**Criteria for an Expedited Review**

Expedited review procedures refer to research that does not involve **vulnerable populations, sensitive topics and involves no more than minimal risk** to human subjects.

**Criteria for IRB approval of expedited review include:**

1. **Risks to subjects are minimized:**
	1. by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
	2. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. **Risks to subjects are reasonable** in relation to the anticipated benefits if any to subjects and the importance of the knowledge that may be reasonably expected to result.
3. **Selection of the subjects is equitable.**
4. **Informed consent is received from each prospective subject.**
5. **Informed consent is appropriately documented.**
6. **The research plan makes adequate provision to ensure the safety of subjects.**
7. **Adequate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data.**

**Research Categories for an Expedited Review**

The follow categories generally require an expedited review. For further explanation, see

http://www.hhs.gov/ohrp (see expedited review).

1. Clinical studies of drugs and medical devices when either an investigational new drug application or an investigational device exemption application is not required.
2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as per guidelines.
3. Prospective collection of biological specimens for research purposes by noninvasive means, e.g., hair and nail clippings, excreta, skin swab, etc.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
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 diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research employing survey, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
8. Continuing review of research previously approved by the convened IRB:
	1. Where
		1. the research is permanently closed to the enrollment of new subjects;
		2. all subjects have completed all research-related interventions; and
		3. the research remains active only for long term follow-up of subjects; or
	2. where no subjects have been enrolled and no additional risks have been identified; or
	3. where the remaining research activities are limited to data analysis

For more guidance see: <http://www.hhs.gov/ohrp> (under expedited review)