

Quick Guide for Prompt Reporting to the Institution

Use the local UTHSA Prompt Report form for issues sensitive to the institution when prompt reporting to the IRB is not required. Examples:

1. Failure to follow institutional requirements (examples):
 - Personnel engaging in research activities without prior approval
 - Data incidents involving private identifiable information
 - Any issues involving a HIPAA waiver/authorization
 - Any issues involving a conflict of interest (COI)
 - Any issues involving local safety committee approvals
 2. Suspension or termination of site by Sponsor
 3. OHRP Determination Letter
 4. FDA Warning Letter, FDA 483 Inspection Reports or FDA Restrictions placed on an IRB or Investigator
 5. Compliance actions from sources other than UTHSA
 6. Arbitrations or settlements initiated related to human subject protections
 7. Press coverage of a negative nature involving the institution
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What if I've already reported to an external IRB? Send a copy to OCRmail@uthscsa.edu. Do not submit the local UT Prompt Report form.

What if I've already reported to the UTHSA IRB? Further reporting not required. The UTHSA IRB will work directly with OCR for any institutional issues.

** Still unclear? Contact the Office of Clinical Research at 210-567-8555 or OCRmail@uthscsa.edu **