

<b>APPLICATION FOR HUMAN SUBJECT RESEARCH</b>			HSR #		
PRINCIPAL INVESTIGATOR		CODE	PHONE	E-MAIL	
PROJECT TITLE					
PROJECT DESCRIPTION AND METHODOLOGY SUMMARY <i>(Use continuation sheet if necessary)</i>					
Work unit number: _____			Area of Research Pre-approval attached		
APPROVAL REQUESTED <i>(Check all that apply)</i>					
New		Renewal	Continuing Review	Amendment	Closeout
For all but new applications, provide the following:					
Date of Initial Approval: _____			Date of Current Expiration: _____		
LEVEL OF RISK <i>(For exempt and expedited reviews, cite specific justification)</i>					
Minimal Risk		Greater than Minimal Risk			
Exempt		Convened Board Review Required			
Expedited		Category _____			
Expedited		Category _____			
Justification:					
Maximum number of subjects: _____ Time per subject: _____					
Special Populations: Minors Active Military Subordinates Other: _____					
Justification:					
Collaborating Institutions and PIs			Phone/E-mail	Protocol Attached	JRA Attached

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**Checklist for PI (Mark each box indicating the required document is attached or not applicable (N/A))**

<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Principal Investigator Agreement. Required for all applications.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Protocol ( <i>enclosure (3)</i> ). Required for all applications <b>EXCEPT</b> exempt. ( <i>See next</i> ).
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Short description for <b>exempt</b> projects. If the PI thinks a project is exempt, provide a description in sufficient detail to explain the nature of the work. Identify all Associate Investigators and Research Team Members, including non-NRL collaborators.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Informed Consent Document ( <i>enclosure (4)</i> ) or script if documentation has been waived. Required for new and renewal applications. Required for amendments when changing the Informed Consent Document. <b>Use only the current stamped Informed Consent Document when obtaining a subject's consent.</b>
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Questionnaires and other data collection instruments. Required for new applications. Required for renewals, amendments, and exempt only when documents change.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Debriefing sheet or script ( <i>enclosure (5)</i> ). Required for new applications. Required for renewals, amendments, and exempt only when document changes.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Recruitment memo ( <i>enclosure (6)</i> ). Required for new applications. Required for renewals, amendments, and exempt only when the memo changes.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Fully executed DoD Individual Investigator Agreement for each AI or Research Team Member associated with NRL through that document for the purpose of conducting research.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	JRA ( <i>enclosure (11)</i> ). Required for all applications when collaborations are involved.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Collaborators' complete IRB application with attachments. Required for all applications when collaborations are involved. Must include document showing IRB approval of collaborators' protocol application.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Area of Research Pre-Approval from Code 1001. Required for all applications; include both the requesting and approval memos.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Continuing Review and Final Report ( <i>enclosure (8)</i> ). Required for all continuing reviews, renewals that include continuing review, and closeouts <b>EXCEPT</b> exempt ( <i>see next</i> ). The Human Subject Research Summary Sheet ( <i>enclosure (7)</i> ) is sent directly to the Chair with any signed Consent Forms for that reporting period.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Continuing Review and Final Report for <b>exempt</b> projects. Provide a short summary of the progress, mentioning any significant events. List any changes to the protocol. Provide references to publications, talks, and briefings during this period of performance.

**Documents that must be on file (Check each box indicating that the documents are on file).**

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	Training certificates for the entire NRL research team.
<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	Circulum Vitae for the entire NRL research team.

**Electronic submission:**

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	E-mail all of the above documents as PDF or Word documents to the Chair, NRL Human Subjects Institutional Review Board. Please include your HSR number in the subject line of the e-mail.
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**Principal Investigator:** I certify that the information provided in this application is complete and correct.

NAME AND TITLE	SIGNATURE	DATE
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**DIVISION HEAD**

Reviewed for scientific soundness and scholarship.

Verified that research falls within the scope of the attached pre-approved area of research.

NAME AND TITLE	SIGNATURE	DATE
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HS-IRB DETERMINATION

Risk Level:                      Minimal Risk                                      Greater than Minimal Risk

Exempt                      Category \_\_\_\_\_

(Vice) Chair has reviewed and                      does                      does not recommend approval.

REVIEWER NAME	SIGNATURE	DATE
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Expedited                      Category \_\_\_\_\_

(Vice) Chair has reviewed:

Recommend approval (*all criteria of 32 CFR 219.111 have been satisfied*)                      Do not recommend approval.

REVIEWER NAME	SIGNATURE	DATE
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Convened Board Review                                      Convened Board Meeting Date: \_\_\_\_\_

Print Name	Signature	Code	Approve	Disapprove

**HS-IRB (Vice) Chair:** I certify that the investigators have met the research ethics and human subject protection training requirements, and that their Curriculum Vitae are on file.

NAME	SIGNATURE	DATE
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HS-IRB RECOMMENDATION

Based on expedited/exempt review, this protocol has been recommended for:

Approval                       Disapproval

Based on NRL HS-IRB full committee review, this protocol has been recommended for:

Approval                       Disapproval                       Dissenting opinion attached

SIGNATURE ( <i>Institutional Official</i> )	DATE	<input type="checkbox"/> Approved <input type="checkbox"/> Disapproved
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Additional safeguards required