Submission Attachments			
Title	**Use/Description**	**Form/Templates**	**Guidance**
Research Plan	• The Research Plan is a narrative of the project and is a living document to be maintained over the life of the protocol. A Research Plan is required for every protocol submitted to the IRB.	Research Plan Template	Research Plan Guidance
Appendix A – HIPAA/Use of Protected Health Information	• Use this as an appendix to your Research Plan when your research involves use of Protected Health Information (PHI) under the HIPAA Privacy Law.	Research Plan Appendix A: HIPAA-Use of PHI	HIPAA & Human Subjects Research Guidance
Appendix B – Banking Projects	• Use this an appendix to your Research Plan to provide the IRB with information when your research involves banking of information/biospecimens	Research Plan Appendix-B: Banking-Projects	IRB SOP: Banking Projects
Appendix C – Research Involving Genetic Information/Tests	• Use this as an appendix to your Research Plan to provide information to the IRB when your research involves genetic information/tests	Research Plan Appendix-C: Genetic Materials/ Information/Tests	
Funding and Sponsorship	• Include this form with a new protocol submission if your project is funded. • Include with an amendment submission when funding has changed or is being added.	Funding and Sponsorship Form	
IRB Conflict of Interest Disclosure for Investigators	• Include this form with a new protocol submission if you are required to disclose a COI • Include this form with an amendment submission when there has been a change or new COI to disclose	IRB Conflict of Interest Disclosure Form for Investigators Conducting HSR	IRB SOP: Confliction of Interest (COI) in Human Subjects Research
Research Personnel	• Include with all new protocol and continuing review submissions • Include with amendments when changes to personnel are proposed.	Research Personnel Form	IRB SOP: Requirements & Qualifications to Serves as a Principal Investigator
IRB Investigator Agreement	• Include in all new protocol submissions. • Include with amendments when changes to Principal Investigator is proposed.	Investigator Agreement Form	IRB SOP: Responsibilities for Investigators Conducting Human Subjects Research
IRB Authorization Agreement (IAA) Request	• Include with new protocol and amendment submissions when	IRB Institutional Authorization	IRB SOP: Reliance Agreements for Multi-Site Projects

	requesting IRB oversight be deferred to either Campbell University or a collaborating institution.	Agreement (IAA) Request Form	
Investigator-Attestation for Ceded Projects	• Include with new protocol submissions when Campbell University is deferring IRB review to another institution	IRB Investigator Attestation for Ceded Projects Form	IRB SOP: Reliance Agreements for Multi-Site Projects
Individual Investigator Agreement (IIA)	• Include with new protocol and amendment submissions when a member of the research team is independent and unaffiliated with an institution.	IRB Individual Investigator Agreement (IIA) Request Form- CU IRB of Record	IRB SOP: Reliance Agreements for Multi-Site Projects
Letters of Support from External Sites	• Include with new protocol and amendment submissions when working with or conducting research at non-Campbell sites.	Letters of Support from External Sites	Letters of Support from External Sites
Data Use Agreement	• For use when transferring of identified data.	Data Use Agreement	Contact the IRB Office