

*"The high research value of human biological materials does not override the rights of individuals to protect themselves from possible adverse consequences of the research use of such materials." (NBAC Draft Report, p. 124)*

**PART I: Identify the Study**

Study title	
Study ID	
Sponsor Name	
Sponsor Contact	
Contact Phone, Fax, e-mail	

**PART II: Identify the Study Site(s)**

	Investigator(s).	Facility Name/Address	IRB on Site?
1.			<input type="checkbox"/> yes <input type="checkbox"/> no
2.			<input type="checkbox"/> yes <input type="checkbox"/> no
3.			<input type="checkbox"/> yes <input type="checkbox"/> no

**PART III: Expedited Review Request:** Check one Risk Evaluation box and one Procedure box

<input type="checkbox"/> Minuscule	<input type="checkbox"/> Less than minimal	<input type="checkbox"/> Minimal	<input type="checkbox"/> Slightly more than minimal	<input type="checkbox"/> More than minimal
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**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

Selected categories from the list of procedures for which expedited review is allowed.

<input type="checkbox"/>	1bi	Research on medical devices for which an investigational device exemption application is not required
<input type="checkbox"/>	1bii	Research on medical devices for which the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
<input type="checkbox"/>	2a	<b>Collection of blood</b> samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds. (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.)
<input type="checkbox"/>	2b	<b>Collection of blood</b> samples by finger stick, heel stick, ear stick, or venipuncture a 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. (The amount drawn may not exceed the lesser of 50 ml or 2 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.)
<input type="checkbox"/>	3	<b>Prospective collection of biological specimens for research purposes by noninvasive means</b> (The samples are not available at the time the request is made.)
<input type="checkbox"/>	5	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 diagnoses).

**PART IV: Study Description**

**1. Project Purpose** What are you doing for which you need IRB approval?

yes  no

Will there be any ...

Pedigree study

Stem cell work

Reproductive (animal or human) cloning

type of work that is "culturally sensitive"

**2. Kinds of Samples Needed** What type (e.g. blood, urine, etc.) sample is requested? Are they available? (e.g. to be gathered or already shelved?) How many samples and how many per donor?

**3. Source of Samples** Are the samples from volunteer donors, a tissue bank or repository, pathology discard or waste or other?

**4. Privacy and Confidentiality** What identifiers will be available to you? What demographics? Who has identifiers and where is the chain broken? Who has the codes? Where is the firewall? Can you return results that could be used? What might be the worst effect of a breach of privacy?

*"Where identifying information exists, however, there must be an unambiguous system of protections to ensure that risks are minimized and that the samples' sources interests are protected." (NBAC Report)*

**5. Consent** What was/is the stated purpose of the donation? Was consent gained for this purpose or for another purpose? Is there any limit as to how it can be used? Were any promises made? What control can you exert over the consent process? What can the repository tell you about the consent process and form?

Investigator signature \_\_\_\_\_ Date \_\_\_\_\_

Printed name \_\_\_\_\_