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 → Coordinate with sponsor to confirm COVID-19 risk mitigation plan.

- NO → COVID-19 risk mitigation plan needed.

Does the study have an external sponsor?

- YES → 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 using standard pathway for reportable new information.

- NO → 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 voluntary hold.

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