Research Study Compliance Assessment Tool

This compliance assessment tool is a self-assessment tool to assist principal investigators and their study teams with conducting a self-audit of their study, along with preparing for a directed audit and/or post-approval monitoring review. This document is intended as a tool for the research community for the purpose of reviewing their study. This compliance assessment tool will not be reviewed by the IRB unless the study team chooses to submit with continuing review.

1.	**Training and Principal Investigator Responsibility** Review the KSP tab for the study in DISCOVR-e.
	Are all personnel who are involved in the conduct of this study listed as key study personnel (KSP)? ☐ Yes ☐ No If no, ensure that all personnel are listed under the KSP tab for the study, which can be updated administratively by the principal investigator and/or study team members. **Key Study Personnel:** The Principal Investigator and all individuals responsible for the design or conduct of the study. **Notes:**
	Do all key study personnel (KSP) have current Human Subjects Protection training? ☐ Yes ☐ No If no, ensure that all KSP who need Human Subjects Protection training are aware of training opportunities on the HRPP website at: https://www.vumc.org/irb/human-subjects-training **Notes:**

If the study is a clinical trial, do all KSP have current Good Clinical Practice (GCP) training?
☐ Yes ☐ No ☐ N/A

If no, ensure that all KSP who need GCP training are aware of training opportunities on the HRPP website at: https://www.vumc.org/irb/good-clinical-practice

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Notes:

Have credentials been provided for all KSP to allow the Committee to review the qualifications of the study team?
☐ Yes ☐ No

If no, ensure that all KSP have credentials provided under the KSP tab for the study, which can be updated administratively by the principal investigator and/or study team members.

Notes:

Has the Principal Investigator been present to conduct the research personally for the entirety of his/her role as the Principal Investigator?
☐ Yes ☐ No

If no, did the Principal Investigator submit a plan to ensure there was appropriate oversight during this time (ex., Temporary change of principal investigator)?
☐ Yes ☐ No

Note: It is the Principal Investigator's responsibility to ensure that all KSP have met the ongoing human subjects training and the have met the institution's GCP training requirement.

Notes:

2. Documentation Storage Requirements

Review the application and regulatory binder.

Are documents/data being stored as described in the approved IRB application?
☐ Yes ☐ No

If no, how are documents/data being stored?

Notes:

Does the principal investigator have a plan to maintain all research records for at least 3 years after study completion?
☐ Yes ☐ No

If no, what are the storage methods and the plan that the principal investigator intends to follow?

Per HRPP Policy VI.B: At a minimum, investigators must maintain research records for at least three (3) years from the date the research is closed with the IRB. All research records must be accessible for inspection and copying by authorized representatives of the HRPP, federal regulatory agency representatives, and the department or agency supporting the research.

Note: The study sponsor or the FDA may require that research records to be maintained longer than 3 years.

Notes:

If PHI will be used for the research, does the principal investigator have a plan to maintain authorization documents for 6 years from the authorization?
☐ Yes ☐ No

If no, describe how the principal investigator has decided to address this.

Per HRPP Policy VI.B: All Health Insurance Portability and Accountability Act (HIPAA) related documentation must be maintained for at least six (6) years from the date of the last use or disclosure of the Protected Health Information (PHI).

Note: Your institution (i.e., VU or VUMC) may require that the authorization documents be maintained longer than 6 years.

Notes:

Does the principal investigator and study team have a paper document binder and/or secure shared electronic file in which they keep copies of all approval letters from the IRB (e.g., Original IRB Approval, Continuing Review Approvals, Amendment Approvals, etc.), all approved study documents, and all approved stamped versions of the consent forms?
☐ Yes ☐ No

If yes, then please describe here. If no, then the principal investigator and study team will need to create a paper document binder and/or secure shared electronic file for these documents. The principal investigator and study team can access all of the approved documents in DISCOVR-e.

NOTE: The DISCOVR-e electronic submission system does not meet the requirement to be used as a regulatory binder for a study.

Notes:

3.	**Storage and Documentation of Informed Consent** Review of the signed consent/assent forms.
	Does the principal investigator and study team have a document binder, individual participant binders or secure shared electronic storage in which they keep all of the signed consent/assent forms? ☐ Yes ☐ No If no, then the principal investigator and study team will need to create a document binder, individual participant binders or secure shared electronic storage for the signed consent/assent forms. **Notes:**
	Does the principal investigator and study team have a document in their records to show that they have documented the consent process including who obtained consent and that a copy of the document was provided to the participant? ☐ Yes ☐ No If no, then if the study is still open to enrollment, the principal investigator and study team will need to create an internal document to show when the consent process occurred, who obtained consent/assent, and when a copy of the consent/assent form was provided to participants. **Per HRPP Procedure IV.B.1., Section I.F:** The person obtaining consent should document the consent process in the participant's medical record or the participant's research record. See additional information regarding what this may include within this HRPP procedure. **Note:** Please see the example of a consent process checklist attached on the compliance webpage. **Notes:**

4.	**Enrollment Numbers and Withdrawals** Review the currently approved application and the most recent continuing review application.
	What is the currently approved accrual goal at Vanderbilt? _____ (Subjects Population section) What is the total number of participants enrolled since the beginning of the study? _____ Has the study over enrolled? ☐ Yes ☐ No If yes, then consider submitting a noncompliance with the protocol to report the over enrollment along with submitting a separate amendment to increase the accrual goal for the study. **Note:** If your study is nearing the approved accrual goal, consider submitting an amendment to increase the accrual goal. **Notes:**
	Have there been any participants who withdrew (including PI initiated withdrawals), dropped out, or were lost to follow-up? ☐ Yes ☐ No If yes, have these been reported appropriately each year at the time of continuing review? ☐ Yes ☐ No If no, then ensure that you have a plan to report these at the time of the next continuing review. **Notes:**

5. Continuing Review and Study Status

Review the previous and most recent continuing review applications (if applicable).

What is the current status of the study? (check one below):

☐ No participants have been enrolled to date.
☐ Recruitment and/or enrollment of new participants or review of records/specimens continue.
☐ Study is no longer enrolling but participants still receive research-related interventions (e.g., still receiving treatment, obtaining blood draws, etc.).
☐ Study is no longer enrolling and participant have completed research-related interventions. The study remains active only for long term follow-up.
☐ Study enrollment is permanently closed, participant have completed all research-related interventions, and long-term follow-up has been completed. The remaining research activities are limited only to data analysis that may require contact with records or specimens.

Note: All studies regardless of continuing review requirements should submit a continuing review application through DISCOVR-e for closure at study completion.

Notes:

Does this study require continuing review?
☐ Yes ☐ No

If yes, has the principal investigator consistently submitted the continuing review application prior to study expiration each year?
☐ Yes ☐ No

If no, did all research procedures cease until approval was obtained? Was a status update on the study provided during expiration?

Per HRPP Policy III.K: It is the policy of the Institutional Review Board (IRB) that research activities be periodically reviewed at intervals appropriate to the degree of risk, but not less than once per year as required by the federal regulations.

Note: Some studies may be currently approved under the 2018 revised common rule, in which continuing review is no longer required. Check the regulatory determinations document attached to the end of the last continuing review FAL letter.

Notes:

6. Appropriateness of IRB Documentation

Review of amendments, adverse events, noncompliance with the protocol, DSMB reports, new findings.

Have there been any changes to the study since the most recent approval (continuing review approval)?
☐ Yes ☐ No

If yes, has the principal investigator submitted an amendment with revised study documents regarding these changes?
☐ Yes ☐ No

Have all changes been reviewed and approved by the IRB prior to implementation?
☐ Yes ☐ No

If no, then VHRPP advises submitting a noncompliance with the protocol to report these changes which were implemented prior to IRB review and approval, along with submitting a separate amendment with revised study documents regarding these changes.

Per HRPP Policy II.F: It is the responsibility of the Investigator not to deviate from the protocol approved by the IRB, except to avoid an immediate hazard to the participant. The Investigator must submit an amendment request to the IRB and receive written approval prior to implementation of any change to the protocol.

Notes:

	Have adverse events (AEs), non-compliances with the protocol, DSMB reports, and new findings been submitted to the IRB for review? Adverse Events (AEs) ☐ Yes ☐ No Non-compliances with the Protocol ☐ Yes ☐ No DSMB Reports ☐ Yes ☐ No New Findings ☐ Yes ☐ No **Note:** These may be provided at the time of continuing review if reporting is not required by HRPP Policy III.L. Regarding any non-compliance with the protocol, the principal investigator and study team are responsible for creating an action plan to prevent reoccurrence and to promote future compliance. **Notes:**
	Have there been any participant complaints regarding the research? ☐ Yes ☐ No If yes, then have these been reported to the IRB? ☐ Yes ☐ No If no, then ensure that these are reported to the IRB with the next continuing review. **Note:** You may discuss any participant complaints regarding the research with the VHRPP Research Subject Advocate by calling the VHRPP office at (615) 322-2918 and selecting Option 2. **Notes:**

7.	**Participating Sites** Review the Performance Sites tab in DISCOVR-e.
	Is the Vanderbilt principal investigator responsible for any external sites? ☐ No ☐ Yes If yes, has the principal investigator received and submitted the approvals/letters of cooperation for the external sites to the IRB? ☐ No ☐ Yes If no, then request copies of these documents from the external sites and submit to the IRB. **Notes:**
	Is Vanderbilt the IRB of Record? ☐ No ☐ Yes If yes to the question above, then the following two questions apply. If no to the question above, then skip to the next section below. If yes, do you have documentation of approval for each site? ☐ No ☐ Yes If yes, have these documents been submitted to the IRB? ☐ No ☐ Yes If no for the two questions above, then obtain the approval documents for each site and submit them to the IRB as an amendment. **Notes:**

8.	**Currently Approved Study Documents** Review of all currently approved study documents under the Approved Documents tab in DISCOVR-e.
	Finally, please review each section of the currently approved documents for the study to verify that all of the information is correct and up to date in each document and that the current and previously approved versions are in the study records (e.g., the study title matches across documents, the study purpose and study aims, research activities, research procedures and frequencies, data and safety, drug/device information, contact information in advertisements, recruitment tools, and consent and assent forms, consent documentation and consent process, etc.). Check each applicable box after you have reviewed each type of document: ☐ Protocol ☐ Application ☐ Consent/Assent Documents ☐ Investigator's Brochure ☐ Grant ☐ Advertisement ☐ Recruitment ☐ Study Measures ☐ Study Materials ☐ Other _____ Is all of the information correct and up to date in each currently approved document? ☐ Yes ☐ No If no, then consider creating and submitting an amendment to submit revised documents for IRB review and approval so the information is correct and up to date for the study. **Notes:**
	Thank you for using this compliance assessment tool to review your study!