LIMITED IRB REVIEW FOR EXEMPTION CATEGORIES

In addition to adding new categories of Exemption and revisions to previous categories, the Final Rule may now require limited IRB review for Exemptions 2, 3, 7, and 8. “Limited IRB review” is a process conducted by designated reviewers, IRB chair, or other members of the IRB Committee. It means that these reviewers are not required to consider all the regulatory criteria for IRB approval of research found §46.111 (See our HRP-400 WORKSHEET – Criteria for Approval for more details). Yet, they must determine that the conditions specified in the regulations are met. The Drexel IRB **does conduct limited IRB review** to meet the regulatory standards for **Exemption 2iii** and **3(C)**.

Currently there is no way to comply with requirements associated with broad consent associated with research that meets one or both categories of Exemption 7 or 8. **Consequently, the Drexel IRB does not allow research that meet the criteria for Exemption 7 or 8.**

Please refer to 45 CFR 46.104(d)(2)(iii), 46.104(d)(3)(i)(C), 46.104(d)(7), and 46.104(d)(8)(iii) of the revised Common Rule for the original text.

For details about the categories of Exemption and limited IRB review see below. This information is also found in HRP-423 WORKSHEET- Exemptions.

Exemption 2 – Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

> (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or **(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7)**
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> Note: Research involving children can only qualify for exemption under this category when it involves educational tests or the observation of public behavior and the investigator(s) do not participate in the activities being observed.

Exemption 3 – Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

> (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or **(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).** (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse

lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Exemption 7 – Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

Exemption 8 – Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

The Drexel IRB does conduct limited IRB review to meet the regulatory standards for Exemption 2iii and 3(C). Currently there is no way to comply with requirements associated with broad consent. Consequently, the Drexel IRB does not allow research that meet the criteria for Exemption 7 or 8.

Please refer to 45 CFR 46.104(d)(2)(iii), 46.104(d)(3)(i)(C), 46.104(d)(7), and 46.104(d)(8)(iii) of the revised Common Rule for the original text.