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Topic: Making Exempt Determinations

Overview of the Topic

The six categories of exemptions (45CFR46.101(b)(1-6)) are one of the flexibilities built into the human subject regulations. Their origin is interesting – in response to the mandate of reducing regulation by the incoming Reagan administration in 1981, the exempt criteria were developed by OPRR virtually overnight and added to the regulations (personal communication with Charles McCarthy). Exempt means exempt from the regulations, so the requirements of the regulations basically do not apply to exempt research. It does not mean, however, that the researchers can do anything they want, as they must still follow basic ethical principles and IRB and organizational policies. Also remember that even if the study qualities as exempt, HIPAA, FERPA or PPRA requirements still apply.

One common mistake is that IRBs classify some non-human subject research as exempt. If the research does not meet the definition of research or human subjects, or if it does not fall under the regulations (e.g. quality improvement, oral history, journalism) neither the regulations nor exempt criteria apply. Also, if there are no human subjects to protect, for example a completely de-identified data base, it is not human subject research. The criteria in exempt category 4 mention recording the data without identifiers, so the researcher does view identifiers but does not collect them (this is exempt). But again, if the data is de-identified to begin with, it is not human subject research. Of course some projects fall into a gray area and IRBs need to make the best thoughtful decision, perhaps erring on being more protective and calling research exempt to be sure it meets at least basic ethical requirements

Your IRB should have written policies and procedures for the process to determine whether or not an exemption category applies to the research, including a description of the materials for investigators to submit to the designated individual who reviews the materials. Submitted materials should include the protocol, and instruments or lists of variables, the consent form (if applicable), and the character and age of the subjects. The key is to have adequate information to make the exempt determination including confirmation that no identifiers are being collected (when applicable). Also when applicable, the consent form and process must contain enough information to ensure the basic principles of human research protection including 1) the protocol involves research, 2) what the subjects will be asked to do, 3) participation is voluntary, and 4) contact information for investigations and/or IRB. Additionally, SOPs could describe the process to communicate determinations with investigators, including any template letters. Your IRB or organization may require additional ethical or administrative requirements for exempt research.

Your SOPs should designate one or more individuals with the responsibility to make exempt determinations. The persons making exempt determination should be identified either by name, role, or position. These persons are expected to be well-acquainted with the regulations and the exemptions, as well as risk determinations. Investigators do not have the authority to make an independent determination that research is exempt.

When an exemption determination is made, the specific exemption category or categories must be included in the record, as well as who made the determination. It is best practice to briefly document why it meets the exemption category with enough information to be able to defend the exempt determination. Given that adequate materials have been submitted, exempt determinations should be made expeditiously, usually within one week.

A detailed discussion of exempt categories is not feasible here, but for recollection, below is a condensed list of the six categories. However, you should use the complete text of each category, including the limitations, in your SOPs and determinations. You may want to review the complete categories after reading or discussing this issue of IRB EasyEd.

1. Normal educational practices, comparisons of instructional strategies.
2. Educational tests, survey procedures, interview procedures or observation of public behavior.
3. Research involving tests, surveys, interviews or observation of public officials or candidates.
4. Collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.
5. Research and demonstration projects which are led by or subject to the approval of department or agency heads
6. Taste and food quality evaluation

Note that the regulations do not speak to risk in exempt research, although almost universally IRBs consider exempt research to be of the lowest risk. However, category 3, research on appointed, elected, or candidate public officials,

and category 5, approved public demonstration projects may still be exempt even if greater than minimal risk (although you can have organizational policies which are stricter and require a higher level of review). When thinking about low risk, it is useful to use the definition from category 2: [exempt] 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. So, if both the data is collected with identifiers and disclosure involves any of the risks stated, it cannot be exempt. For category 4, collection of existing data or specimens, the limitation is "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." An important point is that the data or specimens must exist at the time of the IRB application.

Subparts B, C, and D address exempt criteria. All exempt categories may include pregnant women. While Subpart C says that research involving prisoners cannot be exempt, most IRBs may classify prisoner research as exempt if it involves only data and no direct contact with prisoners. For children, categories 1,3,4,5,6 may be used but category 2 may not be used except for educational tests or observation of public behavior when the investigator(s) do not participate in the activities being observed. Exemptions 1-5 may not be applied to FDA regulated research, but category 6, food tasting, may be applied. While not outright exclusions, when the research involves deception or incomplete disclosure, student research pools, course credits, research on one's own students, audiotaping or videotaping, or any procedures that may require expedited or full board review, the reviewer should give greater scrutiny as to whether the research can be exempt.

Continuing review is not required for exempt research, although it is best practice to have brief follow-up at 3 years to determine if research has been completed or is ongoing and if any changes have been made which may affect the exempt status. Some organizations require investigators to report when an exempt project has been completed in order to take them off the list of active research at the organization.

Exempt determinations should not be taken lightly and organizations have been cited for incorrect determinations, some leading to very public controversies. A complete exempt policy in your SOPs and expeditious and well documented determinations is a must for quality HRPP and IRB.

Note that the 2015 Notice of Proposed Rule Making proposes changes to the exempt categories. Until, and if, the NRPM becomes regulations, you should continue to follow the current regulatory categories.

Questions for the Exempt Reviewer to Consider

1. Have sufficient materials been submitted to allow for an exempt determination?
2. Are there issues that do not allow the research to be considered exempt (e.g. FDA regulated, children)
3. Does the research project meet the criteria for one of the exempt categories?
4. Is consent required and if so, is the consent form adequate?
5. Is the decision, exempt category and identification of the reviewer documented in the IRB records?

Case Studies

Case 1. An investigator submits a study for an exempt determination involving an anonymous survey of senior high school students about their high school experiences. The survey was not included in the submitted materials. What should the IRB do? Is there any other information the IRB needs to make the exempt determination?

Case 2. A political science professor submits a study of candidates for the State Legislature that includes intelligence tests and interview questions about their finances, past employment, and drug use. Does this study qualify as exempt? Are there additional questions you need to ask to make a determination?

Case 3. A psychology professor proposes to have a confederate ask college students passing by to hold and watch their bicycle while they go into a drug store to pick up a prescription. The confederates are of different races and gender to determine if these characteristics make a difference in people's responses. Does this study qualify as exempt? Would you require consent of the subjects? Would you require a debriefing?

Prospective Thinking: Discuss the most difficult exempt determinations your IRB has faced. Why were they difficult? Were the determinations correct and consistent? What can be done to make these determinations easier (e.g. additional information submitted, additional IRB training, clarification of problematic categories, etc.).