CUHS Guidelines for Reviewing Scientific Investigations that Do Not Meet the Definition of Research Involving Human Subjects Provided in the Common Rule

1. Assess experience/training of investigators. If investigators are students or inexperienced investigators, ensure that faculty supervision is appropriate. If investigators are undergraduates, also assess risk to investigators.

2. Assess risks to human subjects. Ensure that they are the minimum consistent with the objectives of the research. Work with investigator to amend project as appropriate.

3. In addition to obvious risks, assess the experience of being a subject. Might an individual become upset or worried or bored or be inconvenienced in some way? Can the discomfort be mitigated or avoided entirely?

4. Ensure that selection and recruitment of subjects is equitable, ethical, and non-coercive. Consider whether the number of subjects to be involved is appropriate for the proposed research. Assess any compensation to be provided.

5. Assess proposed informed consent procedures and work with investigator to modify if necessary (i.e., should consent be written or oral? A signed document or an information sheet? Is a witness required? Would a signed consent form increase the risk to subjects?) Does the consent process give subjects all the information they need to make an informed judgment about their participation? Do subjects understand they can quit at any time and for any reason? If they choose to quit early, do they know whether--and to what extent--their compensation for participation may be affected?

6. Consider any proposed use of deception (i.e., would the deception have significance to the subject? Is it necessary for the project?) Ensure that the investigator has considered other ways to obtain the same information without deceiving subjects. Note that subjects may not be deceived about risks.

7. If special protections are needed for a class or classes of subjects, ensure that investigator understands the need and that appropriate measures have been taken.
   a. Parental consent for minors; assent for minor subjects
   b. Consent of appropriate authorities or guardian if subjects have diminished mental capacity
   c. Special protections for physically infirm subjects--brief sessions, opportunities for rest, etc.
   d. Need for translator/translated documents if subjects' English skills are weak
   e. Confidentiality of information also appropriate to subjects' perception of the need for protection.

8. What benefits are there for subjects as a result of participation? In particular, if subjects are students, does participation have educational value?

9. Determine if appropriate additional permissions have been obtained. (Review by another IRB, school board, or other entity; review by other University committee; etc.)

10. Assess what will happen to the data following completion of the study. If data are to be retained, is it necessary to retain identifiers? Where will data be stored and who will have access? Will data be archived and is there a possibility for followup with same subjects? If so, what kind of contact will be necessary in future? Are subjects told about the possibility of additional studies?