REPORTABLE NEW INFORMATION

Please post this prominently in your research or office space.

Report the information items that fall into one or more of the following categories to the IRB within 5 business days using this form:

Information that does not fall under any of the categories does not require reporting to the IRB.

1) Information that indicates a new or increased risk. For example:
   a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
   b. An investigator brochure, package insert, or device labeling is revised to indicate an1.6 (,)6.5 ( )0b 3.1 (ser T**0** Tc 0 Tw ( )Tj-0.
   welfare of subjects).

11) Audit, inspection, or inquiry by a federal agency.
12) Written reports of study monitors.
13) For Veterans Administration (VA) research only: any local or internal serious adverse event or serious problem that is both unanticipated and related to the research.
14) Determination from IRB of Record for continuing non-compliance, serious non- compliance, serious & continuing non-compliance, unanticipated problem, suspension or termination at UMB (External IRB studies ONLY).
15) RNI submission for OAC, HRPO & VA R&D Use only
16) Research Resumption Plan during COVID-19 pandemic