

APPENDIX B
INFORMATION NEEDED FOR RESEARCH PROPOSAL TO THE NIST INSTITUTIONAL REVIEW BOARD

Date of submission:

Through: Group Leader [Need signature]

Division Chief [Need signature]

From: Principal Investigators and Other Investigators: [Name, degree, whether PI or other (post-doc, guest researcher, NIST employee or contractor, etc.), NIST address, telephone number, email address, FAX]

1. Title of Project:
2. Site:
3. Estimated Duration of Study (including Experimental Schedule)
4. Number of Subjects:
5. Types of Subjects (include Selection Criteria for Subjects and method of recruitment of subjects; vulnerable subjects include people with mental or cognitive impairment, handicapped, economically disadvantaged, and other) NOTE: Research involving protected classes of subjects under 45 CFR Part 46 Subpart B, C, or D, i.e., pregnant women, fetuses and human in vitro fertilization, prisoners, and children, may not be reviewed by the NIST IRB. Such research must be reviewed by an outside IRB that possesses current assurances, appropriate for the research in question, from OPRR.
6. Purpose of Project:
7. Source of Funding:
8. Background and Objectives:
9. Experimental Protocol and Analysis Methods: (References for prior research in field can be added)
10. Summary of Human Subject Protocol
11. Potential Risks and Benefits:
12. Protection of Subjects against Potential Risks and Protection of the Subjects' Privacy:
13. Informed Consent Form:
14. THE FOLLOWING CERTIFICATION MUST BE INCLUDED: "I hereby certify that the information furnished concerning the procedures to be taken for the protection of human subjects is correct. I will seek and obtain prior Institutional Review Board (IRB) approval for any substantive modification of this protocol and will report any unexpected or otherwise significant adverse effects encountered in the course of this study."

_____ [Signature of Principal Investigator(s) and date]

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Director of Administration - Management and Organization Division
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