**UTHSCSA Tracking Number:**

**Date Amendment Request Form Completed:**

***Steps to submitting this amendment:***

1. ***Use the most current IRB-approved forms (which were emailed to you from the IRB with the approval letter)***
2. ***Make necessary changes to existing IRB approved forms using tracked changes, and/or***
3. ***Develop new forms for submission, and***
4. ***Complete this amendment form, and***
5. ***Complete*** [***Form A-1***](https://www.uthscsa.edu/sites/default/files/Services/forms/form_a-1.pdf) ***(signed by the PI), and***
6. ***Submit all forms (Form A-1, Amendment Form, New Forms and Revised forms with tracked changes) to*** [***IRBMail@uthscsa.edu***](mailto:IRBMail@uthscsa.edu)

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| --- | --- | --- | --- | --- | --- |
| 1. **Current Principal Investigator** | | | | | |
| Principal Investigator  (First name, Last name) | | |  | | |
| Person to contact about this amendment | | | |
| Contact Name (if not PI) |  | | |
| Phone/Pager | Phone #: | | Pager: |
| Email (if other than UT Outlook) |  | | |

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| **2. What type of change is being made?** | |
| |  | | --- | |  | | **Minor Change -** For example: administrative changes, clarifications of procedures, new minimal risk procedures, recruitment methods/materials, new/modified safety monitoring procedures to decrease risks, etc. |
| |  | | --- | |  | | **Major Change -**  For example: major changes to study design, new/increased risks, change in the use of drugs, new vulnerable populations, new more than minimal risk procedures, new/revised procedures involving radiation, reducing safety monitoring procedures, etc. |

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| **3.** **Is this modification request in response to an external sponsor’s amendment, IB, or other communication?** | |
| |  | | --- | |  | | **No**. |
| |  | | --- | |  | | **Yes**. *If yes, complete information below* |
|  | Sponsor Amendment Number/version:       and date: |
|  | Sponsor Investigator’s Brochure version:       and date: |
|  | Other Sponsor Communication type (letter, email, etc.):       and date: |

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| **4. Does the new information add a new risk, increase the severity or change the frequency of a known risk?** | | | | | | | | |
| |  | | --- | |  | | **No.** | | | | | | | |
| |  | | --- | |  | | **Yes.** | | | | | | | |
|  | If **Yes**, was a UPIRSO **(IRB Issue Prompt Report)** report submitted? | | | | | | | |
|  | |  | | --- | |  | | **No.** Provide an explanation of why the event does not meet criteria for UPIRSO **here🡪** |  | | | |
|  | |  | | --- | |  | | **Not previously, but** the event meets criteria for UPIRSO and is being reported as part of this amendment. | **Describe why this was not previously promptly reported (e.g. insufficient information to make a determination, no changes study protocol or informed consent document were planned, etc.)** | | | |
|  | |  | | --- | |  | | **Yes.** Has the UPIRSO **(IRB Issue Prompt Report)** issue been resolved? | |  | | --- | |  | | Yes | |  | | --- | |  | | No | | |
|  |  |  | If **No**, provide an explanation **here🡪** |  | | | | |

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| **5.** **Changes implemented without IRB Approval to eliminate a hazard**  Have any of the changes listed in this amendment already been implemented without IRB approval to eliminate an apparent immediate hazard to the subjects? | |
| |  | | --- | |  | | **No.** |
| |  | | --- | |  | | **Yes. Promptly submit an IRB Issue Prompt Report (UPIRSO).** |
|  | If **Yes**, **explain here 🡪** |

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| **6.** **Current status of the study**  What is the current status of research activities related to human subjects and identifiable private information? | | | | | | | | | |
| |  | | --- | |  | | | Not yet recruiting - No subjects have been enrolled to date *go to* [*Item 7*](#Item7) | | | | | | | |
| |  | | --- | |  | | | Recruiting – participants are currently being recruited through open recruitment or by invitation only, *continue to* [*Item 6a*](#Item6a) | | | | | | | |
| |  | | --- | |  | | | Temporarily closed to enrollment – enrollment has been halted, but will potentially resume, *continue to* [*Item 6a*](#Item6a) | | | | | | | |
| |  | | --- | |  | | | Permanently closed to enrollment– enrollment in the study is complete and will not resume, *continue to* [*Item 6a*](#Item6a) | | | | | | | |
|  | | |  |  | | | | | |
| **6****a. Subject notification**  Based on the subject status below, indicate how subjects will be **notified of the changes** in this amendment. (Select all that apply) | | | | | | | | |
| |  | | --- | |  | | | N/A - No subjects have been enrolled to date *go to* [*Item 7*](#Item7) | | | | | | |
|  | | | | Re-consented and sign a revised consent form | Notified by letter, however, a revised consent form is not needed  **REQUIRED: Attach a copy of the letter for IRB review** | Notified in person, a revised consent will not be signed  **REQUIRED: Include plan for documenting subject notification** | Other - ***provide details below*** | Not applicable to subjects ***Provide rationale below*** |
| **Current subjects** who are **actively participating** in the research (procedures, assessments, or treatments) will be: | | | | |  | | --- | |  | | |  |  | | --- | --- | |  | *A copy of the letter is attached for review* | | |  | | --- | |  |   ***Provide plan* 🡪** | |  | | --- | |  |   ***Provide details* 🡪** | |  | | --- | |  |   ***Provide details* 🡪** |
| **Current subjects** who are participating in **long term follow-up** will be: | | | | |  | | --- | |  | | |  |  | | --- | --- | |  | *A copy of the letter is attached for review* | | |  | | --- | |  |   ***Provide plan🡪*** | |  | | --- | |  |   ***Provide details* 🡪** | |  | | --- | |  |   ***Provide details* 🡪** |
| **Previous subjects** who have **completed** or **withdrawn** from the research will be: | | | | |  | | --- | |  | | |  |  | | --- | --- | |  | *A copy of the letter is attached for review* | | |  | | --- | |  |   ***Provide plan 🡪*** | |  | | --- | |  |   ***Provide details* 🡪** | |  | | --- | |  |   ***Provide details* 🡪** |

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| 1. **Amendment Changes**   For **each change** being made, provide a description of the change, why the change is being made and update/submit applicable documents with the actual changes (using tracked changes where applicable). Submit this form with the revised documents (with changes tracked) to the IRB.  **Click here if you have a Summary of Changes provided by the Funding Entity (Sponsor) that inludes the change description and reason for the change.**  **Include the Summary of Changes with this Amendment form. *You do not restate the changes below.* However, you must include changes to local IRB application forms as applicable.**  *For a* ***reference*** *of applicable documents which require changes, see table at the end of this document or* [**click here**](#HELP) | | | |
| **Describe Change 1:** | | **Explain *why* the change is being made:** | **List the corresponding forms being submitted/changed**  ***(***[***submit revised forms with changes tracked***](#HELP)***)*** |
|  | |  |  |
| **Describe Change 2:** | **Explain *why* the change is being made:** | **List the corresponding forms being submitted/changed**  ***(***[***submit revised forms with changes tracked***](#HELP)***)*** |
|  |  |  |
| **Describe Change 3:** | **Explain *why* the change is being made:** | **List the corresponding forms being submitted/changed**  ***(***[***submit revised forms with changes tracked***](#HELP)***)*** |
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| **Describe Change 4:** | **Explain *why* the change is being made:** | **List the corresponding forms being submitted/changed**  ***(***[***submit revised forms with changes tracked***](#HELP)***)*** |
|  |  |  |
| **Describe Change 5:** | **Explain *why* the change is being made:** | **List the corresponding forms being submitted/changed**  ***(***[***submit revised forms with changes tracked***](#HELP)***)*** |
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| **Describe Change 6:** | **Explain *why* the change is being made:** | **List the corresponding forms being submitted/changed**  ***(***[***submit revised forms with changes tracked***](#HELP)***)*** |
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| **Describe Change 7:** | **Explain *why* the change is being made:** | **List the corresponding forms being submitted/changed**  ***(***[***submit revised forms with changes tracked***](#HELP)***)*** |
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| **Describe Change 8:** | **Explain *why* the change is being made:** | **List the corresponding forms being submitted/changed**  ***(***[***submit revised forms with changes tracked***](#HELP)***)*** |
|  |  |  |
| **Describe Change 9:** | **Explain *why* the change is being made:** | **List the corresponding forms being submitted/changed**  ***(***[***submit revised forms with changes tracked***](#HELP)***)*** |
|  |  |  |
| **Describe Change 10:** | **Explain *why* the change is being made:** | **List the corresponding forms being submitted/changed**  ***(***[***submit revised forms with changes tracked***](#HELP)***)*** |
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**REFERENCES/HELP TABLE**

|  |  |  |
| --- | --- | --- |
| Use these tables to help decide which forms need to be submitted as new or modified depending on the type of change being made.  Note: Items with an IRB icon ( IRB review) ***require*** approval by the IRB.  Items ***without***an IRB icon may not require IRB approval, however may require institutional approval  When **ICD** is listed in the table below, consider revising all active consent forms for your study (Form D, D-1, D-2, D-3, E, E-1, E-2, E-3, D-IS) | | |
| **Note about Forms:**   * *Studies submitted after February 2018, use Inst Form/Inst CT Form & IRB Form* * *Studies submitted before February 2018 but after May 2014, use Step 1, Step 2-Inst, and Step 2-IRB Forms* * *Studies submitted before May 2014, use Form B, Form C, etc.* | | |
|  | **Required/Likely Needed** | **Possibly Needed** |
| ***Consent*** | | |
| Process IRB review | IRB Form, Step 2-IRB, or Form C | Script, Form F |
| Document (long consent/ information sheet) IRB review | ICD | IRB Form, Step 2-IRB Form or Form C |
| Waiver of consent (not obtaining consent) IRB review | Form F | IRB Form, Step 2-IRB Form or Form C |
| Alteration of consent (not including all elements consent) IRB review | Form F, IRB Form, Step 2-IRB, or Form C | Form D-IS, Script |
| Waiver of documentation (not obtaining signature at time of consent) IRB review | Form F, Form D-IS | IRB Form, Step 2-IRB, or Form C |
| ***Data management, Confidentiality and Privacy*** [***Back to top***](#top) | | |
| Collection of private identifiable information IRB review | Inst Form/Inst CT Form, Step 2-Inst, or Form C | Form J, Form F |
| Storage of private identifiable information IRB review | Inst Form/Inst CT Form, Step 2-Inst, or Form C | Form J |
| Sharing/Disclosures of private identifiable information IRB review | Inst Form/Inst CT Form, Step 2-Inst, or Form C | Form C, Form J |
| HIPAA Waiver IRB review | IRB Form, Step 2-IRB Form, Form J | Form J, Form C |
| ***Drugs and Devices*** [***Back to top***](#top) | | |
| Use of drug(s) IRB review | Inst Form/Inst CT Form or Step 2-Inst, Form BB, Coverage Analysis | Form B, Form C, Form O, Form O-1, Form BB, ICD, Form O-2, IRB Form or Step 2-IRB, ICD |
| Use of device(s) IRB review | Inst Form/Inst CT Form or Step 2-Inst, IRB Form or Step 2-IRB, Form BC, Form O, Form CC, Form BB, Coverage Analysis | Form CC, Form S, Form B, Form C, Form P, Form BB |
| Investigators Brochure or Device Manual | Inst Form/Inst CT Form or Step 2-Inst, IRB Form or Step 2-IRB, Form BC | Form P, Form CC, Form DD |
| Storage | Form BB, Form BC, ICD, Inst Form/Inst CT Form or Step 2-Inst | Form B, Form C |
| Dispensing | Inst Form/Inst CT Form or Step 2-Inst, Form B | Form CC, Form DD, Form BB , Form C, ICD, Form B |
| ***Funding*** [***Back to top***](#top) | | |
| Source IRB review | Inst Form or Step 2-Inst, Coverage Analysis, Form BB, Form AA | Form B, ICD |
| Participant Payment IRB review | Inst Form or Step 1, ICD, Inst B or Form C | Form C, ICD |

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|  | **Required/Likely Needed** | **Possibly Needed** |
| ***Personnel*** [***Back to top***](#top) | | |
| PI IRB review | Inst Form or Step 1 or Form B; Form A(For new PI), Form A-1 (Signed by current PI or copy on submission email); Inst-M, ICDIRB review | Approval to Transfer Research Data Request; Coverage Analysis; Inst B |
| Co-PI | Inst Form or Step 2-Inst or Form B; Inst-M, ICDIRB review, Form A, Justification for Co-PI |  |
| By name | [Personnel Change](https://www.uthscsa.edu/vpr/services/personnel-change) | ICDIRB review |
| Roles IRB review | Inst Form or Step 2-Inst, Inst M or Form B-2 | ICDIRB review |
| Contact Information | Inst Form or Step 1 or Form B | ICDIRB review |
| ***Populations*** [***Back to top***](#top) | | |
| ChildrenIRB review | IRB Form or Step 2-IRB or Form B; Form W; Form BC; ICD |  |
| PrisonersIRB review | IRB Form or Step 2-IRB or Form B; Form V; Form BC |  |
| Decisionally ImpairedIRB review | IRB Form or Step 2-IRB or Form B; Form T; Form BC; ICD | Form C |
| Pregnant Women/Fetuses IRB review | IRB Form or Step 2-IRB or Form B; Form U; Form BC, ICD | Form D-PP (ICD) |
| Neonates (viability=uncertain or non-viable) IRB review | IRB Form or Step 2-IRB or Form B ; Form U, Form BC, ICD |  |
| ***Procedures*** [***Back to top***](#top) | | |
| **Clinical services** to provide protocol directed conventional care or research proceduresIRB review | Inst Form or Step 2-Inst or Form C; Coverage Analysis; ICD; Form BC | Step 1; Form C; Form R |
| **Research only** proceduresIRB review | Inst Form or Step 2-Inst or Form C; Form BC; Coverage Analysis; ICD | Form R; IRB Application or Step 2-IRB |
| Data Collection tools (Surveys, CRFs, etc.) IRB review | Form M; Inst Form or Step 2-Inst or Form C | ICD, Coverage Analysis |
| ***Protocol*** [***Back to top***](#top) | | |
| Status (i.e., closed to enrollment): IRB review | SPECIFY NEW STATUS IN CHANGE ABOVE | |
| Title IRB review | Inst Form/Inst CT Form or Step 1 or Form B; ICD | Form BB |
| Purpose/Objectives/AimsIRB review | Form BC or Form C or Form BB; ICD | IRB Application or Step 2-IRB |
| Research methodsIRB review | Form BC or Form C or Form BB; ICD | IRB Application or Step 2-IRB |
| Number subjectsIRB review | Inst Form or Step 1 or Form B or Coverage Analysis | ICD; Form BC or Form BB |
| Reasonably expected risksIRB review | Form BC or Form C or Form BB; ICD | IRB Application or Step 2-IRB |
| BenefitsIRB review | IRB Application or Step 2-IRB; ICD; Form C or Form BC or Form BB |  |
| Data Safety Monitoring PlanIRB review | Form R; IRB Application or Step 2-IRB; Form BC or Form BB |  |
| Committee Approval: (specify committee): | Inst Form or Step 2-Inst or Form B; Approval Letter(s) |  |

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| --- | --- | --- |
|  | **Required/Likely Needed** | **Possibly Needed** |
| ***Recruitment*** [***Back to top***](#top) | | |
| Inclusion criteriaIRB review | Form BC or Form C or Form BB | Inst Form or Step 1; ICD |
| Exclusion criteriaIRB review | Form BC or Form C or Form BB | Inst Form or Step 1; ICD |
| ProcessIRB review | Inst Form or Step 2-Inst; IRB Form or Step 2-IRB or Form C | Form F; Form J; Form L |
| Material (fliers, letters, etc.) IRB review | Inst Form or Step 2-Inst; IRB Form or Step 2-IRB or Form C | Form F; Form J; Form L |
| ***Study Sites*** [***Back to top***](#top) | | |
| UTHSCSA | Inst Form/Inst CT Form or Step 1; ICD; Inst Form or Step 2-Inst or Form B | Coverage Analysis; Inst M; Form J |
| University Health System (UHS) | Inst Form/Inst CT Form or Step 1; ICD; Inst Form or Step 2-Inst or Form B | Coverage Analysis; Inst M; Form J |
| South Texas Veteran’s Healthcare System (STVHS) | Inst Form/Inst CT Form or Step 1; ICD; Inst Form or Step 2-Inst or Form B | Coverage Analysis; Inst M; Form J |
| Baptist Health System (BHS) | Inst Form/Inst CT Form or Step 1; ICD; Inst Form or Step 2-Inst or Form B | Coverage Analysis; Inst M; Form J; Form K-2; Communication Plan |
| Other Sites | Inst Form/Inst CT Form or Step 1; ICD; Inst Form or Step 2-Inst or Form B | Coverage Analysis; Inst M; Form J; Form K-2; Communication Plan; SMART IRB Reliance Forms or Letter of Support |