**Consent Addendum Template– 9.3.2024**

**This template provides guidance and examples of text to be used when reconsenting.  Please customize sections in red in accordance with new information to be presented to the participant.**

**INFORMED CONSENT**

**ADDENDUM**

**TITLE: Double Blind, Phase III Evaluation of Drug Y**

**PRINCIPAL INVESTIGATOR: John Doe, M.D., Principal Investigator**

|  |  |
| --- | --- |
| **Sponsor:** | List all agencies, companies, or other Universities that are supporting this research. If internally sponsored, list the department. |

**NEW INFORMATION:**

You are currently a participant in a research study to evaluate the safety and effectiveness of the investigational drug(s) (a drug not yet approved by the Food and Drug Administration for general use), Drug-Y. We have recently received new information on a potential adverse reaction to Drug-Y that was not addressed in the original information provided to you. The manufacturer of Drug-Y has reported that abnormal liver function tests have been observed in 3 individualsreceiving Drug-Yin research studies. In each of these individuals, the liver function tests returned to normal after they took a lower dose or stopped taking Drug-Y. Thus, it would appear that this adverse reaction was caused by Drug-Y. As of the date of this report, a total of 1225 individuals have received Drug-Y in various research studies. Hence the current reported incidence of this adverse reaction to Drug-Y is approximately 0.25% (1/400). As addressed in the original information provided to you, tests of your liver function are performed monthly as part of this research study. These tests will detect this adverse reaction to Drug-Y should it occur. In such an event, you will be given a lower dose of Drug-Y or, if the tests indicate a serious reaction, you will stop taking Drug-Y.

**STATEMENT OF CONSENT:**

You have been given and have read or have had read to you this new information. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary, and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to continued participation in this study and you understand that you will receive a signed copy of this form.

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Signature of Subject Date

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Name of Subject Printed

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*Minor Providing Assent Date*

*(applicable for children 11 years of age or older dependent upon their understanding)*

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*Name of Minor Providing Assent Printed*

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*Signature of Legal Guardian or Legally Authorized Representative Date*

*(applicable for children and subjects unable to provide consent)*

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*Name of Legal Guardian or Legally Authorized Representative Printed*

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Signature of Principal Investigator or Designee Date

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Name of Principal Investigator or Designee Printed

Name of Principal Investigator:

Address:

Telephone Number: