

Exempt vs. Expedited Category Guidance

The federal regulations (45 CFR 46) allow certain categories of minimal risk research to be reviewed by a single HSC reviewer. “Exempt” means that a study is not required to comply with the federal regulations, but the research must still be reviewed by the HSC to ensure ethical standards are met and institutional policies for human subject research are followed. “Expedited” refers to the quicker HSC review process that is possible with a single IRB reviewer rather than a committee.

When selecting categories, first look at the exempt categories. One research study may have multiple activities that fit under multiple categories. If all research activities in a study do not fit under one or more of the exempt categories, the study will not qualify for exemption. Choose expedited categories instead. Research that does not qualify for exempt or expedited review must be reviewed by the full board.

Exempt Level of IRB Review	Expedited Level of IRB Review
<p><u>General Requirements</u></p> <ul style="list-style-type: none"> ● No more than minimal risk ● Pregnant women allowed ● Prisoners not allowed ● Children allowed for most exempt categories except part of Category 2 ● Formal informed consent process not required ● Annual continuing review not required ● Only certain types of changes require amendments ● Reports required 	<p><u>General Requirements</u></p> <ul style="list-style-type: none"> ● No more than minimal risk ● Pregnant women allowed ● Prisoners sometimes allowed ● Children allowed for all expedited categories ● Formal informed consent process required (unless waived) ● Annual continuing review required ● All changes to the study require an amendment ● Reports required
<p>Drug or device studies do not qualify for exemption</p>	<p><u>Research About Drugs or Devices</u></p> <ul style="list-style-type: none"> ● Clinical research ● Do not need to submit to FDA for an IND or IDE ● Medical device is cleared for marketing & used as labeled <p><i>Expedited Category 1</i></p>
<p>Studies collecting blood do not qualify for exemption</p>	<p><u>Research Involving Blood Collection</u></p> <ul style="list-style-type: none"> ● Finger stick, heel stick, ear stick, or venipuncture ● Frequency = no more than 2x/ week ● Healthy, non-pregnant adults, weight >110 lbs <ul style="list-style-type: none"> ○ Total volume not exceeding 550 mL in 8 weeks ● Other adults or children <ul style="list-style-type: none"> ○ Total volume not exceeding the lesser of 50 mL OR 3 mL per kg in 8 weeks <p><i>Expedited Category 2</i></p>
<p>Studies collecting biological specimens do not qualify for exemption</p>	<p><u>Research Involving Biological Specimen Collection</u></p> <ul style="list-style-type: none"> ● Non-invasive means of collection ● Prospective collection for research purposes <p><i>Expedited Category 3</i></p>
<p>Studies involving non-invasive procedures do not qualify for exemption</p>	<p><u>Research Involving Non-Invasive Clinical Procedures</u></p> <ul style="list-style-type: none"> ● Procedures routinely employed in clinical practice ● Not involving general anesthesia or sedation ● Not involving procedures that use x-rays or microwaves ● Medical devices must be cleared/approved for marketing ● No more than moderate exercise <p><i>Expedited Category 4</i></p>
<p><u>Research Using Secondary Data/Specimens</u></p> <ul style="list-style-type: none"> ● All data/specimens exist at time of IRB submission <ul style="list-style-type: none"> ○ Only retrospective collection ○ No prospective or longitudinal collection ● Recorded with NO identifiers <ul style="list-style-type: none"> ○ No coding key may be kept ○ No way to go back to a specific record <p style="text-align: center;">OR</p> ● Is publicly available secondary data/specimens <ul style="list-style-type: none"> ○ No login required, anyone can access it <p><i>Exempt Category 4</i></p>	<p><u>Research Using Secondary Data/Specimens</u></p> <ul style="list-style-type: none"> ● Data/specimens may or may not currently exist <ul style="list-style-type: none"> ○ Retrospective and/or prospective collection ● May record and keep identifiers <ul style="list-style-type: none"> ○ May keep a coding key ○ Able to go back to a specific record ● Originally collected for research or non-research purposes <ul style="list-style-type: none"> ○ Previous research studies, registries, repositories ○ Health records, pathology specimens, waste samples ○ Other types of records, documents, data, specimens <p><i>Expedited Category 5</i></p>

<p>No equivalent exempt category, but recordings may be collected under certain exempt categories that allow for the retention of identifiers</p>	<p><u>Research that Collects Recordings</u></p> <ul style="list-style-type: none"> • Data from voice, video, digital, or image recordings • For research purposes <p><i>Expedited Category 6</i></p>
<p><u>Research Involving Any of the Following Methodologies:</u></p> <ol style="list-style-type: none"> 1. Surveys 2. Interviews (or focus groups) 3. Educational tests 4. Observation of public behavior <ul style="list-style-type: none"> • Identifiers allowed except if: <ul style="list-style-type: none"> ○ Disclosure of identifiable responses could place subjects at risk (legally, or damage financial standing, employability, or reputation) ○ Data sensitivity increases overall risk ○ Inadequate data confidentiality protections • No tasks (e.g. playing a game) • No surveys, interviews, or focus groups with children • No observations with children if the researcher will participate in the observed activities <p><i>Exempt Category 2</i></p> <ul style="list-style-type: none"> • If NOT exempt under category 2 because <ul style="list-style-type: none"> ○ Human subjects are elected or appointed public officials or candidates for public office, OR ○ Federal statutes require without exception the confidentiality of the personally identifiable info will be maintained • Same methodologies as for exempt category 2 • May keep identifiers with appropriate confidentiality protections <p><i>Exempt Category 3</i></p>	<p><u>Research Involving Any of the Following Topics or Methodologies:</u></p> <ol style="list-style-type: none"> 1. Surveys 2. Interviews 3. Focus groups 4. Oral history 5. Program evaluation 6. Human factors evaluation 7. Quality assurance methodologies, OR 8. Research on individual or group characteristics or behavior <ul style="list-style-type: none"> ○ Perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior <ul style="list-style-type: none"> • Can include other social/behavioral or educational research methodologies (e.g. ethnography, tasks, deception, educational or psychological interventions, etc.) • Surveys, interviews, and focus groups with children allowed • Observations with children where the researcher will participate in the observed activities allowed • Risks related to invasion of privacy and breach of confidentiality are no greater than minimal <p><i>Expedited Category 7</i></p>
<p><u>Educational Research</u></p> <ul style="list-style-type: none"> • Conducted in an established/commonly accepted educational setting • Involves normal educational practices <ul style="list-style-type: none"> ○ Instructional strategies ○ Effectiveness or comparison of instructional techniques, curriculum, or classroom management • Could involve a variety of data collection methods <p><i>Exempt Category 1</i></p>	
<p><u>Contracted Public Benefit/Service Research</u></p> <ul style="list-style-type: none"> • Conducted by federal department or agency heads OR • Subject to approval of federal department or agency heads • Designed to study, evaluate, or examine <ul style="list-style-type: none"> ○ Public benefit/service programs ○ Procedures to obtain benefits/service under programs ○ Changes in/alternatives to programs ○ Changes in methods or level of payment for benefits/services <p><i>Exempt Category 5</i></p>	<p>No equivalent expedited category</p>
<p><u>Taste & Food Quality Evaluation and Consumer Studies</u></p> <ul style="list-style-type: none"> • Wholesome foods without additives • Food contains a food ingredient, agricultural chemical, or environmental contaminant at or below a safe level <p><i>Exempt Category 6</i></p>	<p>No equivalent expedited category</p>