

Virginia Department of Social Services
 IRB Guidance Document
 Study Disclosure Standards Research Determined Exempt

Human subjects research determined exempt from the requirements of 45 CFR Part 46, at a minimum, must disclose to prospective volunteers the items listed in Table 1. An investigator shall make the disclosure only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Reading level of disclosure information: Write disclosure statements so it is understandable to a lay audience, e.g., 8th grade reading level or lower.

Required VDSS consent language: If prospective participants will be recruited from among VDSS/LDSS clients, include the following statement:

"It is your decision whether or not to participate in the study. Your social services and benefits will not change based on what you decide about the study. You can walk away from the study at any time. There is no penalty."

Table 1. Information to be disclosed to prospective participants in research determined exempt from the requirements of CFR Part 46

Disclosure item:	Research involves interaction with subjects	Self-administered survey procedures
1. A statement that the study involves research	X	X
2. A statement that participation is voluntary	X	X
3. A statement about the right to refuse to answer questions and/or withdraw from the study	X	X
4. Explanation of the purpose of the research	X	X
5. Explanation of the procedures to be performed	X	
6. Provide contact information for questions about the research	X	X
7. Confidentiality explanation	X	X
8. Privacy explanation	X	X
9. If subjects will receive payment, describe method and amount. Describe payment (may be prorated if appropriate) should the subject decide to withdraw or be withdrawn by the investigator	X	X
10. Information that might lead the reasonable subject (or any reasonable subset of subjects) to refuse to take part	X	