Risk Assessment Tool: Expedited vs Full Board Review

By regulation, a study must meet the criteria of minimal risk to allow an expedited review by the IRB.

**Regulatory definition of minimal risk**:

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(i)).

**Examples of types of studies and the amount of review that will likely be required:**

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| **Risk** | **Amount of Review** | **Types of studies** |
| No greater than Minimal Risk and procedure fits under an expedited review category | Expedited | * Blood draw (*minimal amount as required by expedited category*) from finger stick, heal stick or venipuncture at the amounts and frequencies described in Category 2a and 2b
* ECGs
* physical exam
* standard psychological testing
* epidemiological studies
* buccal swab
* nutritional assessments
* surveys or questionnaires of a non-sensitive nature
* looking for differences in gene sequence, gene mutations or polymorphisms and or doing whole genome work /genome wide association (GWAS) studies and you WILL NOT return results to subjects
* use of banked specimens for minimal risk research (*e.g. not testing of polymorphisms)*
* database is being developed that contains data gathered from existing sources such as the medical record
* where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable, HOWEVER, appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal AND documentation of the application for a Certificate of Confidentiality is submitted prior to approval. (S*ee Certificate of Confidentiality information on the IRB-HSR website)*
* randomization to different arms of the study where none of the arms present greater than minimal risk to the subject
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| Does NOT fit under an expedited category but may be sent to Full Board to determine if minimal risk.  | Full Board | * small amount of additional fluid, tissue is being collected for research purposes and the collection method itself presents greater than minimal risk (*collection of additional CSF, biopsy tissue etc.)*
* trials with procedures such as indwelling catheters
* oral glucose tolerance test
* eye exam using drops to dilate eyes
* induced sputum
* skin biopsy
* imaging studies (except MRI without contrast and non-invasive ultrasound)
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| Greater than Minimal Risk  | Full Board | * randomization to one of several approved drugs/devices OR to two different standard of care options where any of the arms of the study present greater than minimal risk to the subject.
* collection of identifiable sensitive information without a certificate of confidentiality
* clinical trials of an investigational drug
* studies that involve randomizing to a placebo group
* anything is being ingested, injected, dropped, applied or implanted or sprayed onto or into the body, such that systemic absorption will occur, even if the item being used for the research is not the item under study.
* anything is being introduced into an orifice solely for research, *Examples: pap smears, ear probes that are inserted further into the ear than the entrance of the auditory canal; rectal swabs, anything being placed into the nose farther than a finger could go*
* blood samples for research are being collected from an existing central line.
* Looking for differences in gene sequence, gene mutations or polymorphisms and or doing whole genome work /genome wide association (GWAS) studies and you WILL return results to subjects.
* additional CSF is being collected from an existing shunt or externalized CSF drain.
* throat swab
* endoscopy
* lumbar puncture
* bone marrow biopsy
* studies involving exercise of greater than moderate intensity (For Guidance on Determination of Intensity of Exercise, go to IRB/IRB-HSR/Administrative FAQs/Expedited Studies/Guidance on Determination of Intensity of Exercise)
* therapeutic intervention trials involving procedures such as insulin clamp or organ biopsies
* studies involving subjects with illnesses begin treated with study procedures that may result in moderate to severe adverse events
* assessments, surveys or questionnaires of a sensitive nature where HIPAA identifiers will be retained
* databases that contain sensitive information that is identifiable **and** NO Certificate of Confidentiality will be sought
* clinical trials of diseases where the endpoints are major morbidity or mortality
* assessment of serious toxicity requiring comparison of toxicity rates
* implantation of a device with an IDE
* use of a new chemical or drug for which there is limited or no available safety data in humans
* gene transfer
* high risk clinical procedures if performed solely for research purposes
* classified research involving human subjects
* where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable AND no documentation of the application for a Certificate of Confidentiality is submitted prior to approval. (S*ee Certificate of Confidentiality information on the IRB-HSR website*
* the subjects are being randomized to different standard of care treatment groups and the standard of care procedures present greater than minimal risk. (For example: the standard of care involves treatments with drugs or devices (whether approved or not approved). *(See Attachment # 1 of this document for more information.)*
* the subjects receiving any ionizing radiation exposure (any scan except Ultrasound and MRI). Imaging studies requiring the injection of contrast for research purposes
* there is potential for participants to perceive coercion, or there is undue influence to participate in the research (e.g., the professor will find out whether students participated in the research, there is a very high payment for participating),
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**Minimal Risk Assessment**

* **Risks of ordinary, non-invasive, non- sensitive diagnostic tests may be considered minimal risk**
Examples: routine blood draws in adults (minimal amounts) , general physical exams, pen-and-paper tests, ultrasound exams
* **Minimal risk assessment may be age- or context- dependent**
Example: Blood draw may be minimal risk for an adult, but not for a small child who is afraid of needles
* **Remember that risks need not be "physical" in order to be "more than minimal"**
Examples: A serious privacy risk, confidentiality risk, informational risk or risk of embarrassment may be enough to push a study into the "greater than minimal risk" category and thus to full board review

**International Research and Minimal Risk**

Research conducted in foreign locations with possible cultural sensitivities ***may*** have circumstances that require special attention to risks to participants, researchers and/or communities. Such risks and any measures to mitigate them should be addressed, where appropriate, in the IRB submission.

Examples of issues which should be addressed fully are:

* Risks to researchers inherent in the location of the research (e.g. war-torn countries, volatile conditions)
* Risks to research subjects, particularly those due to power imbalances (e.g. between subject and researcher; between subject and individuals/groups receiving research results)
* Language and cultural sensitivities

If any of these risks are deemed to be greater than minimal, then full board review will be required.

In addition to UVA IRB approval, any requirements for local permissions, licenses or agreements should be investigated and such requirements must be in place before the research begins.

**Randomization and Minimal Risk**

In determining whether a randomized, controlled trial should be designated as minimal risk, the potential sources of risk that must be considered are as follows:

* physical risk from study treatments,
* the loss of individualized care,
* risk from non-therapeutic components of the research protocol,
* the psychological impact of participation, particularly if the research takes place without informed consent in an emergency setting.

The risks of research participation should be considered in comparison with the risk of non-participation(e.g., the risks specific to research participation should be considered separately from the risks inherent in treatment of the potential research participant's underlying condition.)

Participation in a randomized, controlled trial may pose no more than minimal risk when:

* all of the treatment options included in the research study fall within the current standard of care and that standard of care does not present greater than minimal risk;
* the non-therapeutic components of the research are safely under the minimal risk threshold;
* there is an expedited review category to cover every research activity described as part of the protocol
* The potential for research participation to have a negative psychological impact on participants or their families is considered to be minimal or less than minimal.

If the expedited study is randomized, then the requirement for informed consent should only be waived to the extent necessary, and opportunities for the research participant or surrogate to decide whether to participate in the research should be maximized.

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