**Request for Modification to External IRB Studies for Local UTHSA Approval**

**Protocol Tracking Number:**

**Principal Investigator:**

|  |  |
| --- | --- |
| Person to contact about this modification | |
| Contact Name (if not PI) |  |
| Phone/Pager | Phone #: |
| Email (if other than UT Outlook) |  |

**NOTE: Modification requests must be submitted to the Office of Clinical Research (OCR) for institutional changes. Regulatory changes without an institutional component are to be reported to the** **external IRB only and do not require review by the OCR. Please contact our office if you have questions.**

***Steps to submitting a modification request:***

1. ***Use the most current OCR approved forms (which were emailed to you from the OCR with the Activation Letter)***
2. ***Make necessary changes to existing OCR approved forms using tracked changes, and/or***
3. ***Develop new forms for submission, and***
4. ***Complete this modification request and***
5. ***Submit all forms with tracked changes and include approval letter from External IRB (where applicable) to*** [***OCRmail@uthscsa.edu***](mailto:OCRmail@uthscsa.edu)***, copying the PI***

**This modification request is for the following: (check all that apply):**

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| --- | --- | --- | --- |
|  | **Type of change:** | **Consider form changes and/or IRB Approval:** | **Reason for the change or addition:** |
| 1. | Institutional Component  *Changes to the institutional research application (e.g. point of contact, list of identifiers used, sharing or storage of data/specimens, drug/device storage, use of electronic platform)* | Institutional Research Application, IRB approval letter, protocol and summary of changes |  |
| 2. | Coverage Analysis | Coverage analysis, IRB approval letter, protocol and summary of changes |  |
| 3. | Informed Consent (Only for revised injury statements or surrogate consent form changes)  *NOTE: OCR does not need to review all revised informed consent changes if the IRB of record provides a site-specific final “IRB Approved” informed consent document that already contains UTHCSA specific local contact information. However, OCR may request to see all informed consent document changes if the IRB of record only provides an example consent form. (e.g. NCI IRB).* | Forms D, D-2, H-1, IRB approval letter |  |
| 4. | HIPAA Authorization | Forms D, D-2, H-1, IRB approval letter |  |
| 5. | HIPAA Waiver  *When external IRB will not act as privacy board and provide. This applies to NCI CIRB studies. Commercial IRBs (e.g. WCG IRB, Advarra) will provide HIPAA waiver. Other institutional IRBs differ in requirements (check with OCR first if unsure).* | Form J, Form J-1 (for decedents) |  |
| 6. | Local study staff engaged in research | Forms B-2, Step 2-Inst or Inst M |  |
| 7. | Conflict of Interest disclosure | Form X or COI Approved Management Plan (with documentation of External IRB review), Inst M |  |
| 8. | Local principal investigator  Change of PI must be approved by the IRB of Record. This letter must be included with the modification. | Forms A, B-2, D, D-2, Institutional Research Application, Inst M, IRB approval letter, coverage analysis |  |
| Yes  No, Will the PI be leaving the institution and transferring research data to a new institution?  If Yes, what type of data will the PI be transferring?  Identifiable Data  De-Identifiable Data |
| 9. | Change to research that affects local safety committee approvals  Radiation Safety Committee  Radioactive Drug Research Committee  Institutional Biosafety Committee  Other; Specify: | Institutional Research Application, Forms Q, Q-1, D, D-2, IRB approval letter, protocol and summary of changes, coverage analysis |  |
| 10. | Participant Payment | Forms Inst B, D, D-2, IRB approval letter |  |
| 11. | Sites | Institutional Research Application, Form B) Forms D, D-2, IRB approval Letter, coverage analysis |  |
| 12. | Other, Specify: |  |  |