DSHS Institutional Review Board #1
Consent Document Checklist

Federally Required Elements *(If any of the following elements are missing, approval will be delayed)*

- ☐ A statement that the study involves research
- ☐ An explanation of the purpose of the research
- ☐ The expected duration of the subject's participation
- ☐ Approximate number of subjects involved in study
- ☐ 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
- ☐ An explanation of whom to contact for an explanation of research subjects' rights (include DSHS IRB #! toll-free number)
- ☐ An explanation of 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 entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

DSHS IRB #1 Required Elements *(If any of the following elements are missing, approval will be delayed)*

- ☐ The title of the study on the top of the first page
- ☐ In the section concerning Questions, add the following statement, "For questions concerning your rights as a research subject you may call the Department of State Health Services Institutional Review Board Office at 1-888-777-5037."
- ☐ Language and reading comprehension level and the method used to calculate it on the first page of the consent document

Additional Federal Elements, as needed

- ☐ 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