COMPLAINTS/CONCERNS

COMPLAINTS OR CONCERNS → RESOLVED? → NO → REPORT TO MAINEHEALTH IRB WITHIN 10 BUSINESS DAYS

STOP HERE NOT REPORTABLE

OTHER REPORTABLE INFORMATION

- MONITORING, AUDIT, INSPECTION, SURVEILLANCE, COORDINATING CENTER REPORTS
- DATA SAFETY MONITORING REPORTS THAT SHOW CHANGES TO STUDY DESIGN
- ANY NEGATIVE ACTION BY GOVERNMENT OWNERSHIP (DEBT, EMPLY, OTHER REGULATORY AUTHORITY)
- ANY Litigation, arbitration or settlement related to human research protections
- NEGATIVE PRESS COVERAGE

UNANTICIPATED PROBLEM (UP) / SERIOUS ADVERSE EVENT (SAE)

WAS THE PROTOCOL FOLLOWED AS WRITTEN? → NO → REVIEW FOR POTENTIAL:
- NON-COMPLIANCE
- OTHER REPORTABLE INFORMATION

REPORT TO MAINEHEALTH IRB WITHIN 10 BUSINESS DAYS

STOP HERE THIS IS NOT A UNANTICIPATED PROBLEM

IS THE INCIDENT, EXPERIENCE OR OUTCOME UNEXPECTED (IN NATURE, SEVERITY OR FREQUENCY) PER THE IRB'S DEFINITION? → NO

IS IT RELATED OR POSSIBLY RELATED TO THE RESEARCH? → NO

STOP HERE THIS IS A REPORTABLE SAE

IS THERE ANY INDICATION THAT THE EXPERIENCE, INCIDENT OR OUTCOME PLACES PARTICIPANTS OR OTHERS AT GREATER RISK OF HARM THAN PREVIOUSLY RECOGNIZED? → NO

THIS IS A POTENTIAL UNANTICIPATED PROBLEM AND SHOULD BE REPORT TO MAINEHEALTH IRB WITHIN 10 BUSINESS DAYS

MEETS THE DEFINITION OF A UP AND OCCURS AT MAINEHEALTH OR OCCURRED AT ANOTHER Site RESULTING IN STOP-WRITING CHANGE TO PROTOCOL/ICF

STOP HERE THIS SHOULD BE REPORT TO MAINEHEALTH IRB WITHIN 2 BUSINESS DAYS IF SAE IS OR RESULTS IN DEATH WITHIN 48 HOURS

RES-G-001; Rev 0 Effective Date: 11/4/2019