at trammellj@sou.edu

Not Exempt under Category 4

Fill out non-Exempt Application

NOTE
*Use of de-identified data or biospecimens for research purposes is not regulated by the IRB. Applications to SOU's IRB are not needed.

NOTE
Data/biospecimens from prisoners could be allowed as long as the research wasn’t designed to recruit prisoners and prisoners were only incidental subjects of the research.

Updated January 7, 2019
Public Health or Service Research: Does Exemption 5 Apply to Your Research?

45 CFR 46.104(d)(5)

Research involves the collection of information but is not eligible for exemption under Categories 1, 2, or 3.

Is research being conducted or supported by a federal agency?*

Yes

No

Not Exempt under Category 5, but may be exempt under 1, 2, 3, or 6

If not, fill out non-Exempt Application

Will research study, evaluate, improve, or examine public benefit or service programs?

Yes

Has the project been published on a publically available website?

Yes

Exempt under Category 5

No

No

Does the protocol include a plan and timeline?

No

**NOTE**

Projects eligible for this exemption will be posted on Federal websites.

Updated January 7, 2019
Food and Taste Evaluation: Does Exemption 6 Apply to Your Research?

45 CFR 46.104(d)(6)

Research involves taste and food quality evaluation and consumer acceptance studies?

Yes

Are prisoners the intended and targeted study population?

Yes

Not Exempt under Category 6, but may be exempt under 2, 3, or 5

If not, fill out non-Exempt Application

No

*Note: Prisoners may be included in the sample as long as they are not the targeted population.

Yes

**Study involves the consumption of wholesome foods without additives?

Yes

Exempt under Category 5

No

The level of additives consumed are considered safe by the FDA, EPA, or USDA?

Yes

**NOTE
Studies involving the consumption of alcohol, vitamins, and other supplements do not qualify for exempt status.

No

*No

**Note: Prisoners may be included in the sample as long as they are not the targeted population.
Storage, Maintenance, or Use of Secondary Data with Identifiers: Do Exemptions 7 or 8 Apply to Your Research?

45 CFR 46.104(d)(7,8)

Note: These exemption provisions carry significant requirements for documenting or waiving Broad Consent and for ensuring privacy of subjects and confidentiality of data. The SOU IRB recommends that projects involving secondary use of identifiable private data or biospecimens that cannot be exempted under Category 4, are reviewed by the SOU IRB via the non-exempt review process and granted IRB approval. Contact the IRB with questions at trammellj@sou.edu

Research will use, store or maintain IDENTIFIABLE PRIVATE data or biospecimens for secondary research use?

*Note: Prisoners may be included in the sample as long as they are not the targeted population.

Are prisoners the intended and targeted study population?


Were data/biospecimens collected with a different primary purpose?

Yes

Did the people whose information or biospecimens you are storing or using give or waive broad consent?

Data will be stored for future research use?

Currently stored data will be used for your research?

SOU IRB must conduct a Limited review to determine if Broad Consent is appropriately documented or waived.

SOU IRB must conduct a Limited review to determine if provisions for privacy and confidentiality are adequate.

Maybe Exempt under Category 7, contact the IRB office at trammellj@sou.edu

Maybe Exempt under Category 8, contact the IRB office at trammellj@sou.edu

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