

# E-PROTOCOL TIP SHEET FOR DETERMINING LEVEL OF IRB REVIEW

***This tip sheet provides information to assist students in determining what type of IRB review (exempt or expedited) is required for their research and explains the IRB process.***

## ***Read these tips before you begin...***

- Determine appropriate level of IRB review (Non-Human Subject Research, Exempt, Expedited, or Full Review). A study may fall under more than one category within that review level (Exempt, Expedited).
- Expedited Review is a type of IRB review. It **does not** mean a faster review.
- Allot enough time for the IRB submission and review process. The IRB review process takes approximately two to three weeks.
- Exempt Applications require one faculty reviewer, while expedited applications require two faculty reviewers.
- It is highly encouraged that researchers provide subjects with information sheets when conducting research that is determined to be exempt by the GPS IRB. An Informed Consent must be provided when interviews are being recorded.
- If the interaction with the subject takes place **remotely** or **virtually**, in most situations, the researcher provides the participant with an **“Information Sheet.”** As such, **written signed consent is NOT required.**
- Some site/schools require permission to conduct research even if the research is exempt from IRB review.
- **All colleges and universities including community colleges** have either an Institutional Review Board (IRB) or a research review board which you will likely need approval from in order to do research at that specific institution.
- If accessing LAUSD resources to conduct research studies, the researcher must also obtain approval from the LAUSD Committee for External Research Review (CERR)
- Adhere to [FERPA](#) (Family Educational Rights and Privacy Act) and [PPRA](#) (Protection of Pupil Rights Amendment) requirements, as applicable.
- Adhere to HIPPA Privacy Rules which informs individuals about the uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities.

## **EXEMPTION CATEGORIES 1-4**

**Exemption Category 1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

### ***Tips for Exempt 1***

- Research must pertain to what is being done in the classroom, not what subjects do on personal time.
- Research can pertain to educational meetings.
- Observations of classroom and educational meetings or activities are allowed.
- Minors can be included as long as the study does not involve their direct participation.
- If enrolling non-English speaking subjects, all study materials must be translated in the subjects’ native language.
- If accessing student grades, signed parental permission is required per [FERPA](#). Self-reporting of grades/GPA does not require parental permission.

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## *Examples*

- 1) A study focusing on the extent to which Hawaiian language and culture is used in a middle school math class. Math teachers will be the participants of the study. Research methodology includes classroom observations and interviews of math teachers focusing on classroom management methods and how teachers incorporate Hawaiian language and culture into their teaching.
- 2) A study to describe actions taken by District and site administrators to promote and provide in-depth descriptions on how to teach 21st century skills while providing standards based education. The methodology involves interviews of district and site administrators, document analysis, and observations (observations of faculty meetings, general environment, human factors on the site, and instructional practices in the classroom). Interview questions focus on various aspects of the standards based education and how the job and school environment relate to those standards based educational system. The focus of the observations of the classrooms and faculty meetings is on the effectiveness of the how the education system works.

**Exempt Category 2:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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.

## *Tips for Exempt 2*

- Research involves surveys, interviews with adults (18 and older).
- Research involving educational tests with adults/minors is permitted.
- Observations of public behavior are permitted except for circumstances in which a reasonable expectation of privacy is assumed (i.e. restrooms).
- Minors **cannot** be surveyed nor interviewed.
- Minors **can be** observed as long as the researcher(s) are not interacting with them.
- Data can be identified as long as the responses do not place subjects at risk.
- Studies in which subjects are asked for sensitive information (e.g., drug use, criminal activity, sexual conduct) is not exempt unless the survey/interview is anonymous. Studies that contain identifying information and elicit this type of information require a full board review.
- Informed Consent is required is always required, or if seeking a waiver of informed consent, an application to waive informed consent must be completed.
- If enrolling non-English speaking subjects, all study materials must be translated in the subjects' native language.
- Survey questions and/or interview guides must be submitted for IRB review.

## *Examples*

- 1) A study to determine what policies, procedures and teacher development programs are available regarding bullying behavior. The study is open to teachers, administrators and counselors in grades 4-8 in elementary and middle schools in Hawaii. The study involves a one-time anonymous survey examining how teachers determine which bullying behaviors are "actionable." In addition, the degree to which their decision to report behavioral issues varies by perceptions of school climate (support from counselors, administrators; school rules, school culture).

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- 2) A study to identify types of community college students who place in college math but choose to enroll in remedial/developmental math courses and examine the internal and external factors that contribute to their choice of placement. This is an interview based study of community college students over the age of 18 who have enrolled at a community college in Hawaii. The interview questions will be coded using pseudonyms. Questions will focus on high school experience, transitioning to college, how students prepared for the COMPASS exam, and why they chose to take a remedial math.

**Exempt Category 3:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

## *Tips for Exempt 3*

- Subject must be **elected/appointed public officials or candidates for public office**
- Research involves **surveys, interviews, or educational tests**.
- If enrolling non-English speaking subjects, all study materials must be translated in the subjects' native language.

## *Example*

- 1) A study to identify common characteristics of women superintendents in order to inform women who may be interested in pursuing superintendency. A secondary purpose of this study is to determine the barriers to the superintendency that women encounter. The study is a mixed method design. Quantitative data will be gathered through the use of surveys and qualitative data will be gathered through interviews. Questions will focus on barriers women face in attempting to reach the superintendency, similar characteristics women superintendents' share, such as leadership styles, training, and background, and whether women superintendents identify mentors who impact their ability to carry out their position.

**Exempt Category 4:** 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.

## *Tips for Exempt 4*

- All materials must already exist at the time of IRB submission; no on-going or prospective collection of material is permitted.
- If using sources that are publicly available: Publicly available means that the general public can obtain the data/documents. Sources are not considered publicly available if access to the data/documents is limited to researchers or professionals.
- The information is recorded by the investigator in such a manner that subjects cannot be identified, directly (name, address, student ID or SS#) or through identifiers (code sheets) linked to the subjects.
- An investigator may review identifiable data/documents, but must record information in the research record in a non-identifiable manner. The data extraction must be permanently and completely de-linked at the time of extraction.

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## *Example*

- 1) A study which proposes to access higher education data collected by the Higher Education Research Institute (HERI) at the the surveys allows researchers to identify changes that occur from the freshman year to the senior year. The study allows for the study of changes and development in international students by examining their level of interaction with faculty members. No individual data from the faculty survey will be obtained and all student identifiers have been removed from this study. The researcher will have no access to any links and therefore cannot directly or indirectly identify the subjects.

## **EXPEDITED REVIEW CATEGORIES 6 & 7**

**Expedited Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

## *Tips for Expedited 6*

- Research must be minimal risk. (Risks of participating in the research are no greater than those risks encountered in normal daily life).
- Can involve adults or minors.
- Research using audio, video, or photographs is permitted.
- **A signed Informed, Assent, and/or Parental Consent form is required.**
- If enrolling non-English speaking subjects, all study materials must be translated in the subject's native language.
- If interviews are audio or video-taped, such studies are generally submitted in conjunction with expedited review category 7 (below).

## *Example*

- 1) A study that evaluates the process of an academic preparation program (outreach program) imparting social capital to educationally disadvantaged students. The particular form of social capital to be examined will be the knowledge needed to successfully prepare for college admission. Procedures will include semi-structured interviews, focus groups, qualitative fieldwork / observations, and document analysis. Interviews and focus groups will be conducted and tape-recorded at the office during a summer program. Individual interviews will be conducted with five 12th grade students at each participating school. The focus groups will be conducted with groups of 6 students in grades 10 -11.

**\*\* Note this study would fall under expedited categories 6 and 7\*\***

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**Expedited Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

## *Tips for Expedited 7*

- Research must be minimal risk. (Risks of participating in the research are no greater than those risks encountered in normal daily life).
- Can involve adults or minors.
- Research involves surveys, interviews, and/or focus groups.
- Involves collection of identifiable information.
- An **informed consent, youth assent, parental consent form is always required.**
- If enrolling non-English speaking subjects, all study materials must be translated in the subjects' native language.
- Survey questions and/or interview guide must be submitted for IRB review.
- Details on privacy and confidentiality protection must be submitted to IRB.

## *Examples*

- 1) A study investigating the specific contextual factors of the schooling process that affect the enrollment of gifted Spanish speaking English Learners (EL) in Advanced Placement (AP) classes. Through qualitative interviews and surveys, the study will gather information on what students in grades 9-10 know about AP courses and their ability to excel in AP classrooms. In addition to interviewing students, the study will interview teachers of gifted Spanish speaking EL students and program coordinators for the purpose of determining their perspectives on the success of gifted Spanish speaking EL students in AP classes. Teachers will be asked to complete a short survey to collect background information on training received and credentials held that may have prepared them to teach EL students.
- 2) A study examining the impact that the Neighborhood Academic Initiative program has on African American male youth's academic achievement and preparation for college. The subject population involves African American males in grades 9-12. An ethnographic approach will be used to understand the relationship between families, students, and the culture of NAI. The PI will be using in-depth interviews, focus groups, participant observations, and document analysis in the study.

## *Contact Information:*

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