

Submission Attachments			
Title	Use/Description	Form/Templates	Guidance
Research Plan	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Use this as 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> For use when transferring of identified data. 	Data Use Agreement	