**Decision Guide: Study-Specific Emergency-Disaster Risk Mitigation Planning**

1. **Open/Active Human Research Study**
   - Does study involve in-person interactions with research subjects? **YES**
     - Does sponsor have a risk mitigation plan? **YES**
       - Does the study offer potential for direct therapeutic benefit? (or Phase I trial with no treatment alternatives?) **YES**
         - Coordinate with Sponsor and consult any Northwestern issued instructions to implement risk mitigation plan.
         - Develop plan to place study recruitment and study activities on temporary hold until normal business/research activities resume.
         - Notify IRB, External IRB (if applicable), and applicable ancillary review committees (e.g. DSMB, DSMC, etc.) of risk mitigation plan:
           - If time permits for mitigation plan to be reviewed/approved by IRB before implementation, submit a modification to the IRB.
           - If immediate action is needed to eliminate an apparent immediate hazard to a subject, take action and notify IRB within 5 business days using standard pathway for Reportable New Information.
         - Consult any Northwestern issued instructions.
         - Determine whether study should be voluntarily placed on hold to recruitment and/or study conduct.
         - Develop more detailed risk mitigation plan specific to the current Emergency-Disaster.
         - Document plan details in study records.
     - No study-specific risk mitigation plan needed.
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2. **Studyspecific risk mitigation plan needed.**
   - Does the study have an external sponsor? **YES**
     - Does study offer potential for direct therapeutic benefit? (or Phase I trial with no treatment alternatives?) **NO**
       - Develop study-specific risk mitigation plan.
       - Notify IRB, External IRB (if applicable), and applicable ancillary review committees (e.g. DSMB, DSMC, etc.) of risk mitigation plan:
         - If time permits for mitigation plan to be reviewed/approved by IRB before implementation, submit a modification to the IRB.
         - If immediate action is needed to eliminate an apparent immediate hazard to a subject, take action and notify IRB within 5 business days using standard pathway for Reportable New Information.
       - Consult any Northwestern issued instructions.
       - Determine whether study should be voluntarily placed on hold to recruitment and/or study conduct.
       - Develop more detailed risk mitigation plan specific to the current Emergency-Disaster.
       - Document plan details in study records.
   - No study-specific risk mitigation plan needed.