Procedure Risk Guidance

# **About the Procedure Risk Guidance**

**The purpose** of the guidance is to assist both IRB Staff and Committee Members in determining the route of IRB review, based on the relevant study procedures.

**The goals** of this guidance are to:

1. Facilitate consistency among reviewers and panels in risk determinations
2. Minimize the burden of determining plans for initial and continuing reviews

**The scope** of this guidance:

This guidance does not provide an exhaustive list of procedures but incorporates commonly seen procedures in reviewed research. Studies that include procedures listed in the risk guidance usually will not qualify for Expedited Review and, thus, require initial review by the convened IRB.

# **Procedure Risk Guidance for Full Board Reviews**

The *Procedure* column lists common examples of research interventions and interactions that require Full Board review, at least initially.

The *Risk Assessment at Full Board* column table indicates whether the listed intervention/interaction either: may be deemed *no greater than minimal risk* and eligible for expedited Continuing Review (depending on the specifics of the study) *OR* must always be considered *greater than minimal risk* and remain under full board review.

| **Procedure** | **Risk Assessment at Full Board** |
| --- | --- |
| **Behavioral studies** involving risky interventions, observations of illegal behavior, or deception that meets the threshold for review by committee (CMTE C) | If the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under category 9. |
| **Acupuncture/dry needling** | If the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under category 9. |
| **Blood draw in healthy *nonpregnant* adults** weighing at least 110 lbs – the amount to be collected exceeds 550 ml in an 8-week period or the collection is more than 2x/week  *Note:* Determine if blood is drawn via indwelling catheter, since that may will impact assessment of “Frequency.” Ensure this information is included in the protocol. | If the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under category 9. |
| **Blood draw in other adults and children** considering age, weight, and health, – the amount to be collected is greater of 50 ml or 3 ml per kg in an 8-week period or collection is more than 2x/week  *Note:* Determine if blood is drawn via indwelling catheter, since that may will impact assessment of “Frequency.” Ensure this information is included in the protocol. | If the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under category 9. |
| **Punch biopsy** | **For biopsies from non-facial, non-genital skin with allowable local anesthesia and limited to 2mm in diameter and not requiring sutures**, if the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under category 9. |
| **Collection of additional information or biological specimens, excluding blood, for research purposes** during procedures already being performed for clinical purposes, provided the additional collection does not introduce more than a minimal increase in risk, pain or discomfort over that imposed by the underlying procedure. | If the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under expedited category 9. |
| **CT Scan** | Must remain under full board review; considered GTMR |
| **Low dose X-Rays and non-CT or PET scans**  *Examples:* Chest, extremity, dental, mammogram. | If the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under expedited category 9. |
| **Electromyography (EMG) (intramuscular)**  *Examples:* the electrode is placed within the top layer of skin and the device’s power is limited to a level considered minimal risk. Intramuscular electrodes would be considered GTMR. | If the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under expedited category 9. |
| **Magnetic resonance imaging (MRI) utilizing contrast agent** | Must remain under full board review; considered GMTR |
| **Nasal swabs that go beyond the nares**  *Example*: nasopharyngeal swab | If the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under expedited category 9. |
| **Other data collection via methods that introduce “significant” energy into the body**, where “significant” is defined as more than what is involved in routine physical or psychological examinations or tests. | If the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under expedited category 9. |
| **Randomized drug or device studies even if it is a comparison of two SoC treatments** | If the convened IRB determines that the overall risk level of the study is NMTMR, may qualify for expedited review in the future under expedited category 9. |
| **Rectal swabs/instrument** that go beyond the rectum | Must remain under full board review; considered GMTR |
| **Vaginal swabs/instrument** that go beyond the cervix and into the uterus | Must remain under full board review; considered GMTR |

# Expedited Review

These types of studies only involve minimal risk to subjects and fit into one or more of the specific Expedited review categories. This type of research does not require review by the fully convened IRB. The IRB review is conducted by the IRB Chair, or one or more experienced reviewers designated from among the members of the IRB.

## Category 1: Approved drug or device being used for its approved indication.

1. Research on drugs for which an investigational new drug application (21 CFR Part 312) 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.)
2. Research on medical devices for which
3. an investigational device exemption application (21 CFR Part 812) is not required; or
4. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

**Note:** The drug or device must be approved and used exactly according to its labeling. All study procedures other than use of the drug or device must themselves be of minimal risk for the study to qualify for expedited review.

## Category 2: Blood Collection

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the 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**
2. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, 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.

**Note:** Determine if blood is drawn via indwelling catheter, since that may will impact assessment of “Frequency.” Ensure this information is included in the protocol.

## Category 3: Noninvasive specimen collection

Prospective collection of biological specimens for research purposes by noninvasive means.

**Examples:**

1. Hair and nail clippings in a non-disfiguring manner
2. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
3. Permanent teeth if routine patient care indicates a need for extraction
4. Excreta and external secretions (including sweat)
5. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
6. Placenta removed at delivery
7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
8. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
10. Sputum collected after saline mist nebulization.
11. Nasal swabs that do not go beyond the nares
12. Rectal swabs that do not go beyond the rectum
13. Vaginal swabs that do not go beyond the cervical into the uterus

## Category 4: Non-invasive procedures

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:**

1. Body composition assessment (not DXA)
2. Detection of naturally occurring radioactivity
3. Diagnostic infrared imaging
4. Doppler blood flow
5. Echocardiography
6. Electrocardiography
7. Electroencephalography
8. Electromyography (EMG) (electrodes only)
9. Electroretinography
10. Flexibility testing where appropriate given the age, weight, and health of the individual
11. Magnetic resonance imaging (MRI) without contrast
12. Moderate exercise
13. Muscular strength testing
14. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy
15. Thermography
16. Ultrasound
17. Weighing or testing sensory acuity
18. fMRI
19. Force plate
20. Tendon tapping
21. Vision testing/evaluation
22. Vital signs (blood pressure, heart rate, respirations, etc.)
23. Colposcopy, assuming there are no biopsies collected

## Category 5: Use of data, records, or specimens

Research involving existing information or specimens that were previously collected for non-research purposes, as well as research involving existing information or specimens that were previously collected for research purposes-provided they were not collected for the currently proposed research. (such as medical treatment or diagnosis).

**Examples:**

1. Retrospective or prospective chart review
2. Analysis of specimens that contain any of the 18 HIPAA identifiers (e.g., name, MRN, etc.)

## Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes

**Example:**

Using video recordings to examine communication styles between faculty and students

## Category 7: Behavioral research

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.

**Example:**

* Survey research
* Behavioral intervention that is more than one-day in length