Expedited Categories 5, 6, 7

Office of Human Research Ethics
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THE UNIVERSITY
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at CHAPEL HILL

Expedited Review Categories (DHHS 1998)

1. Studies of drugs and medical devices when no IND or IDE is needed.
2. Blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Biological specimens for research purposes by "noninvasive" means.
4. Data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes. Evaluation of public benefit service programs
6. Data from voice, video, digital, or image recordings made for research purposes.
7. Research employing survey, interview, oral history, focus group, etc.
8. Continuing review of research previously approved by the convened IRB where:
   (a) only-follow-up remains,
   (b) no subjects enrolled, and no additional risks identified, or
   (c) only data analysis remains.
9. Continuing review where:
   (1) not conducted under an IND/IDE,
   (2) other expedited categories are not applicable, and
   (3) Board considers minimal risk.

A few items to keep in mind

- We will speak about the categories individually, however they often occur together within the same study
- In order to qualify for expedited review **all** activities must
  - Fall into the expedited categories
  - Be no more than minimal risk
- The review level applies to the **whole** study. If certain activities could qualify for exemption, but other activities require expedited review, the whole study must be considered expedited.

Expedited Category 5

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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This can include data/specimens collected from another research study.

It's any and all data/specimens that were collected outside of the current research study.

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Many uses of existing data/specimens are exempt under Exempt Category 4.

As a reminder, UNC does not use Exempt Category 4iii (data covered under HIPAA and staying within a HIPAA covered entity) so data from medical records that could be exempted in this way at other institutions cannot be granted an exemption at UNC.

Expedited Category 5

- This category refers to either retrospective **OR** prospective data, as long as the researchers are not collecting the data
- When the data/specimens are identifiable, the reviewer should ensure that there are adequate provisions to protect subject privacy and maintain confidentiality of the data

Expedited Category 5 Examples

- Medical chart review
- Data/specimens from a biorepository or other existing database
- Excess of blood or other specimens collected for clinical care
- Secondary analysis of data from another research study
- Analysis of data originally collected for program evaluation or quality improvement purposes
- Consumer records
- A clinical trial conducted at another institution and UNC's role is only to analyze the data

Expedited Category 5 and HIPAA

- In order to use identifiable data from medical records, investigators must either
  - Obtain HIPAA authorization from participants
  - Obtain a full waiver of HIPAA authorization from the IRB
- If the data custodian requires a full waiver of HIPAA and consent, even if the IRB could otherwise grant it an exemption, expedited review is required
  - CMS data
  - HIPAA Limited Data Sets coming from CDW
- OHRE has guidance for investigators when completing these requests (in section D.3 of the application)

Full Consent and HIPAA waivers

- Per the regulations, to waive or alter consent:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

Full Consent and HIPAA waivers

Consider participants' right to privacy considering their medical records (or other private information)

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Full Consent and HIPAA waivers

- Per the regulations

The requirement to obtain consent must be "impracticable" (nearly impossible), rather than merely inconvenient.

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Full Consent and HIPAA waivers

- What is impracticable?
- Describe the real (not presumed) barriers to obtaining consent, understanding that having limited financial resources to support the consent process does not justify the waiver.
- Questions to consider:
  - Is contact information of potential subjects readily available?
  - Is the contact information likely reliable? Consider the age of the records and the likelihood that the contact information is outdated.
  - Are potential subjects likely to be deceased or lost to follow-up?
  - How many records are required to review? Would the resources required to obtain consent from all subjects exceed reasonable expectations of any research team? (For example, a large data set containing hundreds of thousands of records)
  - Are subjects geographically dispersed? Consider the feasibility of the research team obtaining consent from individuals located outside the local catchment area.
  - Will subjects be burdened?

Full Consent and HIPAA waivers

- Two additional “criteria” are not specific to the waiver but must be addressed in order to receive IRB approval:

- The risk to privacy is reasonable in relation to the importance of the knowledge to be gained.
- Please explain why it would not be possible to conduct the study with only deidentified data.

Alterations to HIPAA

- HIPAA authorizations are required to be signed unless the investigators request a waiver
- In IRBIS, investigators can request this in section D.3 of the application under “a waiver or alteration of elements” and state that they are requesting to waiver the signature requirement of a HIPAA authorization
- If this is done, the HIPAA authorization form must be read to the participants verbatim

Expedited Category 5 Example

A researcher is interested in cross-examining two datasets to evaluate possible correlated factors between homeownership and education level. The researcher will be requesting datasets from a colleague who conducted similar studies in the past. The researcher will combine the datasets based on identifiable participant information (e.g., name, home address, etc.). The IRB will review the data-sharing agreement to ensure secure data transfer and security. In the data-sharing agreement, only two members of the research team will have access to the identifiable data. These two individuals will secure and de-identify the data before sharing it with the rest of the research team. No record of the identifiable data will be maintained. All information will be stored on an encrypted, password-protected device.

Expedited Category 6

Collection of data from voice, video, digital, or image recordings made for research purposes.

Expedited Category 6

Collection of data from voice, video, digital, or image recordings made for research purposes.

This does not apply to existing recordings or photographs

Expedited Category 6

A researcher is interested in studying how expectant parents attain skills in a parenting class. The class focuses on how to care for an infant, how to properly use a car seat, and how to use a crib. The class meets one hour each week for 6 weeks. The class is regularly led by one of the researchers who is trained in child development and infant care. The research team will video record each class, and they will code the recordings to compare the participants' skill development over the six weeks. The videos will only be used for analysis purposes and will not be used outside of the research study. As the researchers will analyze patterns of how the parents improve (or diminish) in their skill attainment over time, participants must consent to be audio/video recorded in order to participate.

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.

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Expedited Category 7

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What is not exempt:

- Using these data collection methods with children or prisoners
- Topics that are too sensitive to be considered for exemptions
- Experiments that rely on deception or withholding of information AND the subject is not prospectively informed
- Using these data collection methods along with other research methods that do not qualify for exemption

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Expedited Category 7

- The reviewer should determine that the collection and use of the data is no more than minimal risk
- When data is collected in a group setting (i.e. a focus group) the reviewer should pay extra attention to whether subjects are being asked to disclose information that could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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Investigators cannot guarantee confidentiality in a focus group setting, and this should always be disclosed in the consent form.

Waiver of Written Documentation of Informed Consent

- Many interview or focus group studies obtain their consent verbally
- Many survey studies embed their consent form within the electronic survey
- Both of these methods (unless an electronic agreement meets the requirements for a signature) require a waiver of signed consent.
- In IRBIS, this is requested in section D.2 of the application
- Even if the written documentation of consent is being waived, this does not mean there will be “less consent.” Consent language must include all of the required elements of consent *unless* investigators request to waive or alter some of these elements.

Waiver of Written Documentation of Informed Consent

- Investigators are *not* obligated to use the UNC consent template. As long as all required elements are present, alternate formats and language can be acceptable.
- This is an option for study teams that want to shorten the consent form.
- Another option that can be used is to "waive or alter elements of consent". In cases where a study is simple and truly minimal risk, investigators can use this to request to waive the requirement to include the "concise summary" at the beginning of the consent form.
  - This should be used sparingly, but can be used for some brief and benign expedited 7 studies (Investigators can make this request in D.3 of the application in IRBIS)

Expedited 7 Example #1

A researcher plans to interview professional athletes about their thought patterns, daily habits, and sleep schedules before and after a game. She would like to video record the interviews and use them as part of the data analysis and in her published materials. She may also refer to the athletes by name (with their consent) and use their direct quotes in the published findings. The researcher plans to attend three games that are open to the public and take notes about the athlete's performance. Any other athletes or individuals at the game will not be observed for research purposes.

Waiver or alteration of elements of informed consent

- There are studies that rely on withholding information or deceiving subjects as part of their study design
- This can be allowed if it meets certain criteria (as previously discussed)
- The investigators should request “a waiver or alteration of elements” (D.3 in IRBIS)
- Reviewers should pay extra attention to these criteria:
  - The research could not practicably be carried out without the waiver or alteration
  - Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

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  - Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

The default is that participants should be fully informed. Ask yourself whether the withholding/deception is truly a necessary part of the study design.

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    alteration
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- Participants should be debriefed and given the full information after their participation is complete.
- If possible, they should also be given the option to remove their data from the study, once they have the full information.

Expedited 7 Example #2

Investigators are interested in increasing STI testing among MSM. They are interested in exploring the “pay it forward” model and the role of gratitude, where patients’ tests are paid for by a previous patient, and they are then offered the opportunity to pay for another patient’s test.

In this study, all participants are offered free STI tests, however the study team manipulates the reason participants are given for the free test. Group A is told that their test is free because a previous patient paid for it. Group B is told that their test is free because the research study will pay for it. All participants will be asked if they are willing to pay for another patient’s test, but are not told that this is part of the research.

References

- Institutional Review Board: Management and Function
- Code of Federal Regulations: 45 CFR 46 – Protection of Human Subjects
- Columbia University IRB

Questions?

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