

BRADMAN UNIVERSITY INSTITUTIONAL REVIEW BOARD

Expedited Criteria

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the federal requirements. All of the authorities of the IRB may be exercised, except the reviewers may not disapprove the research. Expedited proposals must be discussed at the next IRB meeting.

Expedited review is appropriate for research that involves no more than minimal risk or for review of minor changes to previously approved research projects and protocols. The research proposal and protocols must be submitted to the University IRB to determine that all of the following requirements are satisfied:

- risks to subjects are minimal;
- risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge;
- selection of subjects is equitable and non-coercive;
- informed consent will be sought from each prospective subject or the subject's legally authorized representative;
- informed consent will be appropriately documented;
- when appropriate, the research plan makes adequate provision for monitoring data collected to ensure safety of subjects; and
- when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Below is a list of types of research with human subjects that may be eligible for an expedited review:

1. Collection of hair and nail clippings in a non-disfiguring manner.
 2. Collection of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice.
 4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
 5. Anonymous voice recordings made for research purposes, such as investigations of speech defects.
 6. Moderate exercise by healthy volunteers.
 7. Study of existing data, documents, records, pathological specimens or diagnostic specimens.
 8. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate the subject's behavior and the research will not involve stress to subjects.
 9. Research involving manipulation of the subject's behavior which does not involve stress or risk.
- Expedited review may also be appropriate for minor changes or requests for extensions in previously approved research during the period (one year or less) for which approval is authorized.