PURPOSE

The purpose of this policy is to facilitate the protection of human subjects in research conducted at Wittenberg University. It is intended to ensure that any unanticipated problems that occur in research to subjects or to research investigators is promptly reported to the Institutional Review Board (IRB). This policy is guided by federal regulations from the Office for Human Research Protection (HRP) within the Department of Health and Human Services (45 CFR Part 46) and by the office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services. Federal regulations require institutions engaged in human subjects research to have written procedures for ensur

that can occur during a research study regardless of the level of risk or type of research.

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6. A protocol violation is an accidental or unintentional change to or noncompliance with the IRB-

safety, welfare, and/or the integrity of the data.

7. Any adverse event which is

If the event represents more than minimal risk of harm to subjects in the study, the IRB will decide whether to:

Suspend or terminate the research Have the PI notify current participants when such information might be related to their willingness to continue to take part in the research Require modifications to the protocol and/or consent documents Impose additional monitoring requirements Require additional training of the researcher and research team Notify other institutional committees and/or administrative units

All reports of unanticipated problems involving risks to subjects or others are electronically filed with the appropriate research study materials. The IRB has the authority to suspend or terminate approval or research that has been associated with unanticipated problems. When the IRB takes such action it will provide a statement of reason for the action and will promptly report to the appropriate funding agency, if applicable, the Office for Human Research Protections (HRP), and other applicable regulatory authorities. The reports are also reviewed by the IRB at the time of continuing review.

Further guidance is available here:

HRP: <u>Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or</u> <u>Other and Adverse Events</u> HRP: Glossary of key terms and examples

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