

# Completing and Using the Exempt Evaluation Tool

## Contents

Completing and Using the Exempt Evaluation Tool.....	3
Requirements.....	3
Title .....	3
Principal Investigator .....	3
Faculty Sponsor.....	3
Start & End Date .....	4
Summary .....	4
Exempt Evaluation Tool Guidance – Categories of Exempt.....	4
General.....	4
G1. Does your study meet the Federal definition of research?.....	4
G2. Does your research involve the use of human subjects? .....	5
Prisoner Involvement in Research .....	6
P1. Does your research include prisoners as subjects? .....	6
P2. Is the inclusion of prisoners as subjects incidental?.....	6
Exempt Category 1 – Research in an Established Education Setting.....	6
E1. Is your study conducted in a traditional educational setting (classroom, seminar, lecture, afterschool program, etc.) that involves normal educational practices?.....	6
E2. Will the research likely adversely impact students’ opportunity to learn?.....	7
Category 3: Benign Behavioral Intervention.....	7
B1. Does your study include a benign behavioral intervention that includes data collection through verbal or written responses, or audiovisual recording? NIH sponsored Clinical Trials do not qualify for exempt status. ....	7
B2. Does your subject population limited to adults?.....	7
B3. Does your study involve deception?.....	7
B4. Will the subjects be aware that deception is involved in your study? .....	8
B5. Is the data identifiable? .....	8
B6. Does disclosure of this data introduce risk or harm to the participant?.....	8
Exempt Category 2 – Educational Testing, Surveys, Interviews or Observation .....	8
S1. Does your study involve the use of surveys, interviews, educational tests, or observation of public behavior?.....	8

S2. Does your study population include children? .....	9
S3. Does your study involve educational testing which is publically observable with no intervention? .....	9
S3/4. Is the data identifiable? .....	9
S4/5. Does disclosure of this data introduce risk or harm to the participant?.....	9
Exempt Category 4 – Secondary Use Research .....	9
D1. Does your study involve the use of biospecimen or private information? (This data must exist as of today.).....	9
D2. Are the biospecimen and/or pre-existing dataset(s) publically available? .....	10
D3. Is the data collected on behalf of a government agency, or is the research involving the use of this secondary data being conducted by a Federal agency? .....	10
Exempt Category 6 – Taste and Food Quality.....	10
F1. Is your study an evaluation of taste, food quality, or consumer acceptance? .....	10
F2. Does the food being evaluated contain any additives? .....	10
F3. Does the food contain additives that are above the level found to be safe by the FDA, EPA, or the Food Safety and Inspection Service of the U.S. Department of Agriculture? .....	10

# Completing and Using the Exempt Evaluation Tool

## Requirements

Investigators are required to review and adhere to the policies outlines in the [Investigator Responsibilities for Exempt Research](#). Any investigator involved in the conduct of human subject research is required to complete the [Human Subject Training](#); this includes Faculty Sponsors regardless of their involvement with the research.

## Title

Your Exempt Evaluation should contain a unique title that easily distinguishes this study from your other research activities. Use the summary section to provide supplemental information or context for your study.

## Principal Investigator

Any member of the MIT community may serve as a Principal Investigator (PI) on an exempt research, though not all investigators have automatic PI Status. PI status is automatically granted by MIT for Faculty, Senior Research Scientists (SRS), and Principal Research Scientist (PRS).

Investigators with non-PI status appointments (e.g. undergraduate and graduate students, post-docs, visiting scholars) may require oversight by a faculty sponsor. Research efforts led by undergraduate and graduate students, post-docs, visiting scholars must seek a faculty sponsor prior to submission. Those with non-faculty appointments may also require a faculty sponsor and are reviewed by the COUHES office on a case-by-case basis.

## Faculty Sponsor

Research led by students or investigators without [PI Status](#) requires oversight by a Faculty Sponsor.

Faculty Sponsor responsibilities include:

1. Oversight of all research related activities.
2. Knowledgeable of the rules and regulations governing human subject research.
3. Evaluating if the investigators have sufficient knowledge and experience to conduct the propose research.
4. Ensuring the research activities are conducted within the scope of the submitted Exempt Evaluation.
5. Monitoring the progress of the research.
6. Addressing any concerns or issues and conduct follow-up, as necessary.
7. Reporting any adverse events to COUHES.
8. Providing ongoing supervision of the study.

## Start & End Date

Exempt Evaluation must be submitted prior to the commencement of the research. Research begun before submitting the Exempt Evaluation is a violation of COUHES policy and the Investigator Responsibilities. The end date is an estimation of the completion of the project in its entirety. If research efforts continue beyond the anticipated end date, investigators are required to submit a new Exempt Evaluation.

## Summary

The summary activities should be written in lay language and include information that would allow your Faculty Sponsor and COUHES to distinguish from other submissions. The summary text cannot exceed 1250 characters.

The summary should include:

- Description of research purpose
- Research activities, e.g. interviews, surveys, educational testing, observation, data analysis, etc.
- Research population
- Duration of any intervention

## Exempt Evaluation Tool Guidance – Categories of Exempt

### General

#### G1. Does your study meet the Federal definition of research?

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Examples of generalizable knowledge may include the collection of data for dissertations and publications.

Research includes formal interviews, responses to questionnaires, and related activities that may be quantified as part of study data.

COUHES does not consider surveys, questionnaires or interviews to be research if (1) they are carried out as part of the administrative responsibility of the investigator, AND (2) the data gathered are non-sensitive and will be used for MIT purposes only. For these purposes, “sensitive” data include, but are not limited to, data relating to academic performance, religion, ethnicity, sex, alcohol consumption and the use of illegal drugs.

Following activities are deemed not to be human subject research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship)

Research does not include interviews used to provide quotes or illustrative statements — as in journalism or related projects.

### **Federal Regulation**

45CFR46.102(l)

### **G2. Does your research involve the use of human subjects?**

Human subject means a living individual about whom an investigator is 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.

**Intervention** includes physical procedures by which data are gathered and manipulation of the subject or their environment for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and subject.

**Private information** includes information about behavior which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

Data about individuals collected through online platforms is considered private information and requires COUHES review. This includes data collection through Facebook, Twitter, private or public forums, chatrooms, or app data.

**Identifiable private information or biospecimen** is data from which the identity of the subject is or may readily be ascertained by the investigator.

COUHES does not consider research to involve "human subjects" where the research uses only coded private data, specimens or cells: provided that (1) the data, specimens or cells were not collected specifically for the proposed research by an intervention with a living individual, AND (2) the researcher cannot identify the individual(s) from whom the data, specimens or cells were obtained (i.e. the key to decipher the code has been destroyed or an agreement exists prohibiting the release of the key to investigators).

### **Federal Regulation**

(45 CFR § 46.102(f))

## Prisoner Involvement in Research

### P1. Does your research include prisoners as subjects?

Prisoners are individuals involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.

Those who fall into the following categories are considered prisoners:

- Individuals detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration
- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration
- Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

### Federal Regulation

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects ([45 CFR 46.303\(c\)](#)).

### P2. Is the inclusion of prisoners as subjects incidental?

Research activities are not intended to study prisoners specifically but will include the prisoners as part of the general population.

### A Non-exempt Determination

Prisoners are considered a vulnerable population and therefore require additional safeguards.

### Exempt Category 1 – Research in an Established Education Setting

#### E1. Is your study conducted in a traditional educational setting (classroom, seminar, lecture, afterschool program, etc.) that involves normal educational practices?

Research involving normal educational practices include studies on regular and special education instructional strategies, the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Children can be included in this category of research.

Research under this category of exempt does not include novel or experimental teaching methods, techniques or tools.

## E2. Will the research likely adversely impact students' opportunity to learn?

Research should not adversely impact students' opportunity to learn required educational content or interfere with assessments conducted by educators.

### A Non-exempt Determination

If the research may impact a students' opportunity to learn, it does not meet the criteria for exempt status.

## Category 3: Benign Behavioral Intervention

B1. Does your study include a benign behavioral intervention that includes data collection through verbal or written responses, or audiovisual recording? NIH sponsored Clinical Trials do not qualify for exempt status.

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse and lasting impact on the subjects, and the investigator has no reason to believe the subject will find the interventions offensive or embarrassing. Behavioral interventions in research may be used to study psychological states and processes, cognition, ideas and attitudes or behavior that do not include any physical tasks or manipulations unless they are resulting from the behavioral intervention. For example, research activities that include solving puzzles or playing games under various conditions, data entry by the subject, or data collected by verbal responses or audiovisual recording would meet this definition of exemption. Research activities involving devices that fall under this category of exemption **must** meet the definition of [minimal risk](#).

Activities involving alternations in the subject's physical or sensory environment may be exempt under this category **only** if the alterations are not harmful, painful or cause distress.

Research activities involving deception, the collection of physiological data (e.g.. EEG, EKG, wearable devices, blood pressure monitors, fitness trackers or sensors, children, or personally-identifiable data) or bodily fluids **are not** exempt under this category and requires Comprehensive Review.

B2. Does your subject population limited to adults?

Subject population is 18 years of age or older.

### A Non-exempt Determination

Research activities within exempt category 3 is limited to adults only and cannot include children.

B3. Does your study involve deception?

Research activities involve deception if investigators provide false, incomplete or ambiguous information deliberately misleading participants.

In some types of studies, the nature or validity of research may require that subjects are not fully informed in advance about the intent of and/or procedures in a study.

Such incomplete disclosure is justified only if it is clear that:

- Incomplete disclosure is truly necessary to accomplish the goals of the research,
- There are no undisclosed risks to subjects that are more than minimal, and

Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

#### B4. Will the subjects be aware that deception is involved in your study?

Subjects must prospectively agree to participate in research activities in which the subject is informed that they will be unaware or misled regarding some aspects of the research.

#### **A Non-exempt Determination**

If the research includes deception but subjects do not first prospectively agree to the deception, it does not meet the criteria for exempt status.

#### B5. Is the data identifiable?

Identifiable data includes information that may allow the identity of the subject to be readily ascertained by the investigator or through associated research data.

#### B6. Does disclosure of this data introduce risk or harm to the participant?

Any disclosure of the human subjects' responses outside the research setting would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

This may include surveys regarding illicit activities, sexual orientation or identity and religious or political preferences. Investigators should take special consideration of cultural or societal norms in the context of their research when assessing potential risk or harm.

#### **A Non-exempt Determination**

If the disclosure of the subjects' responses outside the research could reasonably place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation, the research does not meet the criteria for exempt status.

### Exempt Category 2 – Educational Testing, Surveys, Interviews or Observation

#### S1. Does your study involve the use of surveys, interviews, educational tests, or observation of public behavior?

This category of exempt includes the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures or observation of public behavior. The information obtained must be recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects and any disclosure of the human subjects' responses outside the research would not place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Children can be included in this category of research as long as the investigator is no direct involvement or interaction with the subjects.

This category may include interviews with public officials, community outreach surveys and demographic surveys. Evaluations and observations of commonly used educational practices and tools would also be exempt under this category.

## S2. Does your study population include children?

Study population is 17 years of age or younger. Children are defined as a vulnerable population and thus require additional safeguards in research settings.

## S3. Does your study involve educational testing which is publically observable with no intervention?

Educational testing includes cognitive, diagnostic, aptitude, or achievement. Observational research cannot involve an interaction between the investigator(s) and subject(s).

Examples of this type of research include observations of exhibits, seminars, workshops, and educational tools.

### A Non-exempt Determination

If the research activities involve children but are not limited to educational tests, observation of public behavior or involves an intervention by the investigator, it does not meet the criteria for exempt status.

## S3/4. Is the data identifiable?

Identifiable data includes information that may allow the identity of the subject to be readily ascertained by the investigator or through associated research data.

## S4/5. Does disclosure of this data introduce risk or harm to the participant?

Any disclosure of the human subjects' responses outside the research setting would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

This may include surveys regarding illicit activities, sexual orientation or identity and religious or political preferences. Investigators should take special consideration of cultural or societal norms in the context of their research when assessing potential risk or harm.

### A Non-exempt Determination

If the disclosure of the subjects' responses outside the research could reasonably place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation, the research does not meet the criteria for exempt status.

## Exempt Category 4 – Secondary Use Research

### D1. Does your study involve the use of biospecimen or private information? (This data must exist as of today.)

Data must exist prior to the start of the research project and no new data collection can occur during the research.

**Private information** or **biospecimen** is data from which the identity of the subject is or may readily be ascertained by the investigator.

## D2. Are the biospecimen and/or pre-existing dataset(s) publically available?

Publically available means data is readily accessible by the public, without prior authorization, login, or agreement and subjects do not have a reasonable expectation of privacy.

Data about individuals collected through online platforms is considered private information and requires COUHES review. This includes data collection through Facebook, Twitter, private or public forums, chatrooms, or app data.

## D3. Is the data collected on behalf of a government agency, or is the research involving the use of this secondary data being conducted by a Federal agency?

Research in this category may include government-generated or government-collected information obtained for non-research activities. These types of studies may seek to evaluate:

- Public benefit or service programs
- Procedures for obtaining benefits or services under these programs
- Changes or alternatives to these programs including

### **A Non-exempt Determination**

Research involving the use of existing biospecimens or private information that is not already publically available, de-identified, or collected on behalf of a government agency does not meet the criteria for exempt status.

## Exempt Category 6 – Taste and Food Quality

### F1. Is your study an evaluation of taste, food quality, or consumer acceptance?

Study activities are limited to taste testing foods and designed to evaluate subjects' preference and not to measure health outcomes. This excludes research involving supplements or vitamins.

### F2. Does the food being evaluated contain any additives?

Additives are substances added to food to preserve flavor or enhance taste.

### F3. Does the food contain additives that are above the level found to be safe by the FDA, EPA, or the Food Safety and Inspection Service of the U.S. Department of Agriculture?

Investigators must confirm with the appropriate agency that the additives included in the research are within the acceptable levels noted by the agency or federal department.

### **A Non-exempt Determination**

Research evaluating the taste, food quality or consumer acceptance that contains additives outside the levels found to be safe by the FDA, EPA, or the Food Safety and Inspection Service of the U.S. Department of Agriculture does not meet the criteria for exempt status.