# PROTECTION OF HUMAN SUBJECTS

MEETING INSTITUTIONAL REVIEW BOARD (IRB) REQUIREMENTS FOR DISSERTATION RESEARCH

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# Ethical Standards for Research with Human Subjects

- Decision for or against conducting the investigation
- Assuring freedom from coercion to participate
- Fairness and freedom from exploitation in the research relationship
- Confidentiality of the data and anonymity of the individual subject

# DEFINITION OF HUMAN SUBJECT

A human subject means a living individual about whom an investigator conducting research obtains data through an intervention with individual or identifiable private information

# 4 VULNERABLE SUBJECTS

When some or all of the subjects are **likely to be vulnerable to coercion or undue influence**

- Includes children, pregnant women, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons

Additional safeguards must be included in the study to protect the rights and welfare of these subjects.

# 5 RISK

A subject is considered at risk if they are exposed to the possibility of harm as a consequence of the research activity

Physical, psychological, sociological, or other

# MINIMAL RISK

**Is when the anticipated risks of harm are not greater than**

those ordinarily encountered in daily-life or during the performance of routine physical or psychological examinations or tests

# 7 MINIMIZING RISKS OF HARM

- Screening out subjects who may be particularly susceptible to the risk
- Continuous monitoring of subject during data collection procedures
- Minimizing the level and duration of the risk
- Use of measures to detect and correct any consequences of the risk
- Consulting with colleagues for techniques of minimization

# PRIVATE INFORMATION

Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place

Information which has been provided for specific purposes for which the individual can reasonably expect will not be made public

# ANONYMITY AND CONFIDENTIALITY

## Anonymity

- when a person is not named or identifiable in any manner to the researcher

## Confidentiality

- when personally identifiable and private information is entrusted to an investigator to not disclose it.

# CONFIDENTIALITY

## Routine practices for assuring confidentiality

- substituting codes for identifying information;
- removing cover sheets (containing names and addresses);
- limiting access to identified data;
- storing research records in locked cabinets.

## Signed consent forms are records that contain confidential information

- Provide Informed Consent though don't need to obtain signature

# DATA SECURITY

**Describe procedures through which the security of the data will be maintained**

- for both hard copies and electronic formats

**Security procedures include:**

- Maintaining separation of subject identity from subject data
- Storing data securely for the minimum required time (3 years) though not keeping duplicate copies on multiple devices or recordings after data is transcribed.
- Delineation of the terms of data access and use, if data are going to be archived for use by you and/or other investigators in the future

# INFORMED CONSENT

- Explanation of the purpose and duration of research activities
- Description of any reasonably foreseeable risks or discomforts
- Description of any benefits which may reasonably expected
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- Capturing subject signature is NOT a requirement

# 13 INFORMED CONSENT PROCESS

An active process of sharing information between the investigator and the prospective subject

Can occur via one or more of the following modes of communication (among others)

- Face-to-face contact; electronic or snail mail; video; fax; posting to social media

Prospective subjects should be provided with ample opportunity to ask questions and seek clarification from the investigator

Prospective subjects should be in a position to freely decide whether to engage in the research, or later, to withdraw or continue to participate.

IC process should ensure that all critical information about a study is completely disclosed

# GENERAL REQUIREMENTS FOR INFORMED CONSENT (WHETHER WRITTEN OR ORAL)

(1) Before involving a human subject in research.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject **sufficient opportunity to discuss and consider whether or not to participate**

- **and that minimize the possibility of coercion or undue influence.**

(3) The information that is given to the subject **shall be in language understandable to the subject**.

(4) The prospective subject **must be provided with the information that a reasonable person would want to have** in order to make an informed decision about whether to participate,

- and an opportunity to discuss that information.

(5) Informed consent must begin with a **concise and focused presentation of the key information** that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research.

- This **must be organized and presented in a way that facilitates comprehension**.

(6) **No informed consent may include any exculpatory language**

- through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Explanation of the purpose and duration of research activities

Description of any reasonably foreseeable risks or discomforts

Description of any benefits which may reasonably be expected

A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

# 15 BASIC ELEMENTS OF INFORMED CONSENT

# *DOCUMENTATION* OF INFORMED CONSENT

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.

That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context;

If the subjects are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

- Non-human subject research
- Research with minimal risk which qualifies as *Exempt Research*
- Research with minimal risk and involves an *Expedited Review*
- Research requiring *Full Review*



# DIFFERENT CLASSIFICATIONS…

STANDARDS/CRITERIA FOR APPROVAL ARE IDENTICAL FOR EACH REVIEW PROCESS

## Exempt (from Full Review)

- One reviewer

## Expedited Review

- Two reviewers

## Full Review

- Requires review by a quorum of committee members and discussed synchronously

Dr. Kay Davis

# NON-HUMAN SUBJECTS RESEARCH

If your research does *not* involve the participation of human subjects **and** you are *not* using/collecting any data that has been obtained from individual participants, then your research is <u>not</u> subject to IRB review for approval.

- May require screening by the IRB
- If required: a form is submitted along with either a one page abstract (outlining the study's research design and methodology) and signed by Primary Investigator and by Faculty Chairperson

Dr. Kay Davis

# COMMON NON-HUMAN SUBJECTS RESEARCH DESIGNS

- Digital artifacts as source of data
  - Artifacts from on-line communities or organizations (documents, narrative text, images); Social-Media Posts
- Secondary Analysis of existing datasets
  - Is considered non-human subject research as data residing in datasets have been de-identified and most often "aggregated".
- Systematic Reviews
  - Involves a clearly formulated research question with systematic and explicit methods to identify, select, and critically appraise relevant research. Outcome data from completed, selected studies is gathered and analyzed.

# EXEMPT RESEARCH

There are 8 categories that qualify for exempt status

To qualify for review at the exempt level, the research must not be greater than minimal risk and must fall into one or more of the exempt categories [45CFR 46.101(b)]

Exempt review is not allowed if the study involves vulnerable populations, including children

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| Survey research with children is not considered exempt | **However**, observation of children is allowed if there is no participation by the researcher in the activities being observed |

# EXEMPT CATEGORY 1: RESEARCH IN EDUCATIONAL SETTINGS INVOLVING NORMAL EDUCATIONAL PRACTICE

Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

This includes most research on regular and special education instructional strategies, and research on the effectiveness of, or the comparison among instructional techniques, curricula or classroom management methods.

# EXEMPT CATEGORY 1: EDUCATIONAL PRACTICES

includes the caveat that there must not be any impact of subject's opportunity to learn or any negative impact if the research involves an evaluation of the instructors.

there must be protection against negative impact on employment if instructors are being evaluated.

# EXEMPT CATEGORY 2: SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, PUBLIC OBSERVATIONS

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
- any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

# 25 EXEMPT CATEGORY 2: SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, PUBLIC OBSERVATIONS

Category involves data collection interactions: verbal and written responses

The data collection can include audio or video recordings.

- *However, video recordings pose increased risk and additional protections must be included*

Research involving "interventions" that manipulate the environment or physical procedures that elevate the level of risk would not be approvable under this category (see category 3).

Research involving children is eligible for this exemption only when it relates to educational tests or observations in which the investigators don't participate in the activities being observed.

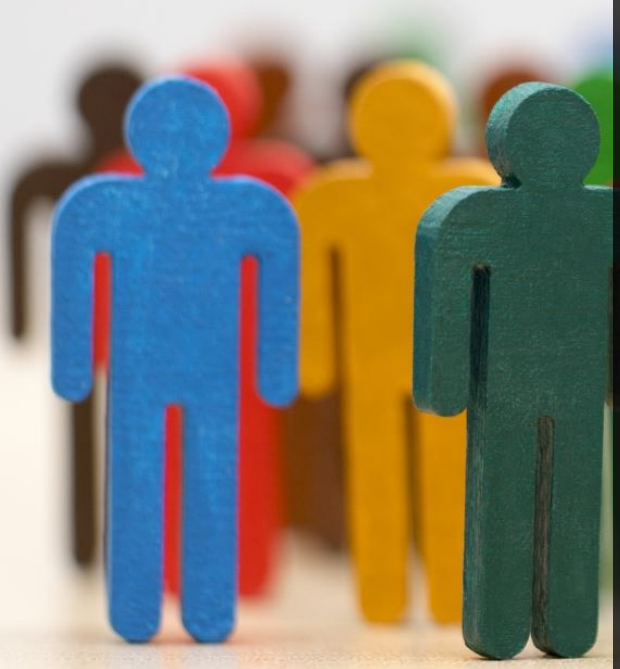
# EXEMPT CATEGORY 3: BENIGN BEHAVIORAL INTERVENTIONS

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.

One of the following criteria must be met:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- OR
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, with additional confidentiality procedures used and any disclosure of the human subjects' responses outside the research 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.

# BENIGN BEHAVIORAL INTERVENTIONS ARE…



- brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects;
  - and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing
- examples include
  - having the subjects play an online game, having them solve puzzles under various noise conditions, having them participate in an educational intervention or having them decide how to assign activities among team members

# EXEMPT CATEGORY 4: SECONDARY RESEARCH



- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or
  - if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

# CATEGORY 5: PUBLIC BENEFIT OR SERVICE PROGRAM

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs

# CATEGORY 6: CONSUMER ACCEPTANCE, TASTE, AND FOOD QUALITY STUDIES

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

# EXEMPT CATEGORIES 7 & 8 INVOLVING: SECONDARY RESEARCH REQUIRING BROAD CONSENT

Category 7: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance to IRB approval; (ii) Documentation of informed consent or waiver of documentation of consent was obtained.(iii)

Category 8: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii)

# IMPORTANT NOTE ON CATEGORIES 7 & 8 INVOLVING BROAD CONSENT

- Because there is no guidance from OHRP and because of the implications of tracking individuals who do not provide consent and excluding their data from all future research, ***Pepperdine will not mandate nor implement broad consent at this time.***
- *Exemption categories 7 and 8, which rely on Broad Consent will not be available in the Pepperdine eProtocol system.* Investigators can continue to use biospecimens that are coded or to seek waiver of consent for use of biospecimens with identifiers retained consistent with current practices.

# WHAT ISSUES ARE CONSIDERED DURING AN IRB REVIEW? (45 CFR 46.111)

- Study design
- Investigator qualifications
- Selection of subjects
- Risks
- Benefits
- Informed consent process
- Subject privacy/confidentiality
- Data confidentiality
- HIPPA applicability & procedures

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# COMMON ERRORS IN IRB APPLICATION

Insufficient information provided and/or the specific application questions are not being answered

Lack of detail about specific procedures to which participants will be exposed

- What is the nature, timing, and sequencing of all proposed contacts with participants?

Failure to allow sufficient time for review

- (e.g., submitting an application a week before you wish to begin data collection)

# KEY TO SUCCESS

1. Understand the guidelines
2. Know the details of your proposed methods
3. Anticipate the possible risks to your subjects
4. Use the required forms and procedures
5. Allow sufficient time for review process

# 36 VISIT THE UNIVERSITY IRB WEBSITE

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| **Institutional Review Board (IRB) website: explains purpose of IRB; The Six Steps to IRB Success and links to other resources including link to ePROTOCOL** | **https://community.pepperdine.edu/irb/** |
| **Direct link to CITI online human subjects training site** | **https://about.citiprogram.org/en/homepage/** |