Self-Assessment Tool and Instructions

This tool was developed to assist principal investigators (PIs) and research teams when reviewing their own research studies. We encourage self-assessments in preparation for Post-Approval Monitoring visits.

This tool is to be used as guidance and successful completion of it does not indicate that a research study is in compliance with all applicable laws, rules, regulations, and policies.

Self-Assessment Tool

Protocol number: _____
Protocol title: _____
PI name: _____

Regulatory Review:

Dated, Documented Approvals/ Authorization	Yes, No, N/A, Not Reviewed	References	Notes
1. Was initial IRB approval granted prior to enrollment of the first subject?		• *21 CFR 56.103, 56.108, 56.109* • *ICH GCP E6 4.4.1* • *Declaration of Helsinki* • *Institutional Review Board (IRB) Review Policy (UW-4145)* • *Investigator Manual, Part 8: Post-Approval Responsibilities*	
2. Were continuing reviews filed with the IRB without a lapse in approval?		• *ICH GCP E6 3.1.4, 4.10.1, 5.18.4(l)* • *Investigator Manual, Part 8: Post-Approval Responsibilities* • *Reliance Manual*	
3. If a lapse in IRB approval did occur, did the study team cease all study activities during the time of the lapse?		• *ICH GCP E6 3.1.4, 4.10.1, 5.18.4(l)* • *Investigator Manual, Part 8: Post-Approval Responsibilities* • *Reliance Manual*	
4. Did all changes* (including adding or not performing procedures) made to the protocol receive IRB approval before they were implemented? *not personnel changes		• *ICH GCP E6 3.3.7, 4.5.1, 4.5.4, 5.18.4(l)* • *FDA 21 CFR 312.53(vi)(a), 312.30, 312.66, 812.35(a), 812.150 (a)(4)* • *Common Rule 45 CFR 46.103(b)(4)(iii)* • *Declaration of Helsinki* • *Institutional Review Board (IRB) Review Policy (UW-4145)* • *Investigator Manual, Part 8: Post-Approval Responsibilities* • *Reliance Manual*	

5. If a change of protocol was implemented prior to IRB approval, was its purpose to avoid an apparent immediate hazard to subjects?		• *Investigator Manual, Part 8: Post-Approval Responsibilities*	
6. Have advertisements or other forms of participant recruitment been approved by the been approved by the IRB prior to use?		• *ICH GCP E6 3.1.2, 4.4.1, 5.11.1(c), 8.2.3, 8.2.7, 8.3.2, 8.3.3* • *FDA 21 CFR 56.109(b)* • *Institutional Review Board Review Policy (UW-4145)* • *Investigator Manual, Part 4: Preparing Supporting Documents*	

Study Personnel	**Yes, No, N/A, Not Reviewed**	**References**	**Notes**
7. Have all members of the study team completed the required HIPAA training prior to their involvement in the study?		• *ICH GCP E6 4.1.1* • *HIPAA Privacy Rule 45 CFR 164.530(b)(1)* • *FWA terms of assurance* • *UW HIPAA Privacy and Security Training Policy (UW-137)*	
8. Do all current members of the study team have non-expired HIPAA training?		• *ICH GCP E6 4.1.1* • *HIPAA Privacy Rule 45 CFR 164.530(b)(1)* • *FWA terms of assurance* • *UW HIPAA Privacy and Security Training Policy (UW-137)*	
9. Are all staff currently working on the study, listed in the IRB application?		• *Investigator Manual, Part 2: Researcher Requirements and Part 5: Submitting IRB Applications* • *HRP-311 – WORKSHEET – Engagement Determination* • *Reliance Manual*	
10. Have all changes in PI been approved by the IRB prior to the individual's involvement in the study?		• *Investigator Manual, Part 2: Researcher Requirements* • *Reliance Manual*	

11. Have all personnel changes (except PI) been submitted to the IRB prior to their involvement in the study?		● *Investigator Manual, Part 5: Submitting IRB Applications* ● *Reliance Manual*	

Study Conduct	**Yes, No, N/A, Not Reviewed**	**References**	**Notes**
12. Has the study enrolled a number of participants or reviewed a number of records less than or equal to the number approved in the protocol and ARROW application?		● *ICH GCP E6 3.3.7, 4.5.1, 4.5.4, 5.18.4(l)* ● *FDA 21 CFR 312.53(vi)(a), 312.30, 312.66,812.35(a), 812.150 (a)(4)* ● *Common Rule 45 CFR 46.103(b)(4)(iii)* ● *Declaration of Helsinki* ● *Institutional Review Board Review Policy (UW-4145)* ● *Investigator Manual, Part 8: Post-Approval Responsibilities*	
13. Is the clinicaltrials.gov record for the study up to date (last verified within the last 6 months to 1 year, recruitment status and record owner are current)?		● *FDA 42 USC 282* ● *Clinical Trials Registration & Results Reporting (KB 34044)*	
14. For the subject files reviewed, did study team adhere to the IRB approved protocol?		● *FDA 21 CFR 312.60* ● *ICH GCP E6 4.5* ● *Institutional Review Board Review Policy (UW-4145)* ● *Investigator Manual, Part 8: Post-Approval Responsibilities*	

<u>Participant Documentation and Data Review:</u>

Informed Consent	**Yes, No, N/A, Not Reviewed**	**References**	**Notes**
15. If required by the IRB, has the legally authorized representative and/or impartial witness signed and dated the consent/assent form document(s)?		● *ICH GCP E6 4.8* ● *FDA 21 CFR 50.20, 50.23, 50.24, 50.27* ● *Common Rule 45 CFR 46.116, 46.117(b)1 & 2* ● *HRPP Operations Policy (UW-4143)* ● *Investigator Manual, Part 3: IRB Review Requirements; Part 7: Conducting Human Participant* ● *HRP-090- SOP - Informed Consent Process for Research*	

16. Has the participant signed the Informed Consent/Assent and HIPAA forms prior to study procedures?		• *ICH GCP E6 4.8.2* • *FDA 21 CFR 50.20, 50.25(b)(5)* • *Common Rule 45 CFR 46.109(b)* • *HIPAA Privacy Rule 45 CFR 164.510(4)* • *Investigator Manual, Part 7: Conducting Human Participant Research*	
17. Has the participant signed all applicable versions of the Informed Consent/Assent and HIPAA forms?		• *ICH GCP E6 4.8.2* • *FDA 21 CFR 50.20, 50.25(b)(5)* • *Common Rule 45 CFR 46.109(b)* • *HIPAA Privacy Rule 45 CFR 164.510(4)* • *Human Research Protection Program (HRPP) Operations (UW-4143)* • *Investigator Manual, Part 4: Preparing Supporting Documents; Part 8: Post-Approval Responsibilities* • *HRP-090- SOP - Informed Consent Process for Research* • *HRP-091 – SOP – Written Documentation of Consent*	

18. Did the study team document or sufficiently describe that the participant was given a copy of the Informed Consent/Assent and HIPAA Authorization forms?		• *ICH GCP E6 4.8.11* • *HIPAA Privacy Rule 45 CFR 164.510(4)* • *Investigator Manual, Part 7: Conducting Human Participant Research* • *HRP-090- SOP - Informed Consent Process for Research* • *HRP-091 – SOP – Written Documentation of Consent*	
19. Are all pages of the original signed (physical, wet-ink) Informed Consent/Assent & HIPAA document(s) present?		• *Investigator Manual, Part 8: Post-Approval Responsibilities*	
20. If an oral consent or other modified consent process is used, has this process and (if applicable) whether consent was given, been sufficiently documented or described by the study team?		• *Investigator Manual, Part 7: Conducting Human Participant Research* • *HRP-090 – SOP – Informed Consent Process for Research*	
21. Was an oral consent or modified consent process used only after the study team gained IRB approval for the process?		• *Human Research Protection Program (HRPP) Operations (UW-4143)* • *Institutional Review Board (IRB) Review Policy (UW-4145)*	

22. Did subjects reviewed meet eligibility criteria at the time of enrollment?		• *FDA 21 CFR 312.60* • *Investigator Manual, Part 8: Post-Approval Responsibilities*	

Data Management and Security	**Yes, No, N/A, Not Reviewed**	**References**	**Notes**
23. Can the study team demonstrate that research data (including physical specimens) is being stored in compliance with the relevant provisions of the IRB approved protocol?		• *45 CFR 46.111(a)(7); 21 CFR 56.111(a)(7)* • *45 CFR Parts 160 and 164* • *20 U.S.C. § 1232g; 34 CFR Part 99* • *Institutional Review Board (IRB) Review Policy (UW-4145)* • *Investigator Manual, Part 2: Researcher Requirements; Part 8: Post-Approval Responsibilities*	
24. If applicable, can the study team demonstrate that research data is de-identified in compliance with the relevant provisions of the IRB approved protocol?		• *45 CFR 46.111(a)(7); 21 CFR 56.111(a)(7)* • *45 CFR Parts 160 and 164* • *20 U.S.C. § 1232g; 34 CFR Part 99* • *Institutional Review Board Review Policy (UW-4145)* • *Investigator Manual, Part 2: Researcher Requirements; Part 8: Post-Approval Responsibilities*	
25. If research data is being shared beyond the study team, can the study team demonstrate that this sharing is occurring in compliance with the relevant provisions of the IRB approved protocol?		• *45 CFR 46.111(a)(7); 21 CFR 56.111(a)(7)* • *45 CFR Parts 160 and 164* • *20 U.S.C. § 1232g; 34 CFR Part 99* • *Institutional Review Board Review Policy (UW-4145)* • *Investigator Manual, Part 7: Conducting Human Participant Research*	

Other	**Yes, No, N/A, Not Reviewed**	**References**	**Notes**
26. Were other discrepancies or inconsistencies found that are not otherwise noted on this form?			