Virginia Department of Health
Institutional Review Board
109 Governor Street, 7th Floor
P.O. Box 2448
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Informed Consent Checklist
Basic and Additional Elements
(45 CFR §46.116)

Basic Elements

Yes	No	NA	Comment	
				An Initial Concise Summary Statement (See Example Below)
				A statement that the study involves Research
				An explanation of the purposes of the research
				The expected duration of the subject's participation
				A description of the procedures to be followed
				Identification of any procedures which are experimental
				A description of any reasonably foreseeable risks or discomforts to the subject
				A description of any benefits to the subject or to others which may reasonably be expected from the research
				A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
				A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
				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
				An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject
				A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitle, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

				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 the legally authorized representative, if this might be a possibility; **or** A statement that the 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.

Additional Elements, as Appropriate

Yes	No	NA	Comment	
				A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
				Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
				Any additional costs to the subject that may result from participation in the research
				The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
				A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
				The approximate number of subjects involved in the study
				A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
				A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
				For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

Checklist for Documentation of Informed Consent (45 CFR § 46.117)

Except as Provided in Paragraph "C" of this section, informed consent shall be documented by the use of a written consent form approved by the VDH IRB, and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the form.

Written	The consent form may be either of the following: A written informed consent form that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.
Done Orally	A **short form written consent** document, stating that the elements of informed consent required by § 46.116 have been presented **orally** to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.
Waiver required signed consent form	The VDH IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either: That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. Or The research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context. Or the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.In cases in which the documentation requirement is waived, the VDH IRB may require the investigator to provide subjects with a written statement regarding the research.
	In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

**Effective 7/19/18 - Changes to the Federal Regulations for Human Subject Research require that the Informed Consent Document contain a concise summary of the project at the beginning of the Informed Consent.*

Concise Summary (EXAMPLE)

The purpose of this research study is to determine the effectiveness of physical therapy in the treatment of patients with fibromyalgia. Participants will undergo a 2-day screening that includes a blood draw, exercise testing, and completion of quality-of-life surveys. Once screening is complete, participants will complete a physical therapy program that will require visits to a fitness center two times each week for 16 weeks, for a total of 32 visits. Each visit will take about 1.5 hours. Participants will also be asked to complete a pain diary and have blood draws every 3 weeks throughout the study. Follow-up phone calls from the study team will occur at 3 weeks and 8 weeks after completion of the physical therapy program. Total study duration is about 6 and one-half months.

The greatest risks of this study include the possibility of injury during the physical therapy program and loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.