This is a dual department form used by:

* IRB to assist with determinations appropriate for use of electronic informed consent and mobile application
* IMS to assess institutional safeguards and to assist with purchasing applications, where necessary.
* If the electronic study tool is used to collect, store, share non-identifiable data, **do not complete this form**.

Using this form – To check the checkboxes, double click once on the box. To enter text in the text boxes, click once on the gray box and then type your response.

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| **Item 1: What tool (s) are being used?**  *[Select all that apply]* | | Electronic Informed Consent tool (eIC); Provide name of program used and URL (if available): UTHSA REDCap *[Answer Items 1 – 14 & proceed to Section A]*  Mobile Application (Mobile App); Provide name of Mobile App to be used and URL (if available):      *[Answer Items 1 –14 & proceed to Section B]*  Online Platform; Provide name of platform to be used and URL (if available):       *[Answer Items 1 –14 & proceed to Section B]* | |
| 1. Are there reference materials related to the eIC tool, Mobile App, or Online Platform?   *[Reference materials can be the Protocol or any other documents that provides a description of tool/app, step-by-step screenshots, user agreements, etc.]* | | Yes, Reference Material(s) or URL:  No |

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| **Item 2: Does the study have a Data Acquisition, Access, Use and Release Request Form?** |
| Yes *Skip to item 10*  No *Continue on to Item 3* |

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| **Item 3: What information will be recorded?**  *[Select all that apply]* | Protected Health Information (PHI) – include the developer in the HIPAA Authorization  Private Identifiable Information (PII) - include the developer in the HIPAA Authorization  Student Identifiable Information (SII) - include the developer in the HIPAA Authorization  Credit Card Data  Sensitive Digital/Proprietary Research Data  Other types of private information; Describe: |

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| **Item 4: Data Storage Plan** | |
| Where will recorded data be stored? | University Server  Non-University Server  If data will be stored on a non-University server complete the following:   * Describe connection and storage: * In what country is the server located: |

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| **Item 5: Security** | | |
| **Describe the system security**  *(e.g. restricted access, methods to ensure confidentiality after consent obtained, etc.)* | | See attached reference material:      , Section  Other; Describe: UTHSA REDCap User Agreement will be followed |
| The program/Mobile App system:   1. Ensure[s] the confidentiality, integrity and availability of all electronic PHI created, received, maintained or shared; 2. Identif[ies] and protect[s] against reasonably anticipated threats to the security or integrity of the information; 3. Protect[s] against reasonably anticipated, impermissible uses or disclosures; and 4. Ensure[s] compliance with UTHSCSA policies.   *(45 C.F.R. § 164.306(a).)* | Check to confirm understanding that the safeguards are followed. |

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| **Item 6: Backup procedures -** Describe back-up plans, including the back-up process, schedule, storage, sharing, and recovery. |
| N/A - Backup procedures are listed in the attached reference material:      ; Section:  Describe: We will be using regular university setup server backups. UTHSA REDCap is backed up on the secure UTHSA server, no additional procedures will be included beyond those already established within REDCap. |

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| **Item 7: UTHSCSA Access Management Provisions** - Will users access University data through the mobile application? |
| N/A - Access Management is listed in the attached reference material:      ; Section:  N/A – Mobile Application not used for electronic platform.  Describe in detail how user accounts are provisioned for users who will be accessing University data through the mobile application: |

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| **Item 8: Will data be shared with 3rd party entities?** *[e.g. developers or for other marketing use - include the developer or other 3rd party entities in the HIPAA Authorization]* | |
|  | Yes - Describe what information is being shared and method used to share the information: |
|  | No |

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| **Item 9: Security controls to prevent unauthorized 3rd party accessibility** | |
|  | Mobile device protected with a research code number or password |
|  | Data sharing to a server behind (Insert site(s)      ) firewall |
|  | Other     User access will be restricted and UTHSA REDCap User Agreement will be followed. Institutional security controls in place already for REDCap which will be in place for e-consent. |

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| **Item 10: General Data Protection Regulation (GDPR) -** Is there a potential for the study to store, collect, control, or process data of individuals currently in a European Union (EU) country?  No – *skip to Item 11*  Yes – Complete the questions below *[Must include GDPR language in consent or have separate GDPR consent in the submission]* | | | | |
| Will explicit consent be obtained before personally identifiable information is received directly from individuals (i.e., they have checked a box indicating their agreement to such data collection)? |  | Yes |  | No |
| Will copies or records of consents be retained? |  | Yes |  | No |
| Will explicit consent be obtained when personal data consists of racial or ethnic origin, political opinions, religious or philosophical beliefs, genetic data, biometric data, sexual orientation, trade union membership, criminal convictions or offenses? |  | Yes |  | No |
| If websites related to the study will collect personal information from visitors, will a privacy policy be posted on the website? |  | Yes |  | No |
| Are visitors notified of the way in which their data is used if their personal information is collected from a website? |  | Yes |  | No |
| Is there a process in place to respond to individual requests about amending or deleting personally identifiable data? |  | Yes |  | No |

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| **Item 11: Will there be a cost to use the eIC or Mobile App?** | No  Yes, *(Include cost of use in the Cost section of the consent form)* |

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| **Item 12: Does the subject need to download a program or Mobile App*?*** | No  Yes, *(Include procedure in the Procedures section of the consent form)* |

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| **Item 13: How will subject questions be addressed**  *A response is required when using REDCap to eConsent subjects.* | In person  Videoconference  Phone call  Live chat, please describe data security and privacy protection:  Other, please describe:  See attached reference material:      , Section: |

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| **Item 14: Describe considerations made for subjects who have impaired vision or motor skills and those who are unfamiliar with working technology.**  *A response is required when using REDCap to eConsent subjects.* | Research team guided  Assistance/involvement of family member or caregiver  Audio options available, please describe:  Paper Informed Consent document will be used  Other, please describe: |

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| **Item 15: Breach of Confidentiality –**Describe any reasonably foreseeable risk associated with a breach of confidentiality |
| N/A, Risk described in the informed consent document – do not complete this portion.  N/A, No reasonably foreseeable risks associated with a breach of confidentiality  Describe: |

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| **Item 16: Sponsor and/or Manufacturer contact information**  **Not applicable, using UTHSA REDCap** | |
| Sponsor:  Email:       Phone: | Manufacturer:  Email:       Phone: |

**Section A. eInformed Consent – Study is being reviewed by UTHSA IRB –**

*When using UTHSA REDCap to eConsent subjects, complete this section*

N/A – Study is being reviewed by an External IRB

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| **Item A1. Where will the consent process occur?** | | |
| **Is the consent process occurring remotely?** | | No, the process will take place in-person, *continue to Item A2*  Yes*, answer question a. below.* |
| 1. What is the process for authenticating the user? | See attached reference material, Section  Other: Describe: |

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| **Item A2. What is the process for ensuring that the responses and signatures within the IC cannot be altered?** | Read-Only signature field  Only the subject has ability to change signature  Other: Describe: |

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| **Item A3. How long will the eIC process take?** |  |

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| **Item A4. How will signatures be captured?** | Using e-signatures (following guidance in [*FDA Part 11*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11&showFR=1&subpartNode=21:1.0.1.1.8.3)*\*)*  Other (e.g. checkbox consent), please describe: |

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| **Item A5. How will subjects receive a copy of the consent form?** | A copy will be emailed to the subject  A copy will be printed for the subject  Other, please describe:  See attached reference material:      , Section  Subject will print/download a copy themselves *(answer a. and b. below)* |

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| 1. How long will subject have access to the signed e-consent form? (Please disclose in consent form) |  |
| 1. If your study is accessing or collecting protected health information, HIPAA requires that a signed authorization be provided to the subject. | Confirm the understanding that a signed version of the consent form (when the consent form is combined with the HIPAA authorization) will be provided to the subject or subject’s LAR unless the IRB grants an alteration (which excludes HIPAA Authorization signature) or a waiver of the requirement to obtain HIPAA authorization. |

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| **Item A6. Will the re-consenting of Subjects need to occur?** | No – Rationale:  Yes *(answer a. and b. below)* |

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| 1. **How will subjects be notified for re-consenting?**   *[Ensure use of most current (IRB-approved) version of consent form, confirm with version date and IRB approval date.]* | See attached reference material:      , Section  Other: |
| 1. **Describe process for re-consenting subjects.**   *[Note: re-consenting of subjects does not need to occur in the same fashion as initial consent.]* | See attached reference material:      , Section  Other: |

**Section B. Mobile App/Online Platform**

(Use the copy and paste function if multiple Mobile Apps/Online Platforms are being used in this study)

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| **Item B1. Device Information**  (*Include a copy of applicable reference materials with your IRB application (User agreements, Guides etc.*) | | | |
| **List Application platform(s) (IOS, Android, Windows Mobile)** | | |  |
| Provide the Institution Name of the Mobile App/Online Platform developer. *[Note: If using a commercially available app, you may need to purchase through the UTHSCSA purchasing office]* |  | UTHSCSA | |
|  | Non-UTHSCSA:  *[Note: A data use agreement or contract may be required – contact Office of Sponsored Programs]* | |

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| **Item B2. What is the purpose of the Mobile App/Online Platform?***[e.g., provide subject documentation of adverse events, etc.]* |  |

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| **Item B3. Is the developer designing the Mobile App/Online Platform for the study?** | No  Yes - If yes, this will involve ownership/intellectual property issues that will require additional review by Office of Sponsored Programs (OSP). |