**Informed Consent Check List**

*Use this checklist as a guide when developing procedures to ensure informed consent by participants in your study. Remember that “informed consent” is a PROCESS, of which the consent form is one part. The Institutional Review Board Chair and Coordinator are available to consult with you on any questions or concerns about developing procedures for obtaining informed consent.*

[ ] Use common, non-technical language that can be clearly understood by the participants. Write at an 8th grade reading level. *Note- determine grade level and reading ease by using spelling and grammar function on Microsoft Word.*

[ ] Key information about the study provided at the beginning (presented in sufficient detail and organized and presented in a way that facilitates an understanding of why one might, or might not, want to participate). Put the really important information up front [purpose, risks, benefits, alternatives].

[ ] Identify the principal investigator (name, student/faculty status, departmental affiliation, school/university affiliation).

[ ] Include a statement that the study involves “research.

[ ] Include the approximate number of subjects involved in the study.

[ ] Describe the procedures to be carried out with each subject group in chronological order.

[ ] Outline how long each participant will devote to the study.

[ ] Explain any foreseeable risks, discomforts, or inconveniences (social, physical or psychological) that subjects may expect from participating in the research.

[ ] Describe any cost to the subject that may result from participation in research.

[ ] Describe any forms of compensation for participation in the research.

[ ] Describe any potential direct benefits to the subject from participating in the research. (Note- compensation is not considered a benefit)

[ ] A disclosure statement of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

 [ ] Include a statement that participation is TOTALLY VOLUNTARY and that the subject may WITHDRAW AT ANY TIME without prejudice or penalty.

[ ] Describe anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s or legally authorized representative’s consent.

[ ] A statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject.

[ ] A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

[ ] Explain who will have access to the data during and after the study, how the data will be stored, and what will happen to the data after the study is completed.

[ ] Include information about how confidentiality will be maintained.

[ ] For signed consent forms, be sure the document does not contain grammatical or typographical errors. *The submitted consent form will be reviewed, approved and date stamped as submitted. The date stamping will contain the IRB protocol number, along with the approval date. This IRB approved and stamped consent document must be the only version signed by participants. Participants should be given a copy of the signed form****.***

[ ] 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 may be obtained, and who will be responsible for the costs.

[ ] Include a statement directing questions about the research or study to the principal investigator, giving the address, telephone number and email address of the PI.

[ ] Include a statement directing questions or concerns about the study’s conduct or rights as a research participant, or to report a research related injury or event, to VCOM IRB Chair, Dr. Gunnar Brolinson at pbrolins@vcom.vt.edu or (540) 231-4981.

[ ] In addition to a signature from the research participant, a signature of the investigator obtaining the signed consent.

***If you will be collecting identifiable private information or identifiable biospecimens, include one of the following statements:***

[ ] A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or legally authorized representative, if this might be a possibility; or

[ ] A statement that a subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

[ ] For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of human germline or somatic specimen with the intent to generate the genome or exome sequence in that specimen).

***If you will be audio- or videotaping subjects…***

[ ] Include a statement that the subjects will be audio- or videotaped and who will have access to the tapes.

[ ] Explain how the tapes will be stored and whether they will be shared.

***If you will be reviewing the subjects’ medical, academic or other records…***

[ ] Include a statement that the PI will be reviewing the subjects’ medical/academic/other records.

[ ] If applicable, explain that the results of the study will be included in the subjects’ permanent medical/academic/other records.