**EXPEDITED CERTIFICATION FORM**

|  |  |
| --- | --- |
| UTHSCSA IRB Tracking Number |       |

**Please read before using this form**

A new human research study can be reviewed by the IRB using an expedited procedure if:

a. All of the research activities involve no more than [minimal risk](https://www.uthscsa.edu/vpr/services/glossary#Minimal-Risk); **and**

b. The **only** involvement of human subjects is in one or more of the Expedited Research Categories listed below.

**Select the applicable category(ies) below:**

**1. Clinical Studies of drugs and medical devices**

[ ]  **Category 1a – Approved Drug(s)**

Research on drugs for which an investigational new drug application ([21 CFR Part 312.2](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.2)) is not required because the following are true:

* The drug product is lawfully marketed in the United States; **AND**
* There is no plan to report the results to the FDA for a new indication or change in labeling; **AND**
* When using a marketed prescription drug, the research will not support a change in advertising; **AND**
* The use of the drug in this study does not significantly increase the risk (or decrease the acceptability of the risks) associated with the use of the product.

[ ]  **Category 1b – In-vitro Diagnostic Testing**

This minimal risk study on an “*In-vitro*” diagnostic biological product(s) but does not require an investigational new drug application (21 CFR Part 312) because (all of the following must be true):

* The product will only confirm diagnosis made by another medically established, diagnostic product or procedure; **AND**
* The product will be shipped with the following label: “CAUTION: Contains a biological

 product for investigational in vitro diagnostic tests only.” (See [21CFR312.2b2](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2))

[ ]  **Category 1c – FDA Approved Device Being Used in an Approved Manner**

This minimal risk study on a medical device(s) for which an investigational device exemption (IDE) application is not required because (all of the following must be true):

* The device is FDA approved; **AND**
* Will only be used in accordance with its approved labeling.

[ ]  **Category 1d – FDA Approved Device Being Used in an Unapproved Manner**

This minimal risk study on a medical device(s) for which the IRB will fulfill the Investigational Device Exemption submission requirements because (all of the following must be true):

* The device is FDA approved, **AND**
* Will not be used in accordance with approved labeling, **AND**
* The device is a “[non-significant risk](https://www.uthscsa.edu/vpr/services/glossary#Nonsignificant-Risk-Device)” device as defined by the FDA.

*Note: the sponsor must comply with the abbreviated IDE requirements under* [21 CFR Part 812.2(b)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.2)

[ ]  **Category 1e – Other Devices For Which an IDE Application Is Not Required**

This minimal risk clinical study on a medical device(s) for which an investigational device exemption application (IDE) is not required because:

* the device is a “non-significant risk” device as defined by the FDA; **AND**
* the device falls into the following special category (select only those that apply – at least one must apply):

[ ]  FDA has determined it to be substantially equivalent (510 (k) Device);

[ ]  A Pre-market approval (PMA) has been approved by the FDA,

[ ]  The device is an in-vitro PMA device being used (choose one):

[ ]  In lab research phase of development;

**OR**

[ ]  In product testing prior to full commercial marketing (e.g., for use on specimens derived from humans to compare usefulness of product with other products or procedures which are in current use or recognized as useful).

**2. Collection of blood samples by finger stick, heel-stick, ear stick, or venipuncture as follows:**

[ ]  **Category 2a – Collecting Blood Samples in Healthy, Non-Pregnant Adults**

This minimal risk study involves the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weigh **at least 110 pounds** and the amounts drawn **will not exceed 550 ml in an 8 week** period and collection will **not occur more frequently than 2 times per week**.

[ ]  **Category 2b – Blood Samples from Unhealthy Adults, Pregnant Adults, or Children**

This study involves the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from unhealthy adults, pregnant adults or children. Considering the person’s age, weight, and health, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected the blood samples intended for this study are minimal risk.

**AND;** the amount drawn **will not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period** and

 **collection will not occur more frequently than 2 times** per week.

3. Non-Invasive Collection of Biological Specimens

[ ]  **Category 3 – Collecting Biological Specimens (Non-invasive)**

This minimal risk study involves the prospective collection of biological specimens for research purposes by [noninvasive or certain minimally invasive procedures](https://www.uthscsa.edu/vpr/services/glossary#Invasive).

 Select all that apply – at least one must be checked:

 [ ]  (a) Hair and nail clippings in a non-disfiguring manner

 [ ]  (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction

 [ ]  (c) Permanent teeth if routine patient care indicates a need for extraction;

 [ ]  (d) Excreta and external secretions (including sweat)

 [ ]  (e) 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;

 [ ]  (f) Placenta removed at delivery

 [ ]  (g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor

 [ ]  (h) 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

 [ ]  (i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings

 [ ]  (j) Sputum collected after saline mist nebulization

[ ]  (k) Minimally invasive procedures:

[ ]  (1) Tissues from non-facial, non-genital skin punch biopsies in adults that do not require sutures

[ ]  (2) Specimens collected in adults by curettage, urethral, vaginal or rectal swabs

[ ]  (3) Specimens collected from the external auditory canal or nares

 [ ]  (l) Other:

**4. Non-Invasive Data Collection**

[ ]  Category 4 – Non-Invasive Data Collection)

This minimal risk study involves the collection of data through [noninvasive](https://www.uthscsa.edu/vpr/services/glossary#Invasive) procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves

**AND** involves the use of A & B below:

A. Non-invasive data collection (select all that apply – at least one must be checked):

 [ ]  (a) 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,

 [ ]  (b) Weighing or testing sensory acuity,

 [ ]  (c) Magnetic resonance imaging (without contrast agent),

 [ ]  (d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography,

 [ ]  (e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

 [ ]  (f)

**AND;**

B. Data collection involves either (select one):

 [ ]  A medical device(s) but the device(s) is (are) FDA approved for marketing and this study will not evaluate the safety and effectiveness of the medical device and will not attempt to identify new indications for an FDA approved medical device;

**OR**

 [ ]  No medical devices

**5. Retrospective or Prospective Materials Collected for Other Purposes**

[ ]  **Category 5 – Retrospective and Prospective Materials**

This minimal risk study involves materials (data, documents, records, or specimens) that were not originally collected for this research. (select all that apply – at least one must be checked):

[ ]  Existing Research Materials: (have already been collected for another research study)

 →Enter dates materials were originally collected: MM/YYYY **to** MM/YYYY

[ ]  Existing Clinical/Non-research Materials: (have already been collected for clinical purposes)

 →Enter dates materials were originally collected: MM/YYYY **to** MM/YYYY

[ ]  Prospective Clinical/Non-research Materials (not yet collected, but will be collected for non-research purposes)

**6. Recordings**

[ ]  **Category 6 – Recordings**

This minimal risk study involves collection of data from (select all that apply):

[ ]  voice, [ ]  video, [ ]  digital, or [ ]  image recordings made for research purposes.

**7. Surveys, Interviews or Program Evaluation**

[ ]  **Category 7 – Survey/Interview, Program Evaluation**

This minimal risk study involves (select all that apply – at least one must be checked):

[ ]  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),

[ ]  Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(NOTE: Some research in this category may qualify as exempt and some may not be considered human research. See the [Exempt Research, Non-Regulated Research or Non-human Research form](http://research.uthscsa.edu/irb/forms.asp)s.)