

<b>NEW PROJECT REVIEW REQUIREMENTS</b>	
<b>Initial Application</b> (Project Approval Form/Project Review Form/UA-ASU-NAU Institutional Agreement/WIRB Submission)	<input type="checkbox"/> Attached
<b>Verification of Training Form</b> (for collaborators at outside institutions attach a copy of the human subjects training completion certificate)	<input type="checkbox"/> Attached
<b>UA Conflict of Interest and Commitment Disclosure Form</b>	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Certificate of Confidentiality</b>	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Informed Consent Form(s)</b> (including study specific Release of Information documents, DHHS approved sample consent forms)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>PHI Authorization Form(s)</b> (VA consent forms on the 10-1086 form, Data Use Agreement if using a Limited Data Set)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Recruitment Materials</b> (telephone scripts, flyers, brochures, websites, email texts, physician letters, radio/television spots, newspaper advertisements, press releases, etc.)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Participants' Materials</b> (study newsletter, physician to participant letter, wallet cards, incentive items, holiday/birthday cards, certificates, instructional videos/written guides, calendars, certification of achievement, etc.)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Site Authorization Letter(s)</b> (for recruiting, study conduct and/or access to administrative records/samples)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Other Committee Approval Letter(s) [only if Committee does not copy HSPP on approval]</b> (Medical Radiation Safety Committee, Institution Biosafety, UMC Biomedical Engineering, AZCC Scientific Review Committee, Institutional Review Committee [conflict of interest committee], tribal)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Data Collection Instruments</b> (Surveys, questionnaires, diaries, case report forms, not included in the protocol; data abstraction form [for medical record review].)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Protocol(s)</b> (Complete DHHS approved protocol if applicable, Protocol should incorporate the latest amendment/revision; sub-studies; extension studies)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Grant Application(s)</b> (A complete copy of the grant is required for all grant-funded research, regardless of institution)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Drug/Device Information</b> (Investigator's Brochure, Drug Product Sheet, Device Manual, Users' Manual, Instructions for Use, package insert, IND/IDE documentation, FDA 1572 form, 510k indication, FDA exemption, sponsor determination of device risk, etc.)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Data Monitoring Charter and Plan</b> (if not integrated in the protocol)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>VA Documentation</b> (10-9012 form, 10-1223 form, VA consent forms on the 10-1086 form)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Use of Retrospective Research Samples and/or Data</b> <ul style="list-style-type: none"> <li>• IRB approval letter</li> <li>• Original consent under which samples/data were collected</li> <li>• Letter allowing access to samples</li> </ul>	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Supplemental Site Information</b> (For sites engaged in research) <ul style="list-style-type: none"> <li>• The CV and medical license (if applicable) of site PI</li> <li>• Documentation of Federalwide Assurance on file with OHRP</li> <li>• Institutional Agreement</li> <li>• A site-specific VOTF</li> <li>• A copy of the site's human subjects training policy</li> <li>• A copy of any approvals granted from that site</li> </ul>	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable

**CONTINUING REVIEW REQUIREMENTS**

Attach the following appendices to the Continuing Review Form. If submitting an amendment concurrently, include notation in section three describing project changes in detail and indicate submission as concurrent and IRB approval is “pending”.

<b>Verification of Training Form</b>	<input type="checkbox"/> Attached
<b>UA Conflict of Interest and Commitment Disclosure Form</b>	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Informed Consent Form(s)</b> (Any new unstamped consenting documents)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Informed Consent Form(s)</b> (Previously stamped consent forms use in the last reporting period – only if enrollment in the last reporting period)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>PHI Authorization Form(s)</b> (Any new unstamped consenting documents)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>PHI Authorization Form(s)</b> (Previously stamped consent forms use in the last reporting period – only if enrollment in the last reporting period)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Publications relating to the study or are study/specific</b> (Peer reviewed articles; abstracts; presentations/slides; pending publications; thesis/dissertation cover page, abstracts, and reference section)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Literature Review</b> (List of references and/or abstracts of relevant articles)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Previously unreported safety reports and summarization of previously submitted tables for Serious Adverse Events</b> (Any data safety monitoring reports not previously submitted)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable

<b>AMENDMENT</b>	
<b>Request for Amendment Form</b>	<input type="checkbox"/> Attached
<b>Sponsor Correspondence</b> (Enrollment status changes, study closures, routine monitoring/audit reports, FDA correspondence, updated 1572 form, study personnel newsletters, etc.)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Verification of Training Form</b> (for collaborators at outside institutions attach a copy of the human subjects training completion certificate)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Certificate of Confidentiality</b>	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Revised or New Informed Consent Form(s)/Addendum to Informed Consent Form(s)</b> (one copy with changes highlighted, one clean copy for stamp)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>PHI Authorization Form(s)</b> (Data Use Agreement if using a Limited Data Set)	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
<b>Data Monitoring Charter and Plan</b>	<input type="checkbox"/> Attached <input type="checkbox"/> Not Applicable
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