HOW DETERMINE WHETHER A STUDY IS EXPEDITED VS EXEMPT

Often, the determination of expedited or exempt research categories is a judgment call rather than a hard line regulatory decision. However, the call should always be grounded on the fundamental principle of human subject research (Ethical Principles of the Belmont Report):

- **RESPECT FOR PERSON**
  - Treat individuals as autonomous agents.
  - Protect persons with diminished autonomy
    - In general respect for person is an important requirement for IRB approval of research and premised on:
      - Voluntary consent to participate in research
      - Informed consent to participate in research
      - Protection of privacy and confidentiality
      - The right to withdraw from research participation without penalty
- **BENEFICENCE**
  - Do unto others as you would have them do unto you:
    - Are the research subjects treated the way I would like to be treated in this situation?
    - Are the risks of research justified by potential benefit to the individual and/or society?
    - Does the study design minimize risk and maximize the potential for benefit?
    - Are conflicts of interest managed so that bias in important judgments related to research conduct are unlikely?
- **JUSTICE**
  - Distribute the risks and potential benefits of research equally among those who may benefit from the research
    - The potential risks of research should be borne equally by the members
    - The research project should not systematically select specific classes or types of individuals simply because of their ease of availability or their compromised positions as opposed to reasons directly related to the of our society who are likely to benefit from the problem being studied.
    - The research project does not exclude specific class or type of person who is likely to benefit from research participation or in whom the results of a specific kind of research are likely to be applied.

HOW I DECIDE WHETHER A PROJECT IS EXPEDITED OR EXEMPT ...PERSPECTIVE OF AN IRB REVIEWER

This summary below is designed to help differentiate expedited from exempt studies. The "How I decide whether a project is expedited or exempt" is an example of a possible thought process the IRB might use when reviewing a study. The side by side comparison are intended to highlight the differences between exempt and expedited.

First Level of Assessment:

- Examine the abstract and methodology, and determine if the research meets the federal definition of both:
  - Research and
  - Human subject research.
- If it does not meet both, then it becomes: "NOT" Human Subjects Research (NHSR) and a letter to that effect is provided.

Second Level of Assessment - If the project:

- Meets the definitions of "Research" and "Human Subject Research", and
- It's using data or specimens that are "coded" with no link available to the investigator "NO IDENTIFIERS" and "NOT LINKABLE to INDENTIFIERS"

Then these projects are also NHSR according to DHHS "Coded Specimen Guidance." A letter to that effect is provided.

For projects that still are not eliminated:

- Examine the six exemption categories and reflect on which category this project fits.
- Once an exemption category that fits the project is identified, then
  - Check to see if the subjects are:
  - Vulnerable subjects (vulnerable population)?
  - Children?
  - Whether the investigator is **collecting** and **keeping** identifiers?
  - Whether the information being gathered is of **private** or **sensitive** nature, and
  - Whether there are risks to participants from the information being collected?
    - If the answers to any of these questions are "yes", then the project should not be exempt.

In comparing expedited and exempt projects:

- Exempt studies generally do not collect identifiers, while
- Expedited studies do collect identifiers.
- If the project does not fit any exempt category, or there are yes answers to the questions below:
  - Forward the project as expedited or full board for further determination by IRB staff.

SIDE BY SIDE GUIDE TO DETERMINE EXPEDITED VS EXEMPT REVIEW CATEGORIES

Side by Side Guide to Determine Expedited vs Exempt Review Categories (note: these are general guidelines, there may be exceptions)		
Points to Consider	**Expedited**	**Exempt**
Is it Human Subjects Research?		
It is Research: Meets federal definition of research (systematic investigation for purpose of generalizable knowledge)	X	X
Involves Human Subjects: Meets Federal definition of human subject research	X	X
Research Categories		
Project meets one or more of the expedited research categories	X	
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm (See attached)		
Project meets one or more of the exempt research categories		X
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm (see attached)		
Number of Interactions / Interventions with Subject		
Interactions once (e.g. one time anonymous survey): No retention of personal / contact information (i.e. No identifiers, or Potentially identifiable information)		X
Interaction more than once (i.e. design requires repeated interactions): Retains personal / contact information for additional interaction or follow-up	X	
Analyzing Data only (no interaction with human subjects)		
Anonymous data / de-identified / no identifiers maintained: May qualify as "Not Human Subjects Research" or Coded Specimen Research		X
Data linked to personal information	X	
Level of risk		
Minimal: risks not greater than those encountered in daily life, or routine physical / psychological exams / tests (e.g. interviews about levels of anxiety or depression, surveying children, blood draws)	X	
None or less than minimal: Risk that is less than minimal as defined above (e.g. questionnaire asks for favorite food, # of vacations in past year, etc).		X
Annual IRB Review (continuing review)		
Continuing Review is Required	X	
Continuing Review is NOT required		X

Are the data (questions) collected (asked) sensitive in nature, or identifiable private information?		
Sensitive: Data could put the subject at risk (e.g. job loss, marriage, reputation, etc.)	X	
Not sensitive: Includes innocuous data/questions only (e.g. food preferences, cell phone usage etc.)		X
Identifiable Private Information: Includes information about behavior occurring in a private context, information gathered for specific purposes where the individual expects the information to be kept private (e.g. medical records), and data/info is identifiable (e.g. name/address). NOTE: identifiable information can qualify as exempt if the information is innocuous.	X	X
Intent or use of information gathered		
Generalizable Knowledge: Intend to share information to benefit society.	X	X
Not intended to contribute to generalizable knowledge: Submit a "Human Subjects Research Determination Request".	NA	NA
Who are the subjects?		
Children: *Exempt category 2 is allowable in studies with children, only when there is passive observation and no interaction with the children. Exempt categories 1 and 3 - 6 (45CFR46) can apply to research with children or adults.	X	*X
Pregnant Women (45CFR46 Subpart B): Exempt research is allowable with pregnant women. However, expedited research with pregnant women requires extra considerations (45CFR46.204)	X	X
Prisoners: Research with prisoners cannot be exempt (45CFR46 Subpart A)	X	
Normal: Generally healthy adults without physical / mental impairments	X	X
Consent and Waivers of Consent		
Informed Consent: Includes all required elements of informed consent, signature required	X	
Waiver of Consent, if applicable: Request to waive entire consent process in some cases (i.e. no consent / no signature required).	X	
Waiver of Written Consent, if applicable: Request to waive signature requirement in some cases (i.e. consent without signature).	X	
Information Sheet (alternative / shortened consent): "Alternative" consent (i.e. contains some elements of informed consent, no signature obtained) NOTE: Information sheets usually apply to exempt research, but may be used in expedited research with an appropriate waiver of consent.	X	X
Who Can Approve the Study for the IRB?		
IRB Designee: Includes IRB Chair, Vice Chair, Director, or designated members	X	X
IRB Liaison or IRB Staff: School / department representatives (liaisons) or the IRB staff		X
Research Methods		
Focus groups / Interviews: Anonymity generally allows expedited or exempt	X	X
Voice / Video / Photograph / Recordings	X	X
Involves Deception	X	X
Uses HIPAA identifiers	X	

EXPEDITED RESEARCH CATEGORIES

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?

Chart 2: Is the Human Subjects Research Eligible for Exemption?

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

Chart 8: May the IRB Review Be Done by Expedited Procedures?

Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?

Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?

Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?