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

Open/Active Human Research Study

→ **Does study involve in-person interactions with research subjects?**

→ **YES** → **Can study be conducted as written under current circumstances caused by the emergency/disaster per institutional policies?**

→ **YES** → **No study-specific risk mitigation plan needed**

(From "Can study be conducted..." box) **NO** → **Study-specific risk mitigation plan needed.**

(From "Does study involve in-person interactions..." box) **NO** → (routes to "No study-specific risk mitigation plan needed")

Study-specific risk mitigation plan needed.

→ **Does the study have an external sponsor?**

→ **YES** → **Does sponsor have a risk mitigation plan?**

→ **YES** → **Coordinate with Sponsor to implement risk mitigation plan.**

(From "Does the study have an external sponsor?") **NO** → **Develop study-specific risk mitigation plan.**

(From "Does sponsor have a risk mitigation plan?") **NO** → **Develop study-specific risk mitigation plan.**

Develop study-specific risk mitigation plan.

→ **Does study offer potential for direct therapeutic benefit? (or Phase I trial with no treatment alternatives?)**

→ **NO** →
- Develop plan to place study recruitment and study activities on temporary hold until normal business/research activities resume.
- Notify IRB if study recruitment and research activities cannot be placed on hold or modified for any research requiring in-person interaction but offering no potential for direct therapeutic benefit.

→ **YES** →
- Determine whether study should be voluntarily placed on hold to recruitment and/or study conduct.
- Develop more detailed risk mitigation plan, considering the items included in HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning.

→ Notify IRB 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.

→ **Document plan details in study record, consistent with information listed in HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning.**

Children's Hospital LOS ANGELES