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 implicatio(u91( )]TJ6 0]TJ6 0]TJ6 0]TJ6 0]TJ6 0]TJ6 9)plicas b 2.9 -1Cev

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