**Exempt Determination Decision Charts**

**Is your human subjects research eligible for an exempt determination?**

Yes

Note:

1. Researchers may not make a self-determination of exemption from IRB review. All research with human subjects must be reviewed by the Einstein IRB office and either granted an Exempt Determination or Approval before study procedures may begin.
2. In order for the research to be eligible for an exempt determination, the only involvement of human participants in the research must fall into one or more of the exemption categories.
3. Definitions and other resources are on the IRB website https://www.einstein.yu.edu/administration/institutional-review-board/

No, but some prisoners might incidentally be included

No

No

No

No

Yes

Yes

Yes

Yes

Go to Category 4

ONLY using identifiable data or biospecimens from living individuals for secondary research?

Einstein IRB does not do exempt determinations under categories 7 &8

Go to Category 1

Prisoners your study population?

Not eligible for exempt determination

Collecting data or biomaterials for research via interaction or intervention?

Storing, maintaining or using previously collected identifiable data or biospecimens for research?

Participant population includes prisoners?

Possibly not human subjects research. Contact

irb@einstein.yu.edu

START: You are conducting human participant research

Yes

Yes

Yes

Yes

Yes

No

No

No

No

No

No, but some prisoners might incidentally be included

Are prisoners the study population?

Not exempt under Category

1. Could be Exempt under 2,

3, 5 or 6

Research involves collecting data or biomaterials

Exempt under

Category 1

Research could adversely affect assessment of instructors?

Research could adversely affect student learning?

Participant population includes prisoners?

Research examines normal education practices?

Research conducted in normal educational settings?

**Normal educational practices: Does Exemption 1 apply? [45 CFR 46.104(d)(1)]**

Yes

No

No

No

Yes

Yes

Yes

No

Yes

Yes

Yes

No

Yes

No

Yes

No

No

Prisoners are not the intended population for the research

Not exempt under

Category 2. Apply for

regular IRB review

Minors enrolled

in the study?

Involves survey or interview procedures?

Are provisions

adequate?

Exempt under

Category 2

Limited IRB review for

adequate provisions to

protect the privacy of subjects

and to maintain the

confidentiality of data

Could disclosure reasonably place participants at risk?

Observations of public behavior?

Involves educational tests?

Record personal identifiers?

Minors enrolled in the study?

Not exempt under Category 2. Apply for regular IRB review

Researchers participate in the observed activities?

Research involves collecting data

(or biomaterials) but not Exempt

under Category 1

**Surveys, tests, observations ONLY: Does Exemption 2 apply? [45 CFR**

**46.104(d)(2)]**

No

No

Yes

Yes

Yes

Is data ONLY collected through verbal or written or AV recordings?

Full purpose of the study disclosed at consent?

No

Yes

No

Yes

Yes

No

No

No

Yes

Yes

Yes

Yes

Yes

Yes

No

No

No

No

No, but some prisoners might incidentally be included

Personal identifiers recorded?

Could disclosure of participants’ responses reasonably place them at risk?

Limited IRB review for adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

Are provisions

adequate?

Exempt under

Category 3

Are the interventions **benign**?

Involves only **behavioral** interventions?

Participants agree to the intervention in advance?

Participants Informed that they will be unaware of or misled regarding research purpose?

Not exempt under Category 3

Apply for regular IRB review

Not exempt under Category 3

Apply for regular IRB review

Prisoners the intended study population?

Minors enrolled

in the study?

Study population includes prisoners?

Collecting information, but research is not eligible for Category 1 or 2 exemption

**Benign Behavioral Interventions: Does Exemption 3 apply? [45 CFR 46.104(d)(2)]**

No

Yes

Yes

Yes

No

Not exempt under Category 4

But may be eligible for expedited review and a waiver of informed consent

No

Can the subjects be re-identified?

Information recorded such that subject identity not readily ascertained?

Data/biospecimens publicly available?

Using IDENTIFIABLE, PRIVATE data or biospecimens for secondary research.

Exempt under

Category 4

**Secondary Research: Does Exemption 4 apply? [45 CFR 46.104(d)(4)]**

Yes

Yes

Yes

Yes

No

No

No

No

Does the protocol include a plan and timeline?

Exempt under

Category 5

Has the project been published on a

publicly available website?

Study, evaluate, improve, examine public benefit or service programs?

Research conducted or supported by a federal agency?

Not exempt under Category 5. Could be Exempt under 6

Collection of information, but not eligible for exemption under Categories 1, 2, or 3

**Public Health or Service Research: Does Exemption 5 apply? [45**

**CFR 46.104(d)(5)]**

No

No

No

Yes

Yes

Yes

Level of additives consumed considered safe by the FDA, EPA or USDA?

Taste or food quality evaluation?

Exempt under

Category 6

Wholesome foods without additives consumed?

Collecting data/

biospecimens for

research

Not exempt under Category 6. Could be Exempt under 2 or 3 or 5

**Food and Taste Evaluation: Does Exemption 6 apply? [45 CFR 46.104(d)(6)]**