

Overview of Expedited, Exempt, and Non-Human Subject Research (NHSR)
 When it is not full committee, what category does my project fall under?

Know differences

<p align="center">45Expedited 45 CFR 46.110 and 21 CFR 56.110. ✓ Protocol Builder</p>	<p align="center">Exempt 45 CFR 46.101 ✓ Protocol Builder</p>	<p align="center">Research Involving Coded Private Information or Biological specimens (NHSR needing o.k. from HIC) OHRP Human Research Report Volume 19, No.10, October 2004 ✓ Protocol Builder</p>	<p align="center">Projects that do NOT require an o.k. from HIC *Do not proceed to Protocol Builder</p>	<p align="center">Quality Assurance (QA) *Do not proceed to Protocol Builder</p>
<p><u>No more than minimal risk to human subjects, and involve only procedures listed in one or more of the following categories:</u></p> <ul style="list-style-type: none"> • Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an IND application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an IDE is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. • Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: <ul style="list-style-type: none"> ⇒ from healthy, nonpregnant adults who weigh at least 110 pounds; amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or ⇒ from other adults and children, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. 	<p><u>Involves no risk to subjects:</u></p> <p><u>Exempt Conditions:</u></p> <p>(1) Research involving the collection of existing data, documents, records, pathological specimens, or diagnostic specimens</p> <p>Existing data means all the data, documents, records or specimens are in existence prior to HIC review; therefore cannot be obtained prospectively (future)</p> <p>(2) These sources (data, specimens, records etc..) are publicly available or the information is recorded by the investigator without identifiers directly or indirectly linking back to the subject</p> <p>(3) Research involving the use of educational tests,</p>	<p>If investigator feels the research involving coded private information or specimens involves NO intervention (physical procedures by which data is gathered) or interaction (communication or interpersonal contact) with the subject then you are NOT doing research with human subjects. <u>Authorization from the HIC is required.</u></p> <p><u>#1 and #2 both must apply</u></p> <p>(1) Material/data was collected for purposes other than this research project (e.g., normal discarded tissue) or for unrelated research project with no extra material collected for this project</p> <p>(2) Material/data is given to the investigator WITH A CODE; however, the <u>investigator receiving the data/material will NEVER have access to the key to the code OR the key cannot be derived from or related to</u></p>	<p>If investigator feels the research (NO codes or identifiers) involves NO intervention (physical procedures by which data is gathered) or interaction (communication or interpersonal contact) with the subject and research team, then you are NOT doing research with human subjects. <u>No authorization from the HIC is required.</u></p> <p><u>#1 and #2 both must apply</u></p> <p>(1) Material/data was collected for purposes other than this research project (e.g., normal discarded tissue) or for unrelated research project with no extra material collected for this project</p> <p>(2) Material/data is given to the investigator WITHOUT A CODE and no code is kept by the receiver or sender.</p>	<p><u>The main purpose of a QA project is problem resolution.</u></p> <p>This differs from research because research projects are designed and primarily intended to increase generalizable knowledge.</p> <p><u>Note:</u> Generalizable knowledge is the communications of findings corroborated by scientific observation and inference</p> <p><u>QA projects may involve intervention and/or interaction, but the intervention or interaction must be performed according to clinical standards of care or per existing policy.</u></p>

Expedited

Exempt

Coded/NHSR

No HIC approval

QA

<p>• <u>Prospective</u> collection of biological specimens for research purposes by <u>noninvasive means</u>. Examples: hair and nail clippings in a nondisfiguring manner;</p> <p>• Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: magnetic resonance imaging;</p> <p>electrocardiography, doppler blood flow, and echocardiography; moderate exercise, muscular strength testing,</p> <p>• 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).</p> <p>• Collection of data from voice, video, digital, or image recordings made for research purposes.</p> <p>• 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.</p> <p>Informed consent should be sought and documented unless a waiver of consent has met the waiver criteria. For further information please refer to SOP#3-7 at our HIC website.</p>	<p>survey, interview or observation of public behavior.</p> <p>Note: If doing research involving the use of educational tests, survey, interview or observation of public behavior, identifiers can be recorded, however, if subjects can be identified directly or through links/codes <u>AND</u> any disclosure of the subject's responses would place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation, the study would NOT qualify for exempt approval.</p> <p>Cannot collect <u>identifiable</u> info from two different sources (medical record, pharmacy log).</p> <p><u>Examples include:</u></p> <p>a) questionnaires or surveys that do not involve a sensitive topic or utilize minors, b) research being conducted in educational settings involving normal curriculum, c) Research on archival data.</p>	<p>information about the subject-if there is a key.</p> <p><u>If there is a key</u>, then one of the following must apply: (a) The key must be destroyed before the research begins or (b) Signed agreement is required between the person releasing the data and the investigator receiving it stating the code will never be released or (c) Confirmation from another IRB for a repository or data center states that the release of the code is strictly prohibited <u>The site will submit the following using protocol builder:</u></p> <ul style="list-style-type: none"> • Application for "HIC Authorization for Coded Research not Involving Human Subjects • Coded Research Data/Specimen Agreement (if applicable) <p>The research project <u>cannot</u> be under the authority of the FDA (does not involve a drug, device or biologic)</p> <p><u>Examples include:</u></p> <p>1) normal discarded specimens</p>	<p><u>Examples include:</u></p> <ul style="list-style-type: none"> • Cadavers • Single Case Reviews • Cell lines • Specimens purchased from commercial supplier. <p>The site will NOT submit any documentation to the HIC.</p>	<p><u>Examples include:</u></p> <ol style="list-style-type: none"> 1. If the main stated purpose of the project is problem resolution. 2. If the data from the project (if positive) will be used to update current practice or alter Standard of Care, Standard procedure or initiate or substantiate policy changes, the project may fall under QA. <p><u>Note:</u> If after a QA project is complete, the researcher wishes to publish the data, an Exempt application must be submitted.</p>
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