

# **University of La Verne Institutional Review Board (IRB)**

For The

Protection of Human Participants in Research

## **EXPANDED EXPLANATION OF EXPEDITED CATEGORY**

(A) Research activities that (i) present no more than minimal risk to human participants, and (ii) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by

45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of

minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review

procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

(B) The categories in this list apply regardless of the age of participants, except as noted.

(C) The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk for criminal

or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving

human participants.

(E) IRBs are reminded that the standard requirements for informed consent (or its

waiver, alteration, or exception) apply regardless of the type of review—expedited

or exempted—utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB

review.

## **RESEARCH CATEGORIES**

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met: (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not

required. [Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is

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not eligible for expedited review.] (b) Research on medical devices for which (i) an