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Exempt Consent Templates and Guidance

Consent Guidance for Exempt Research

Exempt Consent Templates

Consent Guidance for Exempt Research

For exempt research ^[1] that involves interaction with subjects, there usually should be a process to ask subjects to participate and confirm their agreement. However, signed consent is not required for exempt research, and the consent process and documents can be much simpler than those required for non-exempt research.

Verbal or implied consent is usually sufficient for exempt research that involves interaction with subjects. For some purely observational research, consent may not be necessary.

What information should I include in the consent materials?

Include the following information and review the exempt consent templates for sample language.

Required information:

- That the activity involves research and participation is voluntary
- A brief description of the study purpose, and activities or types of questions that will be

asked ? optional when subjects have the opportunity to review a study survey at the time of consent and the purpose of the study is evident from the survey

- If Category 3 (research involving benign behavioral interventions) study involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement (consent) to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
- Why or how the subjects were selected ? optional when evident from description of study purpose or procedures
- Subjects can stop participating at any time and, if applicable, skip survey questions
- Confidentiality of the research data will be maintained
- Name and contact information for the investigator conducting the study and whom to contact with questions (if different)
- IRB contact information
- Identification of UCSF ? optional if evident from the context of the consent process
- Statement of financial interest, only if one exists

Optional information:

- Study title
- How long participation will take ? may be required when participation involves multiple interactions with the subject, or when subjects do not have the opportunity to review the survey at time of consent

What changes are not allowed?

As described on the Modification page ^[2], you can make some minor modifications to the study ? including the consent materials ? without notifying the IRB. However, certain revisions are not allowed in the consent documents:

- Do not remove any of the required consent information (see above).
- Do not add coercive language.
- Do not highlight payment by bold or larger type.

What if I'm enrolling children in my study?

If you are enrolling children in your study and it is appropriate to obtain consent, there generally should be a plan to obtain permission from the parents and the agreement of the children to participate in the study.

Reminders:

- Under the Family Educational Rights and Privacy Act (FERPA, 34 CFR Part 99 ^[3]), schools must have written permission from the parent or eligible student in order to release information from a student's education record.
- Children cannot be enrolled in exempt category 2 research ^[1] (educational tests,

surveys, interviews or observations of public behavior).

Exempt Consent Templates

Note: These templates are appropriate for exempt research [1] only. Use the regular consent and assent form templates [4] for expedited or full committee [1] research studies.

Template by Type of Research	Last Updated
Anonymous Survey	
<ul style="list-style-type: none">• Paper Information Sheet [5]• Email [6]• Online [7]	December 2015
Confidential Survey	
<ul style="list-style-type: none">• Paper Information Sheet [8]• Email [9]• Online [10]	December 2015
Education Survey Information Sheet [11]	December 2015
Focus Group Information Sheet [12]	December 2015
Interview Information Sheet [13]	December 2015
Verbal Consent	
<ul style="list-style-type: none">• Script [14]• Talking Points [15]	December 2015

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Links

- [1] <https://irb.ucsf.edu/levels-review>
- [2] <https://irb.ucsf.edu/modification#exempt>
- [3] <http://www2.ed.gov/policy/gen/reg/ferpa/index.html>
- [4] <https://irb.ucsf.edu/consent-and-assent-form-templates>
- [5] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt-anon-survey-paper.doc>
- [6] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt-anon-survey-email.doc>
- [7] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt-anon-survey-online.doc>
- [8] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt-conf-survey-paper.doc>
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- [10] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt-conf-survey-online.doc>
- [11] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt-education-info-sheet.doc>
- [12] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt-focus-group-info-sheet.doc>
- [13] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt-interview-info-sheet.doc>
- [14] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt-verbal.doc>
- [15] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt-talking-points.doc>