Self-Monitoring Tool

This form is designed for research personnel to use to assess their compliance with TTUHSC El Paso IRB policies and procedures, and federal regulations and guidance governing research with human subjects, on a per-study basis. **For any questions answered "No," please respond in Section F with a Corrective/Preventive Action Plan, including any note-to-file documentation that may be needed, and submit required forms to the IRB.**

This form has 6 sections and the information needed to complete it should be available in the regulatory file binder. Sections completed for self-monitoring:

☐ Section A: General Study Information
☐ Section B: Informed Consent & Subject Records
☐ Section C: Regulatory Documentation
☐ Section D: Investigational Product (IP)/Study Supplies
☐ Section E: Reportable Events, Unanticipated Events & Note to File
☐ Section F: Billing and Subject Compensation
☐ Section G: Sponsor-Investigator Responsibilities
☐ Section H: Corrective/Preventive Action Plan

If the IRB required the self-assessment, please send the completed form to the IRB by email: myrna.arvizo@ttuhsc.edu.

As you complete this form, please consider the IRB's reporting requirements for unanticipated events and noncompliance, as well as the sponsor's reporting requirements. The TTUHSC El Paso Human Research Protection Program Manual (HRPPM) Policies and Procedures are available at the following link, along with other helpful information: http://elpaso.ttuhsc.edu/research/irb/default.aspx.

If you need help with this form, please feel free to contact Jacqueline Marek at 915-215-4814 or Myrna Arvizo at 915-215-4162.

Section A: General Study Information

Date of Completion: _____

A-1 Principal Investigator:

A-2 IRB #:

A-3 Study title:

A-4 Funding source(s):

A-5 Are all staff working on the study listed as approved personnel? ☐ Yes ☐ No

A-6 Is CITI training and a FD current for all approved personnel? ☐ Yes ☐ No

A-7 IF study-specific training is required for all approved personnel, has this training been completed by all study team members prior to study start date? ☐ Yes ☐ No
Do you have documentation that study-specific training has been completed by each study team member?
☐ Yes ☐ No

A-8 Initial IRB approval date:

A-9 Last IRB continuing review approval date:

A-10 Has the study maintained continuous active IRB approval?
☐ Yes (if yes, go to A-12) ☐ No, there has been a lapse in IRB approval.

A-11 During the lapse, did any of the following activities occur? Check all that apply.

☐ Recruitment
☐ Informed consent process
☐ Enrollment
☐ Data collection
☐ Analysis of identifiable subject data

A-12 IRB-approved subject sample size: _____

A-13 Are all IRB-approved study advertisements present? ☐ Yes ☐ No ☐ N/A

A-14 Is the study registered with clinicaltrials.gov? ☐ Yes ☐ No

A-15 Did all other necessary ancillary committees/hospitals approve the research? ☐ Yes ☐ No

Section B: Informed Consent & Subject Records

B-1 How many people are screened to date? _____

B-2 Number of subjects who signed an ICF (enrolled) to date: _____ ☐ N/A
(If no subjects consented yet, go to Section C)

B-3 Has study enrollment (signed an ICF) been less than or equal to the number approved by the IRB?
☐ Yes ☐ No

B-4 If subjects withdrew (or were screen failures), were these withdrawals reported to the IRB at continuing review? ☐ Yes ☐ No ☐ N/A

B-5 **Subject File Review**. Select 3 or more subject files.

First Subject:

- Subject ID#:
- Did the subject meet eligibility criteria? ☐ Yes ☐ No
- Is documentation of eligibility complete and in the record? ☐ Yes ☐ No
- Is there an original copy of informed consent form (ICF) and HIPAA authorization on file? ☐ Yes ☐ No
- Was the person who obtained informed consent authorized by the IRB to conduct the research (HRPPM 3.18.3)? ☐ Yes ☐ No
- Is there documentation of the consent process in the research record (HRPPM 3.18.2)? ☐ Yes ☐ No
- Were the correct, updated and stamped versions of the ICF and HIPAA used for all subjects? ☐ Yes ☐ No
- Did the subject sign, date, and include the time on the ICF prior to the research procedures? ☐ Yes ☐ No
- Is each document properly completed with initials/signatures? ☐ Yes ☐ No, *if no, explain*:
- Did authorized research personnel sign, date and include the time on the ICF? ☐ Yes ☐ No

- Is there documentation that the subject received a copy of the ICF? ☐ Yes ☐ No
- Is compensation provided? ☐ Yes ☐ No - *If yes*, is documentation available? ☐ Yes ☐ No
- If the IRB or sponsor required reconsent of subjects, were all subjects appropriately reconsented? ☐ Yes ☐ No
- List all ICF/HIPAA documents signed by this subject, including version date, IRB approval period, date and time of subject's signature.

Second Subject:

- Subject ID#:
- Did the subject meet eligibility criteria? ☐ Yes ☐ No
- Is documentation of eligibility complete and in the record? ☐ Yes ☐ No
- Is there an original copy of informed consent form (ICF) and HIPAA authorization on file? ☐ Yes ☐ No
- Was the person who obtained informed consent authorized by the IRB to conduct the research (HRPPM 3.18.3)? ☐ Yes ☐ No
- Is there documentation of the consent process in the research record (HRPPM 3.18.2)? ☐ Yes ☐ No
- Were the correct, updated and stamped versions of the ICF and HIPAA used for all subjects? ☐ Yes ☐ No
- Did the subject sign, date, and include the time on the ICF prior to the research procedures? ☐ Yes ☐ No
- Is each document properly completed with initials/signatures? ☐ Yes ☐ No, *if no, explain*:
- Did authorized research personnel sign, date and include the time on the ICF? ☐ Yes ☐ No
- Is there documentation that the subject received a copy of the ICF? ☐ Yes ☐ No
- Is compensation provided? ☐ Yes ☐ No - *If yes*, is documentation available? ☐ Yes ☐ No
- If the IRB or sponsor required reconsent of subjects, were all subjects appropriately reconsented? ☐ Yes ☐ No
- List all ICF/HIPAA documents signed by this subject, including version date, IRB approval period, date and time of subject's signature.

Third Subject:

- Subject ID#:
- Did the subject meet eligibility criteria? ☐ Yes ☐ No
- Is documentation of eligibility complete and in the record? ☐ Yes ☐ No
- Is there an original copy of informed consent form (ICF) and HIPAA authorization on file? ☐ Yes ☐ No
- Was the person who obtained informed consent authorized by the IRB to conduct the research (HRPPM 3.18.3)? ☐ Yes ☐ No
- Is there documentation of the consent process in the research record (HRPPM 3.18.2)? ☐ Yes ☐ No
- Were the correct, updated and stamped versions of the ICF and HIPAA used for all subjects? ☐ Yes ☐ No
- Did the subject sign, date, and include the time on the ICF prior to the research procedures? ☐ Yes ☐ No
- Is each document properly completed with initials/signatures? ☐ Yes ☐ No, *if no, explain*:
- Did authorized research personnel sign, date and include the time on the ICF? ☐ Yes ☐ No
- Is there documentation that the subject received a copy of the ICF? ☐ Yes ☐ No
- Is compensation provided? ☐ Yes ☐ No - *If yes*, is documentation available? ☐ Yes ☐ No
- If the IRB or sponsor required reconsent of subjects, were all subjects appropriately reconsented? ☐ Yes ☐ No
- List all ICF/HIPAA documents signed by this subject, including version date, IRB approval period, date and time of subject's signature.

Section C: Regulatory Documentation

C-1 Is the current IRB-approved protocol included in the regulatory binder/file? ☐ Yes ☐ No

C-2 Are previous IRB-approved versions of the protocols included with the regulatory binder/file? ☐ Yes ☐ No

C-4 Are current CVs and licenses of PI and Co-Investigators, as well as certifications for all, included in the regulatory file/binder? ☐ Yes ☐ No

C-5 Is there a delegation of authority log (HRPPM 3.18.3)? ☐ Yes ☐ No
Is every person working on the study listed? ☐ Yes ☐ No
Are responsibilities assigned to each person appropriate in terms of that person's licensure, training and qualifications? ☐ Yes ☐ No
Is each entry up-to-date with start date (and stop date if applicable)? ☐ Yes ☐ No
Has the PI signed the delegation of authority log with each update? ☐ Yes ☐ No

C-6 Is this an FDA-regulated study?
☐ Yes, test article (drug, biologic, device)
☐ Yes, FDA-approved test article being used outside of labeled indications
☐ Yes, FDA-approved test article being used according to labeled indications
☐ No (If no, go to D)
Is a copy of the Form FDA 1572 (drugs or biologics) or Investigator Agreement (devices) signed by the PI included in the regulatory binder/file? ☐ Yes Date signed:_____ ☐ No

C-7 Are all versions of the Investigator Brochure, package insert, and/or Device Manual included in the regulatory binder/file? ☐ Yes ☐ No
Is the most current version of the Investigator Brochure uploaded in the IRB submission? ☐ Yes ☐ No
Is the IRB approved plan for storage & dispensation of the test article being followed? ☐ Yes ☐ No

C-8 Is the IRB approved data and safety monitoring plan (DSMP) being followed? ☐ Yes ☐ No ☐ N/A

C-9 Is study site monitored in accordance with the IRB-approved DSMP? ☐ Yes ☐ No ☐ N/A (if N/A, go to C-10)
Has the PI reviewed and responded to all monitoring reports? ☐ Yes ☐ No
Have all monitor findings been addressed and corrected? ☐ Yes ☐ No
Is there documentation that findings corrected have been reported to monitor? ☐ Yes ☐ No
Is the corrective action plan being followed, if any? ☐ Yes ☐ No ☐ N/A
Are all monitoring reports included in the regulatory binder/file? ☐ Yes ☐ No
Have all monitoring reports been submitted through iRIS, if applicable? ☐ Yes ☐ No

C-10 Has the data and safety monitoring board (DSMB) met in accordance with the IRB-approved data and safety monitoring plan? ☐ Yes ☐ No ☐ N/A (if N/A, go to Section D)
Are DSMB reports or records of recommendations included in the regulatory binder/file? ☐ Yes ☐ No
Have DSMB reports been submitted to the IRB? ☐ Yes ☐ No

Section D: Investigational Product (IP)/Study Supplies

If not applicable, indicate here: ☐ N/A

Note: If this information is kept on file with the Pharmacy or another department, then include an explanation stating where the information is located.

D-1 Only authorized personnel have access to the IP and can distribute it to the subject. This is documented on the signature and delegation list. ☐ Yes ☐ No

D-2 Check the tracking of IP at the site and recording of the IP on the accountability logs. ☐ Yes ☐ No

D-3 Perform IP accountability/inventory at site and subject level. Document any discrepancies identified. Verify that the information is consistent with the entries in the CRF and what is written in the source documents. ☐ Yes ☐ No

D-4 Check the temperature log to ensure that the storage conditions of the IP are within the ranges defined for the product. Ensure that any discrepancies have been documented and managed in the appropriate fashion. ☐ Yes ☐ No

D-5 Ensure that the expiration date of the IP present on site is still within acceptable range. ☐ Yes ☐ No

D-6 Ensure records of receipt, use, and return of IP are complete and accurate at the site. When applicable, ensure that unused IP is destroyed according to regulatory and client-specific requirements. IP destruction can only be done upon written approval of the sponsor. ☐ Yes ☐ No

D-7 If IP is destroyed, ensure a certification of IP destruction is available at the site. ☐ Yes ☐ No

Section E: Reportable Events, Unanticipated Events & Note to File

E-1 Have all unanticipated events (Protocol Deviations, UPIRSOs, UADEs, SAEs) meeting IRB Policies and Procedures reporting requirements, federal regulations and/or sponsor requirements been reported to the IRB? ☐ Yes ☐ No ☐ N/A

E-2 Have all unanticipated events been reported to the sponsor, as required by the sponsor? ☐ Yes ☐ No ☐ N/A

E-3 Have all instances of noncompliance reported to the sponsor, as required by the sponsor? ☐ Yes ☐ No ☐ N/A

E-4 Have all events that require reporting been reported to the IRB? ☐ Yes ☐ No ☐ N/A

E-5 Has a summary of all events been reported at the time of continuing review? ☐ Yes ☐ No ☐ N/A

E-6 Have all external adverse event (IND) reports been submitted through iRIS, if applicable? ☐ Yes ☐ No

E-7 Are necessary NTFs available? ☐ Yes ☐ No ☐ N/A

Section F: Billing and Subject Compensation:

If not applicable, indicate here: ☐ N/A

F-1 Have subjects received amount specified by ICF? ☐ Yes ☐ No

F-2 Have subjects received payment in method specified by ICF? ☐ Yes ☐ No

F-3 Are there records/receipts of subject payment distribution? ☐ Yes ☐ No

F-4 Are there receipt copies for procedures conducted at UMC/EPCH, and have all receipts been submitted appropriately? ☐ Yes ☐ No ☐ N/A If no, discrepancies are:

F-5 Are SOC procedures being charged to insurance? ☐ Yes ☐ No ☐ N/A If no, discrepancies are:

F-6 Are all study-related non-SOC procedures being charged to study/Sponsor? ☐ Yes ☐ No ☐ N/A If no, discrepancies are:

Section G: Sponsor-Investigator Responsibilities:

Drug Trials

If an investigator holds an IND, complete this section: ☐ N/A

G-1 Is there a signed Form FDA 1571 included with the regulatory documentation? ☐ Yes ☐ No

G- 2 Who is listed as the monitor in section 14 of the 1571, IND application? _____
Is this person/entity monitoring the conduct & progress of the study? ☐ Yes ☐ No

G-3 Have annual IND progress reports been submitted to the FDA? ☐ Yes ☐ No ☐ N/A
Have annual IND progress reports been included with continuing review submission to IRB?
☐ Yes ☐ No ☐ N/A

G-4 Is there a plan for regularly reviewing and analyzing safety information regarding the test article from other studies (U.S. or foreign, conducted by any sponsor), animal studies, literature reports, etc. and reporting the results of such review to the FDA in accordance with FDA reporting requirements (21 CFR 312.32)? ☐ Yes ☐ No

Is there a process for preparing IND safety reports and submitting the reports to the FDA? ☐ Yes ☐ No

The following questions pertain to multi-site trials where an investigator holds the IND: ☐ N/A

G-5 Is there documentation of qualifications for each investigator (i.e., CVs)? ☐ Yes ☐ No
Is there a Form FDA 1572/Investigator Agreement, signed by each investigator? ☐ Yes ☐ No
Is there a financial disclosure statement for each investigator? ☐ Yes ☐ No
Have all investigators been provided a copy of the Investigational Brochure/investigational plan?
☐ Yes ☐ No
Have all regulations been followed to ensure the safe receipt, labeling, disposition, and return of investigational drugs/devices? ☐ Yes ☐ No
Have all participating investigators been advised as to reporting requirements for serious adverse events, study endpoints and non-serious adverse events? ☐ Yes ☐ No
Is there a system for reviewing and analyzing the information received from these investigator reports to determine whether they warrant an IND safety report? ☐ Yes ☐ No
Is there a system for providing IND safety reports to FDA and to participating investigators and communicating to participating investigators safety reports and other safety information concerning the drug? ☐ Yes ☐ No

Device Trials

If an investigator holds an IDE, complete this section: ☐ N/A

G-6 Is there an IDE application that contains all required elements? (Note: there is no specific form for an IDE application, but all required elements are listed at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

G-7 Who is the monitor for the study?_____
Is this person/entity actively monitoring the conduct and progress of the study? ☐ Yes ☐ No

G-8 Have the following reports been submitted:

(a) Current investigator list (to be submitted every 6 months) – submit to FDA. ☐ Yes ☐ No
(b) Progress reports (to be submitted at regular intervals, no less than yearly) – submit to reviewing IRB and for significant risk device, also to FDA. ☐ Yes ☐ No
(c) Final report for significant risk devices (to be submitted 6 months after termination or completion of investigation) – submit to FDA, reviewing IRBs and participating investigators. ☐ Yes ☐ No

Is there a plan for regularly reviewing and evaluating unanticipated adverse device effects reports regarding the test article and reporting the results of the evaluation to the FDA, reviewing IRB and participating investigators? ☐ Yes ☐ No

The following questions pertain to multi-site trials where an investigator holds the IDE: ☐ N/A

G-9 Is there documentation of qualifications for each investigator (i.e., CVs)? ☐ Yes ☐ No
Is there an Investigator Agreement, signed by each investigator? ☐ Yes ☐ No
Is there a financial disclosure statement for each investigator? ☐ Yes ☐ No
Have all investigators been provided a copy of the investigational plan? ☐ Yes ☐ No
Have all regulations been followed to ensure the safe receipt, labeling, disposition, and return of investigational devices? ☐ Yes ☐ No

Section H: Corrective/Preventive Action Plan:

For any questions answered No, please describe a Corrective/Preventive Action Plan, including the corresponding item identifier, e.g., A-6 CITI certification, as a header, and implementation/completion dates.

Item Identifier:

Problem:

Root Cause:

Corrective Action:

Preventive Action:

_____ _____
Signature of study staff member completing this form Date

_____ _____
Signature of Investigator reviewing this form Date