Expedited Review Documentation

This reviewer guide should be completed and retained in the study file for Expedited initial reviews, modifications, and renewals.

|  |  |
| --- | --- |
| **PI Name:** | Click or tap here to enter text. |
| **Protocol Title:** | Click or tap here to enter text. |
| **IRB #:** | Click or tap here to enter text. |
| **IRB Reviewer(s):** | Click or tap here to enter text. |
| **Date Completed:** | Click or tap here to enter text. |

# Modifications only

|  |
| --- |
| **Description & Justification of Modification** (You may refer to summary provided by researcher in documentation) |
| Click or tap here to enter text. |

## CONSENT

1. Should subjects be re-consented?

Yes No N/A, no enrollment yet

1. If so, has the PI provided an adequate plan for reconsenting subjects already enrolled?

Yes No

**COMMENTS:** Click or tap here to enter text.

# Renewals only

Is there any new information relating to the risks and benefits of the study?

Yes No

|  |
| --- |
| **Description of New Information** |
| Click or tap here to enter text. |

The following sections apply to ALL types of reviews.

# Vulnerable subjects:

When appropriate, additional safeguards have been included in the study to protect the rights and welfare of vulnerable subjects:

**Pregnant subjects, fetuses, neonates of uncertain viability, or non-viable neonates:** *complete the Subpart B Reviewer Guide*

**Prisoners:** *complete the Subpart C Reviewer Guide*

**Children:** *complete the Subpart D Reviewer Guide*

**Other** populations vulnerable to coercion or undue influence, such as mentally disabled persons, or economically or educationally disadvantaged persons; **specify**:Click or tap here to enter text.

**None of the above**

**COMMENTS:** Click or tap here to enter text.

# Additional considerations:

All study team members have completed human subjects training, and it is not expired.

No Investigator Conflict of Interest exists

An investigator(s) has a conflict of interest and the executed management plan makes appropriate provisions to protect the rights and welfare of study participants.

Are there additional applicable requirements related to FDA[[1]](#footnote-2), DoD1, DOJ1, DOE, ED, EPA?

Yes, **specify**:Click or tap here to enter text.

No

*Note: Where requirements conflict, apply the stricter requirement; additional requirements do not negate Revised Common Rule requirements.*

**COMMENTS:** Click or tap here to enter text.

# Expedited Review Categories for the study:

*If the study does not fall* ***entirely*** *under one or more of these categories,* ***STOP*** *and refer the submission to the full board.*

|  |  |
| --- | --- |
|  | **Minor modification** to an approved study *(no added risk beyond minimal; no substantive change to study design other than procedures that qualify for expedited review; no substantive change to populations)* |
|  | Clinical studies of **medical devices[[2]](#footnote-3)** when either the study is **exempt from IDE requirements**, an **abbreviated IDE** **was** **previously granted** by the full board, or the device is being used in accordance with its **cleared/approved labeling**. |
|  | Collection of **blood samples** by **finger stick, heel stick, ear stick**, or **venipuncture**.   * Frequency: up to **2 times per week**. * Amount of blood to draw in an **8-week period**:  1. From **healthy, non-pregnant adults** who weigh **110+ pounds:** up to **550 mL** 2. From **other adults** and **children:** Up to the *lesser* of either **50 mL** or **3 mL per kg body weight**. Also, consider the age, weight, and health of the subjects, the collection procedure, and amount and frequency of collection. |
|  | Prospective collection of biological **specimens** by **noninvasive** means**[[3]](#footnote-4)**. |
|  | **Noninvasive** procedures**[[4]](#footnote-5)** **routinely employed in clinical practice**, *excluding general anesthesia, sedation, X-rays, and microwaves*.  Any medical devices being used must be cleared/approved, and the study should *not* be evaluating the safety and effectiveness of the medical device. |
|  | Research involving **data/specimens** that have already been collected and/or that will be collected *solely* for non-research purposes. |
|  | Voice, video, digital, or image **recordings** made for research purposes. |
|  | Research on **individual or group characteristics or behavior** (e.g. psychology, sociology) and/or research employing survey, interview, oral history, focus group, program evaluation, human factors, or QA methodologies. |
| 8a. | **Continuing review** of research previously approved by the full board where the research is **permanently** **closed to enrollment** AND all subjects have **completed** all research **interventions** AND the research remains active only for **long-term follow-up**. |
| 8b. | **Continuing review** of research previously approved by the full board where **no subjects have been enrolled** and **no additional risks** have been identified. |
| 8c. | **Continuing review** of research previously approved by the full board where the remaining research activities are limited to **data analysis**. |
| 9. | **Continuing review** of research where the **full board** has determined that the research is **minimal risk**, and **no additional risks** have been identified. |

**If this is a change to previously-selected categories, explain:** Click or tap here to enter text.

**COMMENTS:** Click or tap here to enter text.

# Risk level of the study:

No more than minimal risk

More than minimal risk: *If any part of the study involves more than minimal risk,* ***STOP*** *and refer the submission to the full board, unless it is either 1) a minor modification, or 2) a renewal that qualifies for expedited category 8.*

**COMMENTS:** Click or tap here to enter text.

# Criteria for IRB Approval of Research:

*(45 CFR 46.111 and/or 21 CFR 56.111)*

|  |  | COMMENTS: |
| --- | --- | --- |
|  | **Risks to subjects are minimized**; sound research design does not unnecessarily expose subjects to risk. | Click or tap here. |
|  | Risks to subjects are **reasonable in relation to anticipated benefits**, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. | Click or tap here. |
|  | Selection of subjects is **equitable**.  *(Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)* | Click or tap here. |
|  | **Informed consent** will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 and/or 21 CFR 50.20:   |  |  |  | | --- | --- | --- | |  | Informed consent will be sought from **each prospective subject OR Legally Authorized Representative.** | | |  |  | The circumstances of consent minimize the possibility of **coercion or undue influence.** | |  |  | All required **elements of consent** are included.[[5]](#footnote-6) | |  | **Waiver or alteration** of informed consent *– complete the Waiver or Alteration of Consent Reviewer Guide* | | |  | Waiver of consent only for **screening, recruiting, or determining eligibility** *– complete the Waiver or Alteration of Consent Reviewer Guide* | | | Click or tap here. |
|  | Informed consent will be appropriately **documented**, in accordance with, and to the extent required by 46.117 and/or 21 CFR 50.27**:**   |  |  | | --- | --- | |  | Consent will be documented in writing with a **physical or digital signature**. | |  | **Waiver of documentation** of informed consent (i.e. verbal consent obtained) *– complete the Waiver or Alteration of Consent Reviewer Guide* | |  | **N/A,** consent will not be obtained | | Click or tap here. |
|  | When appropriate, the research plan makes for adequate provision for **monitoring** the data collected to ensure the **safety** of participants. | Click or tap here. |
|  | There are adequate provisions to protect the **privacy** of subjects and to maintain the **confidentiality** of data. | Click or tap here. |

# Review Determination:

**Select only one:**

**Approve**

**Pending approval** contingent on minor stipulations to be resolved through the DHR office

**Refer to the full IRB**. *Note: Expedited reviewers do not have the authority to disapprove an application. Disapproval is an action that may be taken only at a convened meeting.*

**COMMENTS:** Click or tap here to enter text.

# Length of Approval:

*If FDA or DOJ requirements apply, renewal is necessary with an approval length of no more than 1 year.*

**N/A**, no renewal necessary, or this is a Modification and the previous expiration date is unchanged

**Length of approval:**  1 year  6 months  other: Click or tap here to enter text.

**Renewal is necessary because:** Click or tap here to enter text.

1. Refer to the Significant or Non-Significant Risk Device Checklist; the DOD Checklist; [DOJ Requirements](https://www.ecfr.gov/current/title-28/chapter-I/part-46) (Pre-2018). [↑](#footnote-ref-2)
2. Drug studies can also go under this category; see [expedited categories](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html#footnote2) for requirements. [↑](#footnote-ref-3)
3. Examples of noninvasive specimen collection: hair and nail clippings (non-disfiguring); excreta; sweat; placenta removed at delivery; mucosal and skin cells from cheek scraping. See [expedited categories](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html#footnote2) for more examples. [↑](#footnote-ref-4)
4. Examples of noninvasive clinical procedures: physical sensors that *do not input significant amounts of energy into the subject or involve invasion of privacy*; testing sensory acuity; MRI; ECG; EEG; ultrasound; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing. See [expedited categories](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html#footnote2) for more examples. [↑](#footnote-ref-5)
5. Refer to the Elements of Informed Consent checklist [↑](#footnote-ref-6)