

APPENDIX 5

Submission Timeline for Required Documentation— Human Subjects

Determination of Type and Date of Human Subjects Use As Indicated From Appendix 2	Gate 1 (Initial Proposal)	Gate 3 (Oral Review)
Year 1 Exempt (Item 4 from Appendix 2)	Completed answers to Appendix 3 and/or Appendix 4 as required	All other NIST required materials or clarifications as requested in pre-oral-review questions
Year 1 IRB review required (Item 5 from Appendix 2)	<ul style="list-style-type: none"> Name of the IRB that will be reviewing the protocol FWA or MPA number of the “engaged” institution and the expected date of IRB review 	<ul style="list-style-type: none"> Signed copy of the IRB approved protocol Signed and dated approval letter from the IRB indicating approval and expiration dates Copy of all IRB approved consent forms and advertisements
After year 1 Deferred exemption or deferred IRB review required	No documents are required to be submitted with the initial proposal	A projected date of human subjects use and a schedule of when NIST required materials will be submitted in accordance with the categories listed above

FWA = Federalwide Assurance
 IRB = Institutional Review Board
 MPA = Multiple Project Assurance
 NIST = National Institute of Standards and Technology