1.0 Purpose:

1.1 The regulations of both the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) provide that an IRB "will have authority to observe or have a third party observe the consent process and the research" [45 CFR 46.109(g) & 21 CFR 109(f)].

1.2 In order to ensure that the consent process is appropriate and the approved process is being followed, the IRB may determine that special monitoring of the process must occur. Monitoring of the informed consent process may involve either passive observation or subject advocacy.

2.0 Definitions:

2.1 **Passive Observation -** Witnessing the consent process without asking questions or directly intervening.

2.2 **Subject Advocacy -** This involves ensuring that the rights and welfare of research subjects are protected by asking questions and intervening during the consent process, as necessary. The consent monitor should intervene on behalf of the subject if any of the following principles have not been met;

2.2.1 **Informed Consent -** Subjects should receive a complete disclosure of the purpose, procedures, risks, benefits and alternatives of the research.

2.2.2 **Comprehension -** The manner and context in which information is conveyed to the subject should be fully understood by the subject.

2.2.3 **Voluntariness -** Conditions for the consent process should be free from coercion and undue influence.

3.0 Procedure:

3.1 **Determining when a consent monitor is needed:** The IRB may determine a particular study requires the use of a consent monitor during the regularly scheduled full board meeting. If a situation or concern arises prior to the full board meeting the IRB Chair or Vice Chair may make the determination to assign a consent monitor to a study. If both the Chair and Vice Chair are unavailable then the HRPP Director may make the determination to assign a consent monitor to a study. This decision and rationale behind the decision will be communicated to the IRB at the next full board meeting.

3.1.1 The IRB may determine a consent monitor is needed at any stage of the research review process. The IRB will determine the necessary level of monitoring, documentation, and reporting timelines. The determination to remove the requirement of a consent monitor for specified research will also be made by the IRB.

3.1.2 The consent monitor will be an individual who is identified by the IRB Chair or Vice Chair (in his/her absence). This individual should not have a conflict of interest, or a direct relationship to the research subject or to the project.

3.1.3 Examples when consent monitoring may be particularly needed, for the IRB to meet its responsibilities to ensure human subject protections, include research that:

- Involves a vulnerable population
- Involves use of a highly risky and innovative procedure
- Is conducted by an inexperienced investigator and/or research team
- Is research about which the IRB has concerns that the consent process is not being conducted properly

3.2 **Consent Monitoring Process:** When the IRB has determined a consent monitor is required this will be communicated to the Principal Investigator (PI). The PI or designee will be responsible for contacting the consent monitor in advance of a consent session with a potential subject.

3.2.1 The principal investigator or designee will provide (in advance) to the consent monitor a copy of the current approved informed consent document.

3.2.2 The investigator will introduce the consent monitor to the potential subject and provide an explanation for the consent monitor's presence.

3.2.3 The consent monitor will utilize a copy of the approved informed consent document during the consent process to assure that all elements of the consent document are addressed by the investigator.

3.2.3.1 At any time during the consent session, the consent monitor may request that the investigator review or clarify information for the potential subject and/or seek clarification of comprehension from the potential subject.

3.2.4 The consent monitor has five principal duties: Listen, Observe, Ask questions, Document, and Decide:

3.2.4.1 **Listen:** The consent monitor should listen to the consent process and exchange between the investigator and the subject and the subject's family.

3.2.4.2 **Observe:** The consent monitor should closely observe the communication between the investigator and the subject. The monitor should use his/her knowledge of the consent document and be prepared to ask questions of the investigator or the subject if it appears that things are not clear.

3.2.4.3 **Ask Questions:** The consent monitor should be prepared to ask questions (as needed) in order to facilitate comprehension on the part of the subject. In order to understand whether the subject fully comprehends the research and is making a knowledgeable decision about participation, questions should elicit a response from the subject that requires some deliberation and thought about the research rather than yes/no questions.

3.2.4.4 **Document:** Document the interactions, questions, answers, and the decision making process.

3.2.4.5 **Decide:** Decide with the investigator and the subject whether;

- the subject should be enrolled in the research,
- the subject should be provided additional time to consider participation in the research or,
- the subject should not be enrolled.

3.2.5 The consent monitor may determine that a subject does not understand the consent process or the research and request that the investigator re-review the materials with the subject. If the consent monitor does not believe the subject understands the research or all items of the consent document, then the subject should not be enrolled in the research.

3.2.6 Reports from the consent monitor of the observations made during the consent process and/or documents will be provided to the IRB and documented in the minutes.

3.2.7 The monitoring report will be maintained in the protocol's IRB study file.

3.2.8 A copy of the final monitoring report will be sent to the Principal Investigator.

4.0 Documentation:

4.1 HHC HRPP will maintain all records related to the implementation of this policy, electronic communications, and notifications to investigators, funding or regulatory agencies, etc.

4.2 Records will be archived for a period of at least three years following the termination or completion of the research activities.

5.0 References:

5.1 45 CFR 46.109(g)– *IRB review of research*

5.2 45 CFR 46.111(b) – *Criteria for IRB approval of research*

5.3 21 CFR 56.109(f) – *IRB review of research*

5.4 21 CFR 56.111(b) – *Criteria for IRB approval of research*

5.5 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

5.6 U.S. Office for Human Research Protections' (OHRP, formerly OPRR) *Protecting Human Research Subjects Guidebook (1993)*. http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e5

5.7 FDA, IRB Information Sheets: Frequently Asked Questions, September 1998. http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm116333.htm

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
00	PMJ	7/1/11	New issue
01	CLB	3/15/20	General review. Update regulatory citation.

Element II.3.F. and III.1.F.