SUGGESTIONS FOR MSDH INFORMED CONSENT

Please consider the following tips and suggested language for your target audience (keep language simple – no higher than 8th grade reading level), and write the form in second person.

Purpose of the Study
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

The purpose of this study is to learn about……..

Sponsorship for the Study
This research is funded by (*name of Drug Company, the National Institutes of Health, etc*.). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

Participants
You are being asked to participate in this study because……

You should not be in this study if……..

Procedures
If you volunteer for this study, you will be asked to……..
(*Provide a detailed description of what participants will encounter in the study, including time commitment, specimens collected, etc*.)

Benefits of Participation
[Benefits can never be guaranteed] As an example, state: Research is designed to benefit society by gaining new knowledge. There may be no direct benefits to you as a participant in this study. However, we hope to learn…….. or The benefits to you from being in this study may be…….. or There is little chance you will benefit personally by participating in the study. Do not include payment or incentives as a benefit.

Risks of Participation
There are risks involved in all research studies. { *State the anticipated risks*}. In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers. For *surveys or interviews*, you might add – "You may become uncomfortable when answering some questions."

Cost/Compensation
There will be no financial cost to you to participate in this study. The study will take____ amount of your time. The Mississippi State Department of Health may not provide

compensation or free medical care for an unanticipated injury sustained as a result of participating in this study.

Contact Information
If you have any questions or concerns about this study, you may contact [name of Principal Investigator] at [phone number of Principal Investigator].

For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, you may contact the Chairperson of MSDH Institutional Review Board at **601-576-7725** or by email at irb@healthyms.com.

Voluntary Participation
Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations to the MSDH. You are encouraged to ask questions about the study at the beginning or any time during the study.

For *experimental treatment* consent, add "You will be given any new information gained during the course of the study that might affect your willingness to continue your participation."

Confidentiality and Protection of Privacy
Researchers are required to demonstrate how their methods will maintain the privacy of protected health information (PHI). Federal laws require that research participants receive notice of the researcher's legal duties and privacy practices, including what protected information will be collected in the study, who will have access to this data during and after completion of the study, and how PHI will be stored in a protected and confidential environment. Researchers should review laws and regulations related to HIPAA for an explanation of what constitutes Protected Health Information. The following is an example of language that shall be inserted into a consent form:

All information gathered in this study will be kept completely confidential. No reference will be made in written or oral form that could link you to this study. All records will be stored in a locked facility for at least 3 years after completion of the study. After the storage time is longer than 3 years the information gathered will be filed away in a secure place.

Participation Consent
I have read the above information and agree to participate in this study. I am at least 18 years of age. A copy of this form has been given to me.

_____ _____
Signature of Participant or Guardian (for minors) Date

_____
Participant or Guardian Name (Please Print)