TEACHERS COLLEGE
COLUMBIA UNIVERSITY
525 West 120th St. New York, NY 10027
212-678-3000 | www.tc.columbia.edu

TEACHERS COLLEGE NEW IRB RULE EXEMPT REVIEW CHECKLIST

INTRODUCTION

Researchers can use this checklist to determine whether their Human Research is exempt from IRB review and ensure their protocol is complete prior to submission for Teachers College, Institutional Review Board (IRB) consideration.

Each exempt protocol is reviewed on a case-by-case basis. IRB reviewers will determine, based on the actual submission, if the protocol is exempt or expedited. Following these guides does not guarantee a protocol will be approved or that a researcher will have a flawless review process. It does however, offer some suggestions on how to frame materials for formal IRB review.

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A project requires IRB review if it includes both research and human subjects. The Institutional Review Board (IRB) will make the final determination of whether a study requires review.

VULNERABLE POPULATION DESCRIPTION IN EXEMPT RESEARCH

RESEARCH INVOVLING INDIVIDUALS WITH IMPAIRED DECISION-MAKING ABILITY

- □ Reviewed on a case-by-case basis. However, all adults, regardless of diagnosis or condition, should be presumed competent to consent to participation in research unless there is evidence of serious disability that would impair reasoning or judgment. The IRB will take into consideration whether it is appropriate for investigators to utilize proxy consent.

RESEARCH INVOLVING PREGNANT WOMEN, FETUSES, & NEONATES

- □ Eligible for exempt under all exempt categories.

RESEARCH INVOLVING PRISONERS

- □ Eligible for exempt under all exempt categories when research is aimed at involving a broader subject population that only incidentally includes prisoners.

RESEARCH INVOLVING CHILDREN

- □ Children allowed in exemption categories 1, 4, 5, 6, 7, & 8
- □ Limitations/exclusion of children in category 2 & 3.

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EXEMPTION CATEGORIES

To qualify for exemption, the research must fit into one or more of the following categories and involve only Minimal Risk[1] to subjects.

CATEGORY 1

Research in established or commonly accepted education settings that involves normal educational practices that are:

- □ Not likely to adversely impact students' opportunity to learn or assessment of educators.

CATEGORY 2

Research only includes educational tests, surveys, interviews, observation of public behavior:

- □ One of the following criteria are met[2]:
  - □ Recorded information cannot readily identify the subject (directly or indirectly/linked).
  - □ Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation).
- □ …and ALL of the following are met:
  - □ Data collection only;
  - □ Surveys & interviews do not involve children;
  - □ Educational test or observations of public behavior only include children when investigators do not participate in activities being observed.

CATEGORY 3

Research involving benign behavioral interventions through verbal, written responses, (including data entry or audiovisual recording) from adult subjects who prospectively agree:

- □ One of the following criteria are met:
  - □ Recorded information cannot readily identify the subject (directly or indirectly/linked).
  - □ Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation).

[1] Minimal risk is defined by the federal regulations (45 CFR 46) as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

[2] According to federal regulations, a third criterion exists in which, "Information is recorded with identifiers & IRB conducts Limited Review". Teachers College does not conduct limited review and this criterion does not pertain to Teachers College researchers.

- ☐ …and ALL of the following are met:
  - ☐ No children;
  - ☐ No medical interventions;
  - ☐ Unlikely that subjects will find interventions offensive or embarrassing;
  - ☐ Subjects prospective agreement will be obtained;
  - ☐ Benign behavioral interventions will be:
    - Brief in duration
    - Painless & harmless
    - Not physically invasive
    - Not likely to have a significant adverse impact on subjects

CATEGORY 4

Secondary research use of identifiable information or identifiable biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, and ONE of following criteria met:

- ☐ (i) Biospecimens or information is publically available.
- ☐ (ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked);

  AND

- ☐ Investigator does not contact subjects and will not re-identify the subjects.
- ☐ (iii) Collection and analysis involving investigators' use of identifiable health information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes";

  AND

- ☐ Investigator obtains HIPAA authorization or HIPAA waiver.
- ☐ (iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities[3]

CATEGORY 5

Research and demonstration projects supported by a Federal Agency/Dept. AND designed to study, public benefit or service programs.[4]

CATEGORY 6

Taste and Food Quality evaluation and consumer acceptance studies if ONE of the following:

- ☐ A wholesome food without additives is consumed.

[3] If research generates identifiable private information it is subject to specified federal privacy laws (Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.)
[4] Must be posted on a federal web site prior to the research commencing

☐ 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.

CATEGORY 7

Storage or maintenance for secondary research for which broad consent is required.

CATEGORY 8

Secondary research for which broad consent is required.