



200 Boston Avenue, Suite 3000
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NOTES ON CABCS-FUNDED IRB PROTOCOLS

Human subjects research conducted using CABCS funding requires approval *not only* from the Tufts IRB, but also a secondary Army oversight committee. Both approvals must be in place before commencing any research with human subjects.

The following guide outlines the *specific additional* requirements of the CABCS; we are assuming a basic familiarity with the process of submitting a new human subjects research protocol or modification for review by the Tufts IRB. If you need information about the IRB or want to access necessary forms, please visit the Tufts SBER IRB website at (<http://emerald.tufts.edu/central/research/IRB/index.htm>).

Your IRB protocol should be written to accurately reflect the work outlined in your original proposal. For amendments outside the scope of your proposal please consult your CABCS scientific manager.

As a rule, if you have any questions, large or small, about whether or not you need approval on an action related to your research protocol, please do not hesitate to contact the CABCS program coordinator at centerforabcs@tufts.edu. The program coordinator will consult with the IRB to determine the Tufts requirements while also ensuring compliance with Army reporting requirements. It is extremely important that the CABCS program coordinator be a part of any conversation you have with the Tufts IRB regarding a Center-funded project. Tufts IRB determinations alone are NOT SUFFICIENT to begin data collection on a Center-funded project, and commencing data collection without secondary Army approval can result in loss of funding.

Please note, for the sake of simplifying secondary Army review and in keeping with new Tufts IRB standards, you must submit a *new* protocol to cover the activities of your CABCS-funded project.

Modifications and continuing review of CABCS-funded protocols need also be acknowledged or reviewed by the Army oversight committee and should therefore be sent first through the Center before the Tufts IRB.



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PREPARING A CABCS-FUNDED PROTOCOL

□ **STANDARD APPLICATION MATERIALS**

Complete all required materials for submission to the Tufts SBER IRB by downloading and completing the relevant forms, available at <http://www.tufts.edu/central/research/IRB/Forms.htm>. See below for instructions on form-specific instructions. If you have any other questions about completing these forms, please contact centerforabcs@tufts.edu.

1. Protocol Cover Sheet

○ Section I

- The Principal Investigator must be a postdoctoral scholar or professor (someone who has completed the requirements of a PhD).
- Please list the Study Coordinator using the following information. Assigning the CABCS program coordinator as your study coordinator is to ensure that no reporting requirements are neglected while minimizing the burden of these reporting requirements on the PI.

Name: Amy Wilson	Department: CABCS
Title: Program Coordinator	Phone: 617-627-1059
Address: 200 Boston Ave, Suite 3000	CITI Training Completed: Yes
Email: centerforabcs@tufts.edu	

○ Section III

- Please complete this section using the following information:

<input checked="" type="checkbox"/> Federal*	<input type="checkbox"/> Proposal Submitted <input checked="" type="checkbox"/> Funded	Agency Name: NSRDEC
<input checked="" type="checkbox"/> Institutional/Departmental	<input type="checkbox"/> Proposal Submitted <input checked="" type="checkbox"/> Funded	Describe: CABCS, Internal sponsor of NSRDEC funds – umbrella agreement
Grant title, ID, or #: <i>use the title of your proposal or protocol</i>		
Tufts PI on grant: <i>PI on protocol</i>	Is Tufts University a sub-contract of the grant? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

*You do not need to submit your CABCS proposal with your protocol application.

○ Section VI.B

- Institution Name: Natick Soldier Research, Development, and Engineering Center
- FWA #: N/A, DoD Assurance Number A20124

2. Protocol Application

- See below section on Scientific Review

3. Additional Investigators and Study Personnel

- Please use this form to list any other personnel who will be engaged in the study, including co-investigators, graduate and undergraduate research assistants, NSRDEC collaborators, etc. In cases where one person will be primarily responsible for running the study, it is helpful to indicate them here as a secondary “study coordinator” to encourage their



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inclusion on any e-mail notices from the IRB. The CABCS program coordinator will also ensure that this person receives approvals and stamped documents as well.

4. Other forms as relevant to your study (see the IRB's Protocol Application Checklist for guidance on typical submissions, and see "ADDITIONAL REQUIRED DOCUMENTS" below for instructions on specific language to be included in those documents as needed).

SCIENTIFIC REVIEW

One requirement of the Army review process is securing scientific review for your protocol prior to IRB approval. The CABCS program coordinator will solicit a scientific review on your behalf. Your responsibility is to ensure that your protocol is written up (either in the IRB Protocol Application or in a separate document referenced *within* the IRB Protocol Application) to include the following:

1. At least 1 paragraph demonstrating your knowledge of background literature.
2. Clearly stated hypotheses.
3. Clearly stated independent, dependent, and nuisance variables.
4. Clearly stated rationale for chosen method/procedures.
5. Clearly stated statistical and/or mathematical procedures.
6. Justification for number of subjects being used (sample size estimate and/or citing other paper(s) using similar design and N).

ADDITIONAL REQUIRED DOCUMENTS

Protocols being submitted for Army review must include some additional documentation not typically covered by the standard IRB process. Consent and debriefing forms used for Army-approved protocols must also include certain standardized language. Please prepare the following according to the templates provided at <http://www.centerforabcs.org/index.php/rfp/forms-templates> (tweak to suit your project) and include in your IRB submission packet.

1. Informed Consent Form
2. Debriefing Form
3. Roles and Responsibilities document
4. Relevance to Funding document

SUBMISSION

When you have completed materials according to the above guidelines, please submit EDITABLE documents to the CABCS program coordinator at centerforabcs@tufts.edu. Please also send your CITI completion report verifying human subjects training. The program coordinator will solicit scientific review and double-check for compliance with Army regulations, working with you to make any edits needed.