GUIDANCE FOR IRB MEMBERS: INITIAL REVIEW OF A FULL BOARD OR EXPEDITED STUDY 111 CRITERIA FOR APPROVAL

- ✓ For more information, please refer to IRB Policy & Guidance or contact IRB@downstate.edu
- ✓ *For the full requirements, see: IRB Guidance for Full and Expedited Review or **21 CFR 56.111** or **§46.111***

An IRB member may want to think about whether a change is necessary to safeguard the rights and welfare of a research participant, based on the 111 criteria for approval, which are summarized below. If the answer is "no" they may decide to approve the protocol as it is. If the answer is "yes" they should reject the proposed research or request modifications.

Criteria for IRB approval (111 Requirements)

- Risks to subjects are minimized.
- Risks to subjects are reasonable.
- Selection of subjects is equitable.
- Informed consent will be sought, unless waived.
- Informed consent will be appropriately documented or appropriately waived.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
- Additional criteria are met for vulnerable populations.
- Ensure the research is in compliance with regulations to the extent required by 45 CFR 46, subpart B, C, and D or 21 CFR part 50, subpart D.
- In addition, the following is required, as applicable to FDA regulated investigations:
  - An IND or IDE may be required for a clinical investigation.
  - For investigational device studies, the IRB may determine that a device study is significant risk (SR) or non-significant risk (NSR). A SR device study must have an IDE from the FDA before the IRB can approve the investigation.
  - Clinical investigations for measuring bioavailability or demonstrating bioequivalence shall be subject to principles and requirements of 21 CFR 320.
- ICH-GCP requirements must be met for clinical trials which voluntarily follow ICH-GCP requirements.