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EFFECTIVE DATE: March 2024

d. a persistent or significant disability such to disrupt a person's ability to conduct normal life functions;

2. Only safety reports that meet **all three** of the following requirements will be reviewed by the PI:

- i. Serious adverse events or unanticipated problems or events that otherwise have implications for the safety or health of subjects.

OHRP GUIDANCE ON REVIEWING AND REPORTING UNANTICIPATED PROBLEMS INVOLVING RISKS  
TO SUBJECTS OR OTHERS AND ADVERSE EVENTS

CT 312: Record Archiving and Retention

March 2027

Director, Clinical Trials Office