Decision Guide for Study-Specific COVID-19 Risk Mitigation Planning

Open/Active Human Research Study

- Does study involve in-person interactions with research subjects? YES → Can study be conducted as written while adhering to social distancing recommendations and applicable institutional policies? YES → No COVID-19 risk mitigation plan needed

- NO → COVID-19 risk mitigation plan needed

- Does the study have an external sponsor? YES → Coordinate with Sponsor to confirm COVID-19 risk mitigation plan.

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

- YES → Develop plan to place study recruitment and study activities on voluntary hold.
- 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.

- NO

- No, or Sponsor has no risk mitigation plan

- Develop COVID-19 risk mitigation plan.

- Determine whether study should be voluntarily placed on hold to recruitment and/or study conduct.

- 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.


COVID-19 Supplement to Huron HRPP Toolkit 4.3
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