CBU IRB PROTOCOL REVIEW STANDARDS

Minimal regulatory requirements for IRB review, discussion, and documentation in the meeting minutes
(See: 45 CFR 46.111)

Regulatory Review Requirement	Suggested Questions for IRB discussion
1. Risks to subjects are minimized by using research procedures consistent with sound research design and do not unnecessarily expose subjects to risk and, whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes.	(a) Is the goal(s) and/or hypothesis clearly stated? (b) Is the study design appropriate to the hypothesis? (c) Does the research design minimize risk to the subjects?
2. Risks to subjects are **reasonable** in relation to anticipated benefits to subjects, if any, **and** the importance of knowledge that may reasonably be expected to result.	(a) What does the IRB determine as the level of risk? (See criteria listed on back side) (b) What does the PI state in the application the level of risk, discomfort, and/or inconvenience? (c) Is there prospect of direct benefit to subjects? (See benefit assessment guide on the back of this form.)
3. Subject selection is equitable. If vulnerable subjects, additional safeguards are in place to avoid coercion or undue influence.	(a) Who are the proposed research participants? (b) Is an acceptable rationale for who is included or excluded provided? (c) If appropriate, are appropriate protections in place for vulnerable or protected subjects?
4. Informed consent, and assent when appropriate, is/are obtained from research subjects or their legally authorized representative(s) in accordance with 45 CFR 46.116.	(a) Does the informed consent include the eight required elements? (Listed on back side) (b) Who obtains informed consent (PI, nurse, other?) and in what setting? (b) If appropriate, is there a children's assent? (c) Is the IRB asked to waive or alter any informed consent requirement?
5. Informed consent is appropriately *documented* in accordance with and to the extent required by 45 CFR 46.117.	(a) Is informed consent documented appropriately? (b) Is the consent document understandable to subjects?
6. When appropriate, the research plan makes adequate provision for monitoring the collected data to ensure the subjects' welfare and safety.	(a) Does the research design minimize data risks? (b) Is a data and safety monitoring board or other research oversight process needed to protect subjects' safety?
7. When appropriate, there are adequate provisions to protect the subjects' privacy and to maintain data confidentiality.	(a) Is personally-identifiable research data protected from unauthorized access or use? (b) Are any special privacy and confidentiality issues properly addressed; e.g., using genetic information?
Additional considerations (unusual at CBU)	
8. Collaborative research.	Is this domestic/international collaborative research? If so, are Federal-wide assurances (FWA) or other assurances required? Is there a Cooperative Research and Development Agreement (CRADA) needed and, if so, is one completed?
9. FDA-regulated research	Is an Investigational New Drug (IND) or Investigational Device Exemption (IDE) involved in this protocol?

Basic Elements Required in a Consent Document (adult subjects)

(See: 45 CFR 46.116-117)

1. A statement that the study involves research, explaining the purpose(s) of the research and the expected duration of the subject's participation; a description of the procedures to be followed and identification of any procedures which are experimental
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to other which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and if so, what they consist of, or where further information by be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

NOTE: The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided it finds and documents specific conditions set forth in 45 CFR 46.116 (c) and (d).

Risk/Benefit Assessment

MINIMAL RISK *Definition:* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(i)). Check appropriate risk category:

1. _____ The research involves no more than minimal risk to subjects.
2. _____ The risk(s) represents a minor increase over minimal risk, **or**
3. _____ The risk(s) represents more than a minor increase over minimal risk.

BENEFIT *Definition:* A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other *reasonable* compensation for participation in research is not considered a benefit, but rather compensation for research-related inconveniences. Check appropriate benefit category(ies):

1. _____ No prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition;
2. _____ No prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge to further society=s understanding of the disorder or condition under study); or
3. _____ The research involves the prospect of direct benefit to individual subjects.