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* ● UW IRB Authority and Independence Policy ● UW Initial Review of Research by Full IRB Policy	
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) ● UW Continuing Review by Full IRB Policy ● UW Suspension and Termination of Approved Research Policy	
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) ● UW Continuing Review by Full IRB Policy ● UW Suspension and Termination of Approved Research Policy	
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 ● UW Review of Change of Protocols by Full IRB Policy	
5. If a change of protocol		● UW Review of Change of Protocols by	

was implemented prior to IRB approval, was its purpose to avoid an apparent immediate hazard to subjects?		Full IRB Policy	
6. Have advertisements or other forms of participant recruitment 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)* • UW Recruitment of Research Participants Policy	

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	
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	
9. Are all staff currently working on the study, listed in the IRB application?		• *UW ED and SBS IRB Getting Started Guidance* • *UW Health Sciences IRB Key Personnel Guidance*	
10. Have all changes in PI been approved by the IRB prior to the individual's involvement in the study?		• UW Health Sciences IRBs How do you change the responsible principal investigator? • UW Health Sciences IRBs Personnel Change Guidance • Principal Investigator Responsibilities for Education and Social/Behavioral Researchers	
11. Have all personnel changes (except PI) been submitted to the IRB prior to their involvement in the study?		• UW Health Sciences IRBs Personnel Change Guidance • Principal Investigator Responsibilities for Education and Social/Behavioral Researchers	

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* ● *UW Noncompliance Policy*	
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*	
14. For the subject files reviewed, did study team adhere to the IRB approved protocol?		● *UW Initial Review Policy* ● *UW Noncompliance Policy* ● *FDA 21 CFR 312.60* ● *ICH GCP E6 4.5*	

Participant Documentation and Data Review:

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* ● *UW Review of Research Involving Vulnerable Participants Policy* ● *UW Research with Adults Lacking Capacity to Consent Policy* ● *UW Obtaining and Documenting Informed Consent Policy*	
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)* ● *UW Obtaining and Documenting Informed Consent Policy*	
17. Has the participant signed all applicable versions of the Informed Consent/Assent and		● *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)*	

HIPAA forms?		• *UW Obtaining and Documenting Informed Consent Policy*	
18. Is it documented 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)*	
19. Are all pages of the original signed (physical, wet-ink) Informed Consent/Assent & HIPAA document(s) present?		• *UW Obtaining and Documenting Informed Consent Policy* • *UW Policy on Data Stewardship, Access, and Retention*	
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?		• *UW Obtaining and Documenting Informed Consent Policy*	
21. Was an oral consent or modified consent process used only after the study team gained IRB approval for the process?		• *UW Obtaining and Documenting Informed Consent Policy* • *UW Noncompliance Policy*	
22. Did subjects reviewed meet eligibility criteria at the time of enrollment?		• *UW Noncompliance Policy* • *FDA 21 CFR 312.60*	

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* • *UW Protecting Research Participants Privacy Interests and Confidentiality of Data Policy*	
24. If applicable, can the study team demonstrate		• *45 CFR 46.111(a)(7); 21 CFR 56.111(a)(7)*	

that research data is de-identified in compliance with the relevant provisions of the IRB approved protocol?		● *45 CFR Parts 160 and 164* ● *20 U.S.C. § 1232g; 34 CFR Part 99* ● *UW Protecting Research Participants Privacy Interests and Confidentiality of Data Policy*	
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* ● *UW Protecting Research Participants Privacy Interests and Confidentiality of Data Policy*	

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