

Award Number: W81XWH-06 - 1-0165

TITLE: Family Maltreatment, Substance Problems, and Suicidality: Randomized Prevention Effectiveness Trial

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14. ABSTRACT This study aims to enhance the ability of base, major command (MAJCOM), and Air Staff IDSs to reduce death, injury, and degraded force readiness through (a) dissemination of base, MAJCOM, and AF prevalences of secretive problems; (b) provision of base-level information to identify and prioritize risk and protective factors, (c) assistance in bases' selecting and implementing empirically supported interventions, and (d) evaluation of whether prevalences were lowered.					
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			UU	47	19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	2
Body.....	2
Key Research Accomplishments.....	3
Reportable Outcomes.....	4
Conclusion.....	4
References.....	4
Appendices.....	4

INTRODUCTION:

One-quarter of airmen with serious levels of family maltreatment, suicidality, and problematic alcohol/drug use (i.e., at a level that, incontrovertibly, the AF would intervene therapeutically, administratively, or legally) degrades the AF's ability to fly, fight, and win our nation's wars. However, only 1 out of 6 reaches out to anyone in uniform (friend, first sergeant, commander, service agency). Thus, a prevention approach that decreases secretive problems by improving non-sensitive community health factors (i.e., targeted risk and protective factors) would be both a viable and valuable military readiness effort. This study aims to enhance the ability of base, major command (MAJCOM), and Air Staff community prevention committees to reduce death, injury, and degraded force readiness through (a) dissemination of base, MAJCOM, and AF prevalences of secretive problems; (b) provision of base-level information to identify and prioritize risk and protective factors, (c) assistance in bases' selecting and implementing empirically supported interventions, and (d) evaluation of whether prevalences were lowered. We will conduct a randomized, controlled prevention trial to test the effectiveness of the prevention science-guided NORTH STAR framework in reducing targeted risk factors; increasing targeted protective factors; and reducing base prevalences of family maltreatment, suicidality, and problematic alcohol and drug use. Twelve matched pairs of bases will volunteer and be randomly assigned to either (a) the NORTH STAR implementation condition or (b) the control condition (which will receive comparable prevalence and risk/protective factor information from the 2006 AF Community Assessment (CA+) but not receive any NORTH STAR training, support, or consultation). At the 12 test and 12 control bases we expect average participation (i.e., 912 AD members and 349 spouses per base) in the CA+, providing us with excellent statistical power.

BODY:

Year 1 (since last report)

Complete	<i>Task 6 Provide results of CA+ on secretive problems and risk/protective factors, to intervention sites; work with IDSs to identify other base-level data sources on relevant risk and protective factors</i>
Complete	<i>Task 8 Meet semi-annually with military advisory board (November and May)</i>
Complete	<i>Task 9 (Begin at end of year 1, continue into beginning of year 2) Leadership orientation to framework and plan at intervention sites.</i>
Complete	<i>Task 10: (Begin at end of year 1, continue into beginning of year 2) On-site visits at 12 test bases.</i>

Year 2

In Process	<i>Task 11 Provide the 12 test bases with the following</i> <i>• Quarterly newsletters</i> <i>• Monthly (fading to quarterly if warranted) conference calls or video conferences</i> <i>• Moderated listserv for all individuals connected with projects or interventions</i> <i>• Password protected webpage for cataloging newsletters, useful discussions from listservs, copies of training materials, etc.</i> <i>• At least every-other-week telephone consultation and technical assistance from SB team</i> <i>• Annual on-base individualized consultation and training with member of SB team.</i> <i>We have been providing support as listed above and will continue to do so until this phase of the project is completed over the next few months.</i>
Complete	<i>Task 12 Base leadership post-assessment, training evaluation at 24 sites.</i>

	Post-assessments have been collected and the data is being processed.
Complete	<i>Task 13 At four NORTH STAR pilot sites, review outcomes for targeted risk and protective factors (as indicated by 2nd administration of CA+). IDS iterates through cycle planning process again, this time with somewhat more independence.</i> Outcomes were reviewed and reported to the bases. However, over time all of the 4 pilot bases decided not to extend their participation beyond their original, completed 2 year commitment, due to changes in base and IDS leadership, as well as turnover in IDS team membership. Because they were not part of the randomized trial, the conclusion of their participation has no impact on the key aims of the study.
Complete	<i>Task 14 IDSs at intervention sites identify target populations and prioritize risk and protective factors for each targeted population</i> We have identified the target populations and the accompanying risk and protective factors.
Complete	<i>Task 15 IDSs at intervention sites conduct resource assessments.</i> Resource information as collected at all intervention sites and that information was compiled for each IDS.
Complete	<i>Task 16 SB conducts Community Resource Documentation (to identify policies and programs in each community that are consistent with tested efficacious prevention approaches) at 24 (effectiveness trial) + 4 (pilot) sites.</i> Reviewed approaches with all 24 sites. See Task 13 regarding the 4 pilot bases.
Complete	<i>Task 17 IDS at 12 intervention sites identifies efficacious prevention approaches and develops action plan for implementation targeting at least one target population in at least 3 relevant domains: individuals, families, schools, workplace, and community.</i>
In Process	<i>Task 18 Base leadership follow-up assessments at 24 (effectiveness trial) + 4 (pilot) sites.</i> We are finishing the collection of the follow-up assessments and expect to have them completed in the next couple of months. See Task 13 regarding the 4 pilot bases.
In Process	<i>Task 19 IDS at intervention sites implements action plan with technical assistance (see bulleted list above), systematically monitors impact, and adjusts implementation accordingly)</i> This is ongoing through this phase of the process and will only be completed when the entire phase is executed.
Not applicable	<i>Task 20 IDS at 4 pilot sites implements new action plan with technical assistance, systematically monitors impact, and adjusts implementation accordingly.</i> See task 13.
In Process	<i>Task 21 Meet semi-annually with military advisory board (November and May)</i> We met with the military advisory board 6-7-Jun-07 and 9-10-Jan-08. Our team also has weekly teleconferences with the advisory board's main point of contact, Maj. David Linkh.

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research.

- Successfully supported 12 test sites through the implementation of their community action plans.
- Collected process data on all 24 sites (test and control).
- Maintained momentum 12 test sites in enacting prevention activities, through regular phone, internet, and newsletter contact
- Consulted with the AF on collection of community assessment data (i.e., post test for the prevention initiatives) at all bases in the AF. The assessment will be in the field Apr – Jun 2008.

REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research to include:

Presentations of survey results have been limited to Air Force research meetings.

CONCLUSION: The purpose of this project is to test the effectiveness of the NORTH STAR approach to community prevention. To prepare for this test, training materials had to be revised, an AF survey had to be conducted, bases' readiness for empirically guided prevention had to be assessed, the results of the AF survey had to be analyzed and briefed, and each of the bases in the test condition had to be trained. All of these tasks were accomplished, putting our controlled, randomized, prevention trial on track for completion

REFERENCES: List all references pertinent to the report using a standard journal format (i.e. format used in *Science*, *Military Medicine*, etc.).

Not applicable.

APPENDICES:

Not Applicable

SUPPORTING DATA: N/A

USAMRMC Human Research Protection Office Continuing Review Submission Checklist

CONTINUING REVIEW OR TERMINATION DOCUMENTS TO SEND TO THE HRPO (If Applicable)

☒ The continuing review summary report that was submitted to your IRB

☒ Local IRB approval letter with next expiration date – **We have submitted the WHMC approval letter. The SUNY Stony Brook letter was not ready at the time of this submission but will be sent shortly.**

☒ Current copy of Protocol. Please list or track all Amendments that have occurred since the last time the protocol was submitted to HRPO.

☒ Current consent form, if applicable. List or track all revisions that have occurred since the last time the consent form was submitted to HRPO.

THE FOLLOWING CHECKLIST IS PROVIDED AS A GUIDANCE REFERENCE REGARDING THE REQUIRED ELEMENTS TO BE INCLUDED IN A CONTINUING REVIEW REPORT, PLEASE ENSURE THAT APPLICABLE ITEMS ARE ADDRESSED IN THE CONTINUING REVIEW REPORT OR ATTACHED IN A SEPARATE DOCUMENT: SEE ATTACHED

☐ Total number of subjects enrolled in the study (i.e., number recruited, enrolled, withdrawn by PI, discontinuation by subject, disenrolled [deaths, other])

☐ Breakdown of participants by demographics as appropriate (e.g., groups/cohorts, gender, age, ethnicity, special populations)

☐ Summary of SAEs, adverse events and unanticipated problems involving risks to subjects or others

☐ Summary of withdrawals that have occurred, with reasons for withdrawal

☐ Summary of complaints received

☐ Summary of deviations that have occurred

☐ Report includes a summary of research progress, including results obtained to date

☐ Documentation of literature review update, including databases searched, dates of searches, key words and subject areas searched. Risk/benefit assessment or other protocol activities updated as necessary based on review of literature. Measures included to reduce or minimize any newly identified risks

☐ Summary of any amendments, addendums, or modifications that have been made to the protocol since the initial approval (administrative, minor and major changes)

Name of individual to contact with questions regarding this report _____ **Cheryl Van Dyke**_____

Contact information (include email and phone number) _____ **Cheryl.vandyke@sunysb.edu**; 631-632-7825 _____

Date (day month year) _____ **2/29/08** _____

Continuing Review Report

1. Total number of subjects enrolled in the study (i.e., number recruited, enrolled, withdrawn by PI, discontinuation by subject, disenrolled [deaths, other])

308 IDS members

2. Breakdown of participants by demographics as appropriate (e.g., groups/cohorts, gender, age, ethnicity, special populations)

# of M (18 yrs or older)	UK
# of M (17 yrs or less)	0
# of F (18 yrs or older)	UK
# of F (17 yrs or less)	0
Total:	308
Est. percent of this total that were minorities*	UK

*UK – We did not assess gender or ethnicity, so these numbers cannot be calculated.

3. Summary of SAEs, adverse events and unanticipated problems involving risks to subjects or others
N/A
4. Summary of withdrawals that have occurred, with reasons for withdrawal
N/A
5. Summary of complaints received
N/A
6. Summary of deviations that have occurred
N/A
7. Report includes a summary of research progress, including results obtained to date
SEE IRB application
8. Documentation of literature review update, including databases searched, dates of searches, key words and subject areas searched. Risk/benefit assessment or other protocol activities updated as necessary based on review of literature. Measures included to reduce or minimize any newly identified risks
SEE IRB application
9. Summary of any amendments, addendums, or modifications that have been made to the protocol since the initial approval (administrative, minor and major changes)
SEE IRB application.

**Stony Brook University
Committees on Research Involving Human Subjects**

Application for FIVE (5) YEAR CONTINUED APPROVAL

NOTE: Save this file to your computer before continuing to fill it out. **Checkboxes can be activated with a mouse click and text boxes will expand with user input.** For reference, leave the current, online version of the Handbook for Investigators open on your computer while filling in this form. The Policies and Procedures Handbook for Investigators as well as links to federal policies can be found here:

<http://www.research.sunysb.edu/humans/humansubjects.html>

I. GENERAL PROTOCOL INFORMATION	2
II. STATUS OF STUDY	4
III. PROGRESS REPORT	4
III. A. Original number of subjects approved for this study at SBU:	4
III. B. On-Site Subject Statistics	Error! Bookmark not defined.
III. C. Unanticipated Problems /Unanticipated Serious Adverse Events	5
III. D. Modifications to the Study	6
III. E. Study Findings	7
IV. LAY SUMMARY & PROJECT DESCRIPTION (CONTINUING STUDY).....	7
V. SUBJECT INFORMATION.....	9
V. A. General Information	9
V. B. Vulnerable Populations	11
V. C. Subject Recruitment	13
V. D. Drugs, Devices, Radiation	14
V. E. Consent Procedures	15
V. F. HIPAA	16
V. G. Subjects Data / Biological Specimens	17
VI. OTHER QUESTIONS.....	17
VII. CONFLICT OF INTEREST.....	18
VIII. CERTIFICATION OF PRINCIPAL INVESTIGATOR	ERROR! BOOKMARK NOT DEFINED.
IX. CERTIFICATION OF DEPT. CHAIR/DEPARTMENTAL REVIEW COMMITTEE	ERROR! BOOKMARK NOT DEFINED.
X. APPROVAL OF CORIHS AND INSTITUTION.....	ERROR! BOOKMARK NOT DEFINED.
XI. DOCUMENT CHECKLIST	ERROR! BOOKMARK NOT DEFINED.

I. GENERAL PROTOCOL INFORMATION

(Note: All text boxes will expand with user input)

I. A. Protocol Title

Protocol 2 AF Innovative surveillance and risk reduction systems for family maltreatment, suicidality, and substance problems in USAF
Family maltreatment, substance problems, and suicidality: Randomized prevention effectiveness trial (4957)

I. B. Protocol Department (List all involved)

Psychology

I. C. Primary Research Personnel

1. Principal Investigator: Amy Slep

(MUST have SBU faculty status or BNL clearance as a PI)

Campus Address: Psychology

Zip: 2500

Campus Phone: 2-9346

Campus Fax: 2-7876

Email: amy.slep@sunysb.edu

** Research Category (1, 2, or 3): 1

2. Study Coordinator: same

Phone:

Fax:

Email:

** Research Category (1, 2, or 3):

** **Research Category**: (For each person, enter the appropriate value in Sections I.C. and I.D.)

1 – Interacts directly with human subjects in research that does not involve drugs, biologics, or devices;

2 – Interacts directly with human subjects in research that involves drugs, biologics, or devices;

3 – Only interacts with human data or human tissue in this research activity

I. D. Additional Personnel (Attach a separate sheet if study requires more than 5 people)

Name (Last, First)	Degree	SBU Status*	Department	Direct interaction with human subjects?	Currently CORIHS-Certified?
Richard Heyman, PhD, Faculty			Psychology	☒ Yes ☐ No	☒ Yes ☐ No
Cheryl Van Dyke, MSW, Res. Staff			Psychology	☒ Yes ☐ No	☒ Yes ☐ No
John Nelson, PhD, Res Staff			Psychology	☒ Yes ☐ No	☒ Yes ☐ No
			Psychology	☐ Yes ☐ No	☐ Yes ☐ No
			Psychology	☐ Yes ☐ No	☐ Yes ☐ No

* **Status**: Faculty, Resident/Fellow, Graduate, Undergraduate, Other (specify)

NOTE: All personnel listed on this application must satisfy SBU's requirement for training on the "Protection of Human Subjects" and "HIPAA in Research" in order for this application to receive final approval; Visit: <http://www.research.sunysb.edu/humans/trainopts.html>

I. E. Research Funding [If you are seeking or have secured funding, refer to [Section 24](#) of the Handbook for required consent text and related policy.]

☐ Not Seeking Funding ☐ Internal ☒ External ☐ Internal & External ☐ Seeking Funding

Grant Title: Innovative surveillance and risk reduction systems for family maltreatment, suicidality, and substance problems in USAF

Project / Task / Award #: 1053844 1 39069
(if funded externally) Example: xxxxxxxx - x - xxxxx

Funding Sponsor: DoD

I. F. Research Locations (Check all locations that apply for this study)

☐ Dental School/Clinic ☐ GCRC ☐ Hospital ☐ HSC ☐ LI Veterans Home
☐ Cancer Center ☐ Mod M (Metabolic Treatment Unit)
☐ Satellite (Tech Park, East End Clinic, etc.) ☒ W. Campus ☐ BNL ☐ Other:

Will the proposed activities be conducted in whole or in part at another institution?

☒ NO

☐ YES → Is it a multi-center clinical trial (e.g., Oncology Group, ACTG, Industry-initiated)?

☐ YES

☐ NO → Provide name(s) of participating institution(s) and indicate their role(s) in the study (**attach all relevant IRB approvals**)

--

I. G. University Hospital Involvement

Does this research involve the use of University Hospital patients, facilities, or records?

☒ NO ☐ YES → complete the required UH application
(<http://www.research.sunysb.edu/forms/uhappl.doc>)

I. H. Investigator-Initiated Protocols

1. Is this proposed study investigator-initiated?

☒ NO → Proceed to Section II

☐ YES → Answer the following questions (#2 - 4)

2. Does this research study prospectively assign human subjects to intervention or comparison groups to study the cause and effect relationship between a medical intervention and a health outcome?
 - ☐ NO
 - ☐ YES → You must comply with the clinical trial registration requirements detailed at <http://www.stonybrook.edu/research/humans/2005humsub.html#viii> if you anticipate publishing in a member journal of the International Committee of Medical Journal Editors listed at <http://www.icmje.org/jrnlist.html>
3. Does this research study involve a drug, biologic, or device requiring issuance of an IND, BB-IND, or IDE (respectively) from the FDA?
 - ☐ NO
 - ☐ YES (see note below)
4. Has a patent been filed or is it possible that a patent can be filed for the technology associated with the study intervention?
 - ☐ NO
 - ☐ YES (see note below)

NOTE: If answer to either question 3 or 4 above is checked YES, you are required to consult with SBU's Office of Technology Licensing and Industry Relations (OTLIR), N5002 Melville Library, (631) 632-9009.

II. STATUS OF STUDY

- ☒ Accrual and research intervention will continue
- ☐ Accrual is complete, but research intervention continues with those enrolled
- ☐ No accrual to date, but recruitment is continuing. Provide reason for no accrual:

III. PROGRESS REPORT

III. A. Total number of subjects currently approved for enrollment in this study at SBU
(the total number should reflect any amendments approved by CORIHS): 400

NOTE: CORIHS reminds you that you must amend your protocol and receive CORIHS approval prior to enrolling more subjects than have been approved for this study.

III B. On-Site Subject Statistics

FOR THE PAST APPROVAL PERIOD:

M = Males F = Females	Consented	Screen Failures (post-consent)	Enrolled (study intervention initiated)	Withdrew/ Removed* (explain below)	Still undergoing study procedures	Completed Study

# of M (18 yrs or older)	UK					
# of M (17 yrs or less)						
# of F (18 yrs or older)	UK					
# of F (17 yrs or less)						
Total:	119				119	
Est. percent of this total that were minorities*	UK					

***EXPLANATION FOR EACH SUBJECT WHO WITHDREW OR WAS REMOVED:**

2. Totals, since study began (Note: If this is the first time you are renewing this study, you can skip this section)

M = Males F = Females	Consented	Screen Failures (post-consent)	Enrolled (study intervention initiated)	Withdrew/Removed* (explain below)	Still undergoing study procedures	Completed Study
# of M (18 yrs or older)						
# of M (17 yrs or less)						
# of F (18 yrs or older)						
# of F (17 yrs or less)						
Total:	308				119	189
Est. percent of this total that were minorities*						

***EXPLANATION FOR ANY SUBJECT NOT COVERED IN CHART #1 ABOVE WHO WITHDREW OR WAS REMOVED:**

- 1) **** For each subject withdrawn / removed from this study since last approval (as listed in the table above), describe why:**

- 2) **If this is a multi-center study, total enrollment to date at all sites:**

III. C. Unanticipated Problems /Unanticipated Serious Adverse Events

Refer to the SBU Policy on Reporting UPs/USAEs in the online Handbook for Investigators (<http://www.research.sunysb.edu/HSG/HSGsec16.html>) for definitions and specific reporting requirements.

C1. Have you submitted all required UPs/USAEs for this study according to SBU policy?

- ☒ N/A → there have been no UPs/USAEs in this study – Skip to question **III C3**
☐ YES
☐ NO

- C2.** (a) Provide details for each **SBU subject** enrolled in this study who has experienced a study-related, unanticipated problem **OR** unanticipated serious adverse event **OR** death (except if due to disease progression) and briefly describe their nature and relationship to the study:

- (b) Upload a **summary statement** from the sponsor for **NON-SBU subjects** enrolled in this study who have experienced study-related unanticipated problems **OR** unanticipated serious adverse events **OR** death?

- C3.** (a) Has any **SBU subject** enrolled in this study experienced an anticipated serious adverse event?

☒ NO ☐ YES → Provide details on all such events for each subject:

- (b) Has any **NON-SBU subject** enrolled in this study experienced an anticipated serious adverse event?

☒ N/A ☐ NO ☐ YES → Upload summary statement from sponsor:

- C4.** Based on your knowledge of **ALL unanticipated problems** and **unanticipated serious adverse events** that have occurred in subjects in this study (including those occurring at other sites), do you feel there has been a significant increase in risks to subjects?

- ☒ N/A (no serious adverse events have occurred)
☐ YES → Please explain your assessment:
☐ NO → Please explain your assessment:

- C5.** Did any problems occur in the process of obtaining and documenting informed consent?

☒ NO ☐ YES → please explain the nature of the problem in the box below:

III. D. Modifications to the Study

Provide a **brief summary of any changes** that have been made to the project during the last approval period (changes in consent/assent form or process, investigators, protocol amendments). Highlight those changes that resulted in an increased risk to subjects. **If the study was terminated before completion, explain why.**

There have been no modifications since the last approval period.

III. E. Study Findings

Provide a brief summary, in the box below, of the **a) goals** and **b) results** (preliminary or final) obtained in the study. If there are no results to report at this time, so state, and explain why:

The purpose of this project is to assess base prevention boards' (IDS), leadership's (CAIB), and command members' perceptions of own, IDS's, CAIB's, and wing leadership's (a) ownership of problems and solutions, (b) commitment, support of risk and protective factor prevention approach, (c) collaboration among helpers, and (d) sense that there's an action plan. Base leadership pre-assessment was conducted at 3 sites and now an additional 24. Team training for IDS at intervention sites comprehensively reviewed the project, research plan, and all phases of the community intervention model. This training also included an introduction to project communication and support structure that is in place. We have also conducted a base leadership post-assessment training evaluation at the 3 AF sites.
At this time, we have no preliminary findings to report.

IV. LAY SUMMARY & PROJECT DESCRIPTION (Continuing Study)

NOTE: *(All text boxes will expand with user input)*

IV A. Describe in lay terms the scientific significance and goal of the study. If applicable, include detailed procedures involving human subjects. Upload full protocol in addition to text below.

Background: Of the many concerns about AF's force behavioral health protection, AF commanders identify secretive problems (family maltreatment, suicidality, and problematic alcohol/drug use) as 3 of the top 5 concerns. These problems are prevalent — the PRMRP-funded pilot study for the current proposal revealed that 25% of AF members reported at least one secretive problem at a serious level, yet only 1 out of 6 of these airmen report that anyone in the AF knows that they are having problems. The pilot study also funded the pilot implementation of the NORTH STAR prevention framework at four AF bases.

Objective/Hypothesis: This study aims to enhance the ability of base, major command (MAJCOM), and Air Staff IDSs to reduce death, injury, and degraded force readiness through (a) dissemination of base, MAJCOM, and AF prevalences of secretive problems; (b) provision of base-level information to identify and prioritize risk and protective factors, (c) assistance in bases' selecting and implementing empirically supported interventions, and (d) evaluation of whether prevalences were lowered. Thus, we hypothesize that NORTH STAR will enhance military readiness by reducing the prevalence of these threats and by decreasing the level of risk factors and increasing the level of protective factors in test communities.

Specific Aims: Conduct a randomized, controlled prevention trial to test the effectiveness of the prevention science-guided NORTH STAR framework in reducing targeted risk factors; increasing targeted protective factors; and reducing base prevalences of family maltreatment, suicidality, and problematic alcohol and drug use.

IV B. Describe subject recruitment procedures.

Twelve matched pairs of bases will volunteer and be randomly assigned to either (a) the NORTH STAR implementation condition or (b) the control condition (which will receive comparable prevalence and risk/protective factor information from the 2006 AF Community Assessment (CA+) but not receive any NORTH STAR training, support, or consultation). At the 12 test and 12 control bases we expect average participation (i.e., 912 AD members and 349 spouses per

base) in the CA+, providing us with excellent statistical power.

The sample will comprise those who receive the briefings/training in the NORTH STAR prevention initiatives (IDS members and AF leaders for each participating base.) There will be no additional recruitment for respondents. Pregnant women will not be excluded from participating. There will be no permanent information linking the subjects with the survey they complete.

The Community Assessment will be collected by a contractor. Twelve matched pairs of bases will volunteer and be randomly assigned to either (a) the NORTH STAR implementation condition or (b) the control condition. More specifically, within each MAJCOM, we will match bases (in sets of three) based on estimated prevalence of secretive problems and on 2003 CA data on risk and protective factors*. This will (a) roughly control for non-randomness in base mission and the type of personnel assigned to bases with those missions; and (b) provide for stronger political support within the AF, since each MAJCOM will have the opportunity to be represented. Each of the eight MAJCOMs will be given the opportunity to have one set of its bases participate; four randomly selected MAJCOMs will be given the opportunity to have two sets of its bases participate. Within each MAJCOM, the sets' order of invitation will be randomly selected.

Within the group of three, bases will be randomly assigned to either participate (i.e., test or control) or be the alternate should one of the other two bases decline. The AF Surgeon General's lead behavioral health officer in each MAJCOM (see accompanying letters of support) will contact the wing leadership for bases assigned to participate and attempt to gain their approval. If either base declines, the alternate base will be contacted. If only one of the three bases agrees, that grouping will be skipped and another set within that MAJCOM will be contacted. Each base that agrees to participate will be sent a Memorandum of Understanding (MOU), which will clearly state that bases have a 50-50 chance of being chosen for the test condition. After the MOUs are received, participating bases will be randomly assigned (within pair) to either the test or the control condition. We all selected bases received their briefing packages by the end of the summer 2005.

Members of the IDS/base leadership participating in the study will be presented with the assent form before trainings. They will be given time to read the form and consider their decision. IF they chose to participate they will complete the package and return it. They may complete this process in person, for the intervention group, or via fax, email, or mail for the control group and for follow-ups for both groups.

IV C. List all inclusion/exclusion criteria for subject entry or use of data/tissues.

There are no exclusions except they must be participating IDS members

IV D. Describe the potential risks and benefits to subjects and discuss potential problems related to those risks/benefits.

Some of the questions may make people uncomfortable, we this the chances of this are quite low.

IV E. Describe specific procedures to be used to ensure confidentiality of subjects' data (including, if applicable, the option of obtaining the data anonymously) and discuss potential problems related to confidentiality or other ethical problems. (Certificates of confidentiality may be necessary if a principal risk of the study is breach of confidentiality, where such a breach could place the subject at risk of criminal or civil liability or damage their financial standing, employability, insurability, or reputation. Visit NIH Office of Extramural Research; <http://grants1.nih.gov/grants/policy/coc/>)

Because we use an assent process, data collected cannot be matched to participants. All information is kept in password protected computer files, on password protected computers that are in locked rooms. Only limited staff has access to the data. Only Cheryl Van Dyke has access to the email sent or received.

IV F. Discuss, in detail, your consenting procedures. Specifically address how the capacity to consent will be assessed for all subjects. To satisfy this requirement, please refer to [Sections 12](#) and [13](#) of the online version of the CORIHS Handbook for Investigators. If it is your intent to request a waiver of informed consent, type N/A in the box below.

Both intervention and control groups will be given an assent letter explaining the project as well as their rights as participants. If they chose to continue they will return the questionnaire packet via mail, fax or email, or complete it on the websurvey.

We are using internet questionnaires versus postal mail to make it easier for IDS members to participate. Participants will complete the survey online on a secure website. We can mail or email packets to members who do not want to complete the study online. Additionally, participants can email questionnaires back to an email account created for this study that only Cheryl Van Dyke has access to. They can also fax or send their packets back through postal mail. We are trying to make the process as easy for them as possible. Many times, as members of the Air Force, individuals are sent to another base for temporary duty. Having the flexibility to answer the survey in whatever method may be available will not only make participation a viable option for them but much more efficient to us.

If they choose to log into the website to complete the survey, they will need to create a unique username and password. This process will be done so that they may sign-on and –off as many times as is needed. The user name and password will not be saved to the database. We will clear the system of usernames and passwords from completed surveys on a weekly basis.

V. SUBJECT INFORMATION

V. A. General Information

1. Subject gender for this protocol: ☐ Females only ☐ Males only ☒ Both genders
2. **Total number** of subjects at ALL locations needed to complete this study and answer the research aim: 400
3. If multi-center study (i.e., Oncology group, ACTG), what is the expected TOTAL number of subjects who will be fully enrolled at SBU?
4. Provide statistical justification for the total number of subjects listed in Question V. A. 2 above (i.e., power analysis). If qualitative research, so state, and provide general justification for the total number of subjects proposed:

In conducting randomized trials of community interventions, the unit of randomization is the base, and thus power is a function of number of bases (or pairs of bases) and, to a lesser extent, the number of individuals in the community and the prevalence of the targeted problems. We used Liu, Congdon and Raudenbush's "Optimal Design for Multilevel and Longitudinal Research" software program to estimate the optimal number of pairs of bases. Given an average n per base of 912 AD

members (for suicidality and substance problems) and 684 families (for family maltreatment) and assuming an small effect size of .20 and inter-base effect size variability of .10, the optimal number of bases is 12 test and 12 control.¹ Twelve pairs would provide power of .97 to detect changes in suicidality and substance problems and .81 to detect changes in family maltreatment.

5. Duration of subject participation (# hours / days / weeks): 2 x per year for about 20 minutes

6. Will subjects be withdrawn from therapeutic procedures (e.g., “washout periods”) prior to or during their participation in this study?

☒ NO ☐ YES → Describe the risks involved and address rescue medications/procedures

7. Will those consented for this study be limited to specific ethnic or social group(s)?

☒ NO ☐ YES → Describe below:

8. Federal mandates require that you include minorities (including American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic) in your research unless you can justify their exclusion. Are you including minorities?

☐ NO, minorities are not included (Justify your response in the box below)

☒ YES, minorities are included

9. Federal mandates require that you include non-pregnant women (age 18+) in your research unless you can justify their exclusion. Are you including this population?

☐ NO, inappropriate with respect to the health of the subjects (e.g., drug being studied has been shown to cause ovarian tumors in animal studies)

☐ NO, inappropriate with respect to the purpose of the research (e.g., a study of a drug for the treatment of prostate cancer, or a study investigating men’s role in household chores)

☒ YES

☐ Other (describe below)

10. Federal mandates require that you include minors in your research unless you can justify their exclusion. Are you including minors?

☐ NO, covered under another distinct protocol (i.e., Children’s Oncology Group)

→ Title and PI of that distinct protocol:

☐ NO, inappropriate due to lack of safety data in studies conducted in adults

- ☐ NO, inappropriate with respect to the health of the subject (e.g., drug being studied has been shown to cause growth defects in animal studies)
- ☒ NO, inappropriate with respect to the purpose of the research (e.g., study of treatments for Alzheimer's disease, or a study on the causes of divorce)
- ☐ YES
- ☐ Other (describe below)

V. B. Vulnerable Populations

V. B. 1. Indicate which of the following populations could possibly be included in the research.
Check all that apply and answer questions if asterisk population is selected

- | | |
|---|---|
| ☐ Minors, ages 0 – 17 *
[Complete Section V. B. 2] | ☐ Non-English Speakers *
[Complete Section V. B. 4] |
| ☒ Fetuses / Pregnant Women *
[Complete Section V. B. 6] | ☐ Nonviable/Questionably Viable Neonates *
[Complete Section V. B. 5] |
| ☐ Individuals Unable to Consent for Themselves *
[Complete Section V. B. 3] | ☒ Women of Childbearing Potential *
[Complete Section V. B. 7] |
| ☒ Economically Challenged | ☐ Investigator or Self |
| ☒ Educationally Challenged | ☒ Minorities |
| ☐ Employees or Subordinates of Investigators | ☒ Normal Volunteers |
| ☐ Family Member of Investigators | ☐ Students or Trainees |

*** Instructions:** If you did not check any of the * populations: minors, those unable to consent for themselves, non-English speakers, non-viable/questionably viable neonates, fetuses/pregnant women and/or women of childbearing potential, proceed to **Section V. C.** (Subject Recruitment); If you checked a * population, answer the corresponding questions below.

V. B. 2. Minors, ages 0 - 17

a. Will you obtain parental permission? Refer to [Section 10](#) of the Handbook for Investigators for applicable exceptions.

- ☐ NO → Justify below and state why you will not obtain parental permission
- ☐ YES → Refer to [Section 15](#) of the Handbook for Investigators for the current format

b. What is your assessment of the risk/benefit in this study?

- ☐ Minimal Risk
- ☐ More than minimal risk with possible direct benefit
- ☐ Slightly more than minimal risk without the possibility of direct benefit (both parents must give permission)
- ☐ Other → Justify below

c. Will you obtain minor assent? NOTE: IRB will decide when assent will be obtained for 8 – 11 year olds. Generally, assent is documented between 11 – 17 year olds.

- ☐ NO → Review [Section 10](#) of the Handbook for Investigators and justify below
- ☐ YES → Upload assent form. Review [Section 15](#) of the Handbook for Investigators for format and requirements.

V. B. 3. Those Unable to Consent for Themselves

a. Will the study involve either minimal risk or more than minimal risk with the possibility of direct benefit?

- ☐ NO ☐ YES

b. If your subject population will include adults who will not or may not have the capacity to give informed consent, provide justification for inclusion of these subjects, discuss how surrogate consent will be sought, and provide detailed steps to be taken to ensure additional protection of the rights and welfare of this subject population. (Refer to [Section 13](#) of the Handbook for Investigators for specific information)

V. B. 4. Non-English Speakers

a. How will you ensure that the information you provide will be understandable to the subjects? Refer to [Section 12](#) of the Handbook for Investigators for specific requirements.

- ☐ The IRB-approved English version of the consent form(s) will be translated into a foreign language and an affidavit of accurate translation will be submitted at a later date as an amendment
- ☐ I will use the OHRP method - Upload short consent form (used only for minimal risk studies)

V. B. 5. Nonviable / Questionably Viable Neonates

For detailed information involving the use of neonates in research, see [Section 9](#) of the CORIHS Handbook for Investigators. Contact the Office of Research Compliance with any questions (2-9036).

a. Which category is applicable to your research? (Select both if appropriate)

- ☐ Neonates of Uncertain Viability

☐ Nonviable Neonates

b. Does your research satisfy the criteria outlined in **Section 9** of the Handbook?

☐ NO → Justify below

☐ YES

V. B. 6. Fetuses / Pregnant Women

a. Where scientifically appropriate, have preclinical (animal) studies and clinical studies been done on non-pregnant women to assess potential risks to women and fetuses?

☒ NO ☐ YES

b. Risks to fetus are:

- ☐ Caused by procedures holding out the prospect of direct benefit for the woman or fetus
☐ Minimal and no direct benefit but the purpose of the research is to yield important biomedical knowledge which cannot be obtained by any other means

c. Explain the risk/benefit to fetus and/or mother. Review [Section 9](#) of the Handbook for Investigators for specific consent requirements.

There are no risk to the fetus or the mother

V. B. 7. Women of Childbearing Potential

CORHS requires specific language in the consent form for such instances where women of childbearing potential are included in the subject population of research involving the administration of drugs / tests/ devices with either known or unknown risks to a fetus. Please consult [Section 14](#) of the Handbook for Investigators for specific language to include in the consent form.

a. Will this study involve the administration of drugs/ tests/ devices with either known or unknown risks to a fetus?

☒ NO ☐ YES

b. How will you ensure that pregnancy does not occur during the course of the study?
(Select all that apply)

- ☐ Counseling on birth control and /or abstinence
☐ Pregnancy test during the study
☐ Pregnancy test prior to initiation of the study
☒ N/A

V. C. Subject Recruitment

1. Will subjects be paid for participation?

☒ NO

☐ YES → Provide details of remuneration (i.e., total amount and prorated scheduling)

2. Will physicians or staff refer subjects?

☒ NO

☐ YES → Referring physicians or staff must NOT receive incentives to recommend subjects for study participation

3. Will your subject population consist of West Campus departmental subject pools (e.g., psychology, political science)?

☒ NO

☐ YES → Participation in studies may be offered for credit in class but students **MUST** be given other options for fulfilling the research component that are comparable in terms of time, effort, and education benefit. **Please list alternative activities below.**

4. Describe any other recruitment methods such as the use of advertisements, flyers, and media scripts that you will use in this research and include copies with this submission.

V. D. Drugs, Devices, Radiation (Attach a separate sheet as needed)

1. **DRUGS** – List all study drugs, including experimental and control

Trade & Generic Names	FDA Approved?	FDA Approved for <u>use indicated in protocol</u> ?	IND #
	Y ☐ N ☐	Y ☐ N ☐	
	Y ☐ N ☐	Y ☐ N ☐	
	Y ☐ N ☐	Y ☐ N ☐	
	Y ☐ N ☐	Y ☐ N ☐	
	Y ☐ N ☐	Y ☐ N ☐	
	Y ☐ N ☐	Y ☐ N ☐	
	Y ☐ N ☐	Y ☐ N ☐	

For all drugs listed, upload the following as applicable:

- **Investigator Brochures** (for all experimental, non-FDA approved drugs)
- **Package Inserts** (for all FDA-approved drugs being used off-label or for any FDA-approved drug specifically being investigated in this study protocol)
- Completed copy of **FDA form #1572** (Statement of Investigator Form)
- Completed copy of **FDA form #1571** (IND Application Form)

For all drugs listed that are **non-FDA approved** or non-FDA approved for the use indicated in this protocol, **justify exemption** from obtaining an IND # in the text box below.

(See http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr312_99.html - FDA 21 CFR 312.2 {Applicability} (b) to determine if your research satisfies the five points listed.)

--

2. DEVICES Upload an Investigator's Device Brochure as applicable

	Device 1	Device 2
Trade & Generic Names:		
IDE # & Holder:		
FDA approved?	Y ☐ N ☐	Y ☐ N ☐
FDA approved for the <u>use indicated in this protocol</u> ?	Y ☐ N ☐	Y ☐ N ☐
Device risk – Significant?	Y ☐ N ☐	Y ☐ N ☐
** IDE category:	A ☐ B ☐	A ☐ B ☐

**** IDE Category - Category A:** Experimental/Investigational; innovative device, not previously approved

Category B: Non-experimental/Investigational; proven technology, new application

- a) For devices that are **non-FDA approved** and **do not have an IDE #**, justify use below:
 (See: http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr812_99.html - FDA 21CFR 812.2)
- b) Explain device risk justification for each device listed:

--

3. RADIATION – What form(s)? Include amounts and schedule of administration

- ☐ Diagnostic X-Rays ☐ Radiation Therapy
☐ Radioisotopes ☐ Other, describe:

--

V. E. Consent Procedures

A subject may not be involved in research (including collection/study of their tissue or data) unless informed consent has been obtained. A waiver may be requested under limited conditions.

1. Type of consent to be obtained: **(SELECT ONE)**

- ☐ Written Consent → Upload a copy of the consent form with this application
☐ Waiver of Consent → Describe, in the text box below, how this study meets all four conditions listed in [Section 12](#) of the online Handbook for Investigators. These criteria must be documented by the PI before the IRB considers granting this waiver.
☒ Waiver of Documentation of Consent → Specify, in the text box below, which of the two criteria listed in [Section 12](#) of the online Handbook for Investigators pertains to this study. (**Note:** Examples in which this waiver may be requested include a web-based consent, telephone survey, or anonymous survey.)

We have web-based consent and a consent letter

2. Does this research involve a web-based consent/survey?

☐ NO

☒ YES → Describe the security measures taken to ensure confidentiality. If you will be using an independent research organization or internet-based data gathering firm to collect responses, provide information about the firm (company name, description of primary activities, etc.) and upload a copy of their privacy policy with this application.

Because we use an assent process, data collected cannot be matched to participants. All information is kept in password protected computer files, on password protected computers that are in locked rooms. Only limited staff has access to the data. Only Cheryl Van Dyke has access to the email sent or received.

3. Is deception involved in this research?

☒ NO

☐ YES → Justify below and upload a debriefing statement that will be provided to subjects.

4. How and where will consent be obtained?

5. If subjects are unable to give consent (e.g., minors or those mentally impaired), describe how and by whom permission will be granted. If minor, how will you assess assent?

Subjects that are unable to give consent will not be allowed to participate

V. F. HIPAA

1. Does this research involve the collection of health information from e.g., medical records, healthcare providers, or direct interaction with the subjects? Health information includes physical or mental information regarding the status, diagnosis, treatment and /or prevention of a physical or mental condition of the type that is now, or could be in the future, covered by health insurance.

☒ NO → Skip the next question – Continue with Section V. G.

☐ YES → Answer the next question

2. If you answered **YES to V. F. 1**, select the statement that best applies to the privacy of the health information and follow the steps as indicated. HIPAA Forms may be accessed here: <http://www.research.sunysb.edu/humans/hsforms.html>

☐ Subject's consent and authorization for collection and use of their health information will be obtained.

☐ The health information being accessed or used is de-identified. No identifiers on the de-identification form will be retained. **Complete and upload the HIPAA De-identification Form** with this protocol application. In addition, upload the spreadsheet or case report

form you intend to utilize to collect your data in a de-identified manner. The name of the individual collecting the data on the spreadsheet/CRF must be included.

- ☐ The health information being accessed or used constitutes a limited data set (LDS), i.e., no identifiers on this form will be retained. **Complete** and **upload the HIPAA LDS Form** with this protocol application. In addition, upload the spreadsheet or case report form you intend to utilize to collect your limited data set. The name of the individual collecting the data on the spreadsheet/CRF must be included. **NOTE:** The LDS differs from de-identified health information in that an LDS may contain a) a unique identifying number, characteristic or code (e.g., a registry or study number), b) elements of dates, and c) address information including town, city, state, zip code (BUT NOT Street Address). The entity from which you obtain your data will require that you sign a data use agreement to assure subject privacy.
- ☐ Some or all of the subject identifiers on the HIPAA LDS form will be retained but subject authorization or consent WILL NOT be obtained. **Complete** and **upload the HIPAA Waiver of Authorization** form with this protocol application.

V. G. Subjects Data / Biological Specimens

1. Data collected for the study will be obtained:
 - ☐ anonymously (no way to link sample with subject identity): No identifiers listed on the [De-Identification form](#) will be used.
 - ☒ in a coded manner (a link to the subject is retained; it is possible to find out the identity of the subject from whom the data were obtained, i.e., initials, social security #, medical record #, etc.)
 - ☐ in a fully identified manner (e.g., name)
2. Is banking of data (e.g., 'registry', etc) proposed for future, as yet unspecified research?
 - ☒ NO
 - ☐ YES → Refer to [Section 18](#) of the Handbook for policy
3. Does this research activity involve the collection of biological specimens? (check all 'yes' answers that apply)
 - ☒ NO→Proceed to Section IV.
 - ☐ YES, specimens will be obtained from future, discarded clinical samples
 - ☐ YES, specimens will be obtained from procedures performed specifically for research
 - ☐ YES, retrospective collection (specimens have already been obtained, i.e., already "on the shelf")
4. Biological specimens collected for the study will be obtained:
 - ☐ anonymously (no way to link sample with subject identity): No identifiers listed on the [De-Identification form](#) will be used.

- ☐ in a coded manner (a link to the subject is retained; it is possible to find out the identity of the subject from whom the data were obtained, i.e., initials, social security #, medical record #, etc.).
- ☐ in a fully identified manner (e.g., name)

5. Will the analysis of the specimens be able to provide information that has known clinical significance for diagnosis or prediction of a disease state for either the subject or the subject's family members?

- ☐ NO
- ☐ YES → Refer to [Section 19](#) of the Handbook for policy

6. Is banking of biological specimens proposed for future, as yet unspecified research?

- ☐ NO
- ☐ YES → Refer to [Section 18](#) of the Handbook for policy

VI. Other Questions

1. Please list the expected number of years this study will be active: 5 years

2. Does this study intend to follow subjects for life? ☒ NO ☐ YES

3. If this is an investigator-initiated study involving a non-FDA approved use of a drug or device, provide an abstract from all relevant literature references that includes a comprehensive analysis of the safety profile of the drug or device. (Example: Medline search)

4. Will data be reviewed by an independent Data Safety Monitoring Board (DSMB)?

- ☒ NO
- ☐ YES → Provide the name of the DSMB or describe how the Board was constituted. You must include this information in the "Confidentiality/Protecting the Privacy of Your Health Information" section of the Consent Form.

5. Does this study have a Data Safety Monitoring Plan? (Note: all GCRC protocols are required to have a DSMP)

- ☒ NO ☐ YES

6. Will this research use third party information such as family history or sexual contacts?

- ☒ NO ☐ YES → Describe protections for consent and/or privacy of third party

VII. Conflict of Interest

1. If this activity is, or will be, funded by a sponsor, does the associated contract/agreement allow for an enrollment bonus or incentives (i.e. a sliding scale payment to the institution based on the number of subjects enrolled or number of subjects enrolled within a given time frame)?

☒ N/A

☐ NO

☐ YES → Provide detail below including amount and scheduling of the incentive

2. Do any investigators listed in Sections I. C. and I. D. (Research Personnel) of this application have a **significant (personal) financial interest** in the conduct or results of this study (e.g., consulting fees, honoraria)? Refer to [Section 24](#) of the Handbook for Investigators for the definition of financial interest.

☒ NO ☐ YES → Provide detail below

3. If you answered **YES** to question 1 or 2 above, has your potential conflict of interest been disclosed in the consent form, per SBU policy?

☒ N/A ☐ NO ☐ YES

Section VIII. Certification of Principal Investigator

My electronic signature that will accompany the submission of the application and all supporting documents to CORIHS certifies that the information provided in this application and supporting materials is accurate, and that the associated study will be conducted in full compliance with Stony Brook University's Policies and Federal regulations governing human subject research. Furthermore, I will:

- Conduct all aspects of the project as approved by CORIHS,
- Promptly report any revisions or amendments to the research activity for review and approval by CORIHS prior to commencement of the revised protocols, with the only exception to this policy being those situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject,
- Promptly report any unanticipated problems or serious adverse events affecting risk to subjects or others,
- Assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials,
- Use only CORIHS-approved, stamped consent forms for studies in which consent form(s) have been approved for the research activity, and

- Ensure that all personnel involved with human subjects, or human data and/or biological specimens during the course of this research activity are trained in the Protection of Human Subjects and HIPAA in Research, in full accordance with SBU policy on this matter.

Section IX. Certification of Co-Investigators

My electronic signature certifies that:

- I am fully cognizant of the details of the protocol, and will conduct all aspects of the study as approved by CORIHS
- I will promptly report to the Principal Investigator any unanticipated problems or serious adverse events affecting risk to subjects or others
- I will not be involved in any aspect of the study for which I have not been trained, or conduct any procedure in which I am not certified/licensed.

Section X. Certification of Department Chair/Departmental Review Committee

My electronic signature certifies that I have reviewed the application and all supporting documents pertaining to this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct this project.

Note: If the department chair or member of the departmental review committee is an investigator on this study, s/he can electronically sign as PI if his/her role is as principal investigator, but s/he cannot additionally sign this certification as the chair or member of review committee. The preferable signatory is the Chair (if the investigator is on the review committee), your Dean (if the investigator is the chair), or the VP for Research (if the investigator is Dean). Official designees of these signatories are also acceptable so long as the designee is not a subordinate to the investigator in any way.

ⁱ Raudenbush, S.W., & Liu, Xiao-Feng (2001). Effects of study duration, frequency of observation, and sample size on power in studies of group differences in polynomial change. *Psychological Methods*, 6, 387-401.

February 2008

CONSENT FOR RESEARCH

Study: NORTH STAR Process Evaluation

Sponsor: USAMRMC/ DoD

Investigators: Dr. Amy M. Smith Slep, Research Associate Professor

Dr. Richard E. Heyman, Research Associate Professor

You are being asked to be a volunteer in a research study in the Department of Psychology, The State University of New York at Stony Brook.

Purpose

The purpose of this project is to study the implementation of the NORTH STAR initiative. Integrated Delivery System members (IDS) and leaders at approximately 24 AF bases are participating in this study.

Procedures

IDS members and leaders have periodically participated in NORTH STAR trainings and briefings beginning in Fall, 2003. If you decide to be in this study, you will be asked to complete several short questionnaires. The questionnaire will take approximately 15 minutes to complete.

Risks/Discomforts

There are no risks/discomforts associated with your participation.

Alternatives

Your alternative is to not participate in the study.

Benefits

By participating in this study, you are helping the Air Force test a new orientation toward community prevention. You will have your voice heard about ways in which the NORTH STAR initiative can be improved.

Payment to You

You will not be paid to participate in this study.

Confidentiality

The following procedures will be followed in an effort to keep your data confidential in this study:

- Your name will not be on any data that you provide.
- Data will be stored on a secured computer with limited access.

- Data will be made available only to people conducting the study.
- All information will be kept indefinitely.
- Your identity will not be revealed in any publication or presentation of the results of this research.
- All information you provide will be used for research purposes only.
- To ensure that this research activity is being conducted properly, SUNY Stony Brook's Committee on Research Involving Human Subjects and the sponsors of this study (U.S. Air Force, DoD), have the right to review study records, but confidentiality will be maintained as allowed by law.

Costs to you

There will be no costs to you for participating in this research.

Subject Rights

You do not have to be in this study if you don't want to be

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You can print a copy of this consent form to keep.
- You do not waive any of your legal rights by consenting to participate.

Questions about the Study or Your Rights as a Research Subject

- If at any time you have questions about this study, you may contact Dr. Amy M. Smith Slep at (631) 632-7857.
- If you have any questions about your rights as a research subject, you may contact Ms. Judy Matuk, Committee on Research Involving Human Subjects, at (631) 632-9036.
- If you click below, it means that you have read (or have had it read to you) the information given in this consent form, and that you would like to be a volunteer in this study.

By clicking the button below you are consenting to participate in this study.

Please click here to participate.

[current date]

[SurveyParticipantName]
[Office Symbol]
[BaseName] Air Force Base

Dear [SurveyParticipantName]:

Subject: NORTH STAR Implementation Training Evaluation

You are receiving the enclosed questionnaires as part of our evaluation of the recent NORTH STAR site visit. The goal of NORTH STAR initiative is to reduce suicidality, family maltreatment and alcohol/drug problems within Air Force communities. NORTH STAR uses the data gathered during the community assessment to target problems identified in your base community and implement proven programs to correct those problems.

[BaseName] Air Force Base IDS members and leaders will be [have] periodically participating [ed] in NORTH STAR trainings and briefings beginning [xxxx]. In the summer/fall [xxxxx] we will be visiting [visited] your base to work with the IDS Team. This consultation training will be [was] focused on developing detailed implementation plans for prevention programs that address the [BaseName] Air Force Base community's key risk and protective factors as identified in the 2006 Community Assessment. Those programs will be [are] being implemented shortly [now].

The short questionnaires are designed to evaluate and improve the training consultation provided to your IDS team and the system for training Air Force bases on how to use Community Assessment data to streamline prevention efforts.

The questionnaires should take you about ten minutes to complete. Please go to the following web address to complete the questionnaire [web address will be inserted here]. The questionnaires will only be seen by Stony Brook researchers and all information will remain confidential. If you are unable to access the website you may request a paper copy.

Thank you and we look forward to seeing you at the NORTH STAR training soon.

Best regards,

Amy Slep, Ph.D., Richard Heyman, Ph.D., and John Nelson, Ph.D.

Table of Contents

[Prevention Programming Implementation Questionnaire – Wave 1]	2
[Prevention Programming Implementation Questionnaire – Wave 2]	5
[Prevention Programming Implementation Questionnaire – Wave 3]	7
[Community Readiness Factors Questionnaire]	9
[Collaboration]	9
[Community support for prevention]	9
[Wing leadership support for prevention]	9
[Effective Wing Leadership]	9
[Openness to Change]	9
[Community support for framework]	9
[Wing leadership support for framework]	9
[Barriers to implementation]	10
[Efficacy and outcome expectancy questionnaire]	11
[Pre-test]	11
[Post-test]	12
[Training Test Questions]	14
[Satisfaction with NORTH STAR]	15

[Cover Page – All Waves]

			POSITION
1. I am...			
o	CAIB Member	⟨	
o	Non-CAIB Leadership	⟨	
o	IDS Member:		
o	Alcohol and Drug Addiction Prevention and Treatment	⟨	
o	Chapel	⟨	
o	Drug Demand Reduction	⟨	
o	Family Advocacy Program	⟨	
o	Family Member Support Flight	⟨	
o	Family Support Center	⟨	
o	Health and Wellness Center	⟨	
o	Life Skills	⟨	
o	Youth Services	⟨	
o	OTHER: _____	⟨	

2. How long have you served on CAIB/Leadership/IDS at this base? _____

[Prevention Programming Implementation Questionnaire – Wave 1 - 2003]

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. The 1999/2000 AF Community Needs Assessment data was useful to the community's prevention efforts	μ	μ	μ	μ	μ
2. Regularly collected data (e.g., suicide attempts, alcohol-related incidents, family maltreatment incidents) is useful to the community's prevention efforts	μ	μ	μ	μ	μ

	Yes	No
3. Did your community select new prevention activities to respond to data showing the community's needs?	μ	μ
4. Did your community analyze the data by subgroups within the community?	μ	μ
5. Did your community prioritize subgroups to receive additional services?	μ	μ
6. Did your community compare its data to rates from other bases, the MAJCOM, and/or AF?	μ	μ

	None	A Little	Somewhat	A Lot
7. How much did each of the following criteria influence your community's selection of current prevention activities?				
a. Analysis of needs based on data about your community	μ	μ	μ	μ
b. A desire to support existing prevention programs	μ	μ	μ	μ
c. Data on risk and protective factors	μ	μ	μ	μ
d. Review of research on effective programs to identify those that might work for your community	μ	μ	μ	μ
e. Funding available for particular programs or activities	μ	μ	μ	μ
f. Data showing that some subgroups needed more activities	μ	μ	μ	μ

	Yes	No
8. Does your community use a risk and protective focused framework to prevent family maltreatment, suicidality, and alcohol/drug problems?	μ	μ
9. (If yes) In your opinion, what are the most important steps in implementing the risk and protection focused prevention approach?		

	Yes	No
10. Did your community prioritize risk and protective factors that it wanted to address with prevention activities?	μ	μ
11. (If yes) Which risk and protective factors did you prioritize?		
12. Did your community choose what programs to implement based on this prioritization?	μ	μ
13. (If yes) Which programs did your community choose to implement based on this prioritization?		
14. Did your community evaluate if programs affect risk and protective factor levels among the individuals participating in these programs?	μ	μ
15. (If yes) Have your community's prevention programs changed as a result of this evaluation?	μ	μ
16. In your estimation, what percent of the prevention services offered at your base use this prevention approach to guide their programming of prevention services and activities?	_____	%

[Prevention Programming Implementation Questionnaire – Wave 2 - 2004]

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. The 2003 AF Community Needs Assessment data was useful to the community's prevention efforts	μ	μ	μ	μ	μ
2. Regularly collected data (e.g., suicide attempts, alcohol-related incidents, family maltreatment incidents) is useful to the community's prevention efforts	μ	μ	μ	μ	μ

	Yes	No
3. Did your community select new prevention activities to respond to data showing the community's needs?	μ	μ
4. Did your community analyze the data by subgroups within the community?	μ	μ
5. Did your community prioritize subgroups to receive additional services?	μ	μ
6. Did your community compare its data to rates from other bases, the MAJCOM, and/or AF?	μ	μ

	None	A Little	Somewhat	A Lot
7. How much did each of the following criteria influence your community's selection of current prevention activities?				
a. Analysis of needs based on data about your community	μ	μ	μ	μ
b. A desire to support existing prevention programs	μ	μ	μ	μ
c. Data on risk and protective factors	μ	μ	μ	μ
d. Review of research on effective programs to identify those that might work for your community	μ	μ	μ	μ
e. Funding available for particular programs or activities	μ	μ	μ	μ
f. Data showing that some subgroups needed more activities	μ	μ	μ	μ

	Yes	No
8. Does your community use a risk and protective focused framework to prevent family maltreatment, suicidality, and alcohol/drug problems?	μ	μ
9. (If yes) In your opinion, what are the most important steps in implementing the risk and protection focused prevention approach?		

	Yes	No
10. Did your community prioritize risk and protective factors that it wanted to address with prevention activities?	μ	μ
11. (If yes) Which risk and protective factors did you prioritize?		
12. Did your community choose what programs to implement based on this prioritization?	μ	μ
13. (If yes) Which programs did your community choose to implement based on this prioritization?		
14. Did your community evaluate if programs affect risk and protective factor levels among the individuals participating in these programs?	μ	μ
15. (If yes) Have your community's prevention programs changed as a result of this evaluation?	μ	μ
16. In your estimation, what percent of the prevention services offered at your base use this prevention approach to guide their programming of prevention services and activities?	_____	%

[Prevention Programming Implementation Questionnaire – Wave 3-2006]

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. The 2005 AF Community Needs Assessment data was useful to the community's prevention efforts	μ	μ	μ	μ	μ
2. Regularly collected data (e.g., suicide attempts, alcohol-related incidents, family maltreatment incidents) is useful to the community's prevention efforts	μ	μ	μ	μ	μ

	Yes	No
3. Did your community select new prevention activities to respond to data showing the community's needs?	μ	μ
4. Did your community analyze the data by subgroups within the community?	μ	μ
5. Did your community prioritize subgroups to receive additional services?	μ	μ
6. Did your community compare its data to rates from other bases, the MAJCOM, and/or AF?	μ	μ

	None	A Little	Somewhat	A Lot
7. How much did each of the following criteria influence your community's selection of current prevention activities?				
a. Analysis of needs based on data about your community	μ	μ	μ	μ
b. A desire to support existing prevention programs	μ	μ	μ	μ
c. Data on risk and protective factors	μ	μ	μ	μ
d. Review of research on effective programs to identify those that might work for your community	μ	μ	μ	μ
e. Funding available for particular programs or activities	μ	μ	μ	μ
f. Data showing that some subgroups needed more activities	μ	μ	μ	μ

	Yes	No
8. Does your community use a risk and protective focused framework to prevent family maltreatment, suicidality, and alcohol/drug problems?	μ	μ
9. (If yes) In your opinion, what are the most important steps in implementing the risk and protection focused prevention approach?		

	Yes	No
10. Did your community prioritize risk and protective factors that it wanted to address with prevention activities?	μ	μ
11. (If yes) Which risk and protective factors did you prioritize?		
12. Did your community choose what programs to implement based on this prioritization?	μ	μ
13. (If yes) Which programs did your community choose to implement based on this prioritization?		
14. Did your community evaluate if programs affect risk and protective factor levels among the individuals participating in these programs?	μ	μ
15. (If yes) Have your community's prevention programs changed as a result of this evaluation?	μ	μ
16. In your estimation, what percent of the prevention services offered at your base use this prevention approach to guide their programming of prevention services and activities?	_____	%

[Community Readiness Factors Questionnaire]

Definition

“Secretive problems” means spouse abuse, child maltreatment, suicidality, alcohol/drug problems

	Strongly Disagree	Disagree	Agree	Strongly Agree
[Collaboration]				
1. IDS components work together to solve community problems	☐	☐	☐	☐
2. IDS components coordinate prevention strategies	☐	☐	☐	☐
3. IDS components participate in joint planning and decision making about prevention issues	☐	☐	☐	☐
4. IDS components share resources when implementing the IDS' prevention strategies	☐	☐	☐	☐
[Community support for prevention]				
5. People at this base are committed to preventing secretive problems	☐	☐	☐	☐
6. People at this base believe it's appropriate for the AF to do what it can to prevent secretive problems	☐	☐	☐	☐
7. People at this base are supportive of efforts to prevent personal and family problems	☐	☐	☐	☐
[Wing leadership support for prevention]				
8. Leaders at this base are committed to preventing secretive problems	☐	☐	☐	☐
9. Leaders at this base are knowledgeable about IDS' prevention efforts	☐	☐	☐	☐
10. Leaders at this base believe community prevention efforts are worthwhile	☐	☐	☐	☐
[Effective Wing Leadership]				
11. Leaders at this base are able to build consensus across the community	☐	☐	☐	☐
12. Leaders at this base are able to obtain the necessary resources for community initiatives	☐	☐	☐	☐
13. Leaders at this base are able to manage competing needs among different groups within the community	☐	☐	☐	☐
[Openness to Change]				
14. This community is willing to try new ideas to solve community problems	☐	☐	☐	☐
15. IDS components are pretty set in their ways	☐	☐	☐	☐
16. This community is resistant to change	☐	☐	☐	☐
[Community support for framework]				
17. Our base's norms and beliefs are compatible with a risk and protective focused prevention framework	☐	☐	☐	☐
[Wing leadership support for framework]				
18. Leaders at this base are committed to using a prevention approach guided by risk/protective factor data	☐	☐	☐	☐

	...discussed goals for the prevention of this problem	This community has... ...agreed on goals for the prevention of this problem but has not set explicit goals	...agreed on explicit goals for prevention of this problem
19. Family maltreatment	☐	☐	☐
20. Suicide	☐	☐	☐
21. Alcohol/drug problems	☐	☐	☐

	... no clear action plan in place for prevention of this problem	This community has... ... an informal unwritten plan for prevention of this problem	... a general written plan for prevention of this problem	... an explicit written plan for prevention of this problem
22. Family maltreatment	☐	☐	☐	☐
23. Suicide	☐	☐	☐	☐
24. Alcohol/drug problems	☐	☐	☐	☐

	Strongly Disagree	Disagree	Agree	Strongly Agree	No action plan
The action plan for this problem includes a time line for implementing its specific components:					
25. Family maltreatment	☐	☐	☐	☐	☐
26. Suicide	☐	☐	☐	☐	☐
27. Alcohol/drug problems	☐	☐	☐	☐	☐
The action plan for this problem includes assignments of specific components to named individuals:					
28. Family maltreatment	☐	☐	☐	☐	☐
29. Suicide	☐	☐	☐	☐	☐
30. Alcohol/drug problems	☐	☐	☐	☐	☐
Resources have been allocated to support the implementation of the action plan for this problem:					
31. Family maltreatment	☐	☐	☐	☐	☐
32. Suicide	☐	☐	☐	☐	☐
33. Alcohol/drug problems	☐	☐	☐	☐	☐

A lot Some A little Not at all

[Barriers to implementation]

How much did each of the following factors pose barriers to prevention-related activities in your community over the past year?

34. Lack of coordination among IDS components	☐	☐	☐	☐
35. Lack of agreement on goals and methods	☐	☐	☐	☐
36. Lack of leadership	☐	☐	☐	☐
37. A loss of key players	☐	☐	☐	☐
38. Lack of financial resources	☐	☐	☐	☐

	A lot	Some	A little	Not at all
39. Lack of human resources	☐	☐	☐	☐
40. Lack of support in community	☐	☐	☐	☐

[Efficacy and outcome expectancy questionnaire]

[Pre-test]

Definitions

- “Secretive problems” means spouse abuse, child maltreatment, suicidality, alcohol/drug problems
- “Prevention framework” means the procedures and strategies that your IDS *currently* uses to guide prevention at your base

	Strongly Disagree	Disagree	Agree	Strongly Agree
1. My community's prevention framework is effective	☐	☐	☐	☐
2. My community's prevention framework has achieved desirable results	☐	☐	☐	☐
3. I am sure of our ability to use data from our biennial Community Assessments to plan community-based prevention efforts	☐	☐	☐	☐
4. Using data from the Community Assessment has improved the effectiveness of our efforts to prevent secretive problems	☐	☐	☐	☐
5. I am sure of our ability to conduct science-based community prevention	☐	☐	☐	☐
6. A science-based approach to community prevention would be more effective in preventing secretive problems than our current approach to prevention is	☐	☐	☐	☐
7. I am sure of our ability to use a risk- and protective-factor focused prevention approach	☐	☐	☐	☐
8. Focusing on risk and protective factors in our community prevention initiatives would be more effective in preventing secretive problems than our current approach to prevention is	☐	☐	☐	☐
9. I am sure of our ability to identify empirically-supported prevention initiatives to use in our community	☐	☐	☐	☐
10. Knowing about empirically supported prevention initiatives would make us more effective in preventing secretive problems than our current approach to prevention does	☐	☐	☐	☐
11. I am sure of our ability to implement empirically-supported prevention initiatives in our community	☐	☐	☐	☐
12. Empirically supported prevention would be more effective in preventing secretive problems than our current approach to prevention is	☐	☐	☐	☐
13. I am sure of our ability to evaluate the impact of prevention initiatives in our community	☐	☐	☐	☐
14. Regularly evaluating the impact of our prevention initiatives would make us more effective in preventing secretive problems than our current approach to prevention does	☐	☐	☐	☐

[Post-test]

Definition

- “Secretive problems” means spouse abuse, child maltreatment, suicidality, alcohol/drug problems
- “Prevention framework” means the prevention procedures and strategies that your IDS *will be applying* in response to the 2003 Community Assessment

	Strongly Disagree	Disagree	Agree	Strongly Agree
1. My community's prevention framework will be effective	☐	☐	☐	☐
2. The results of my community's prevention framework will be desirable	☐	☐	☐	☐
3. I am sure of our ability to use data from the 2003 Community Assessment to plan community-based prevention efforts	☐	☐	☐	☐
4. Using data from the 2003 Community Assessment will improve the effectiveness of our efforts to prevent secretive problems	☐	☐	☐	☐
5. I am sure of our ability to conduct science-based community prevention	☐	☐	☐	☐
6. A science-based approach to community prevention will be more effective in preventing secretive problems than our previous approach to prevention was	☐	☐	☐	☐
7. I am sure of our ability to use a risk- and protective-factor focused prevention approach	☐	☐	☐	☐
8. Focusing on risk and protective factors in our community prevention initiatives will be more effective in preventing secretive problems than our previous approach to prevention was	☐	☐	☐	☐
9. I am sure of our ability to identify empirically-supported prevention initiatives to use in our community	☐	☐	☐	☐
10. Knowing about empirically supported prevention initiatives will make us more effective in preventing secretive problems than our previous approach to prevention did	☐	☐	☐	☐
11. I am sure of our ability to implement empirically-supported prevention initiatives in our community	☐	☐	☐	☐
12. Empirically supported prevention will be more effective in preventing secretive problems than our previous approach to prevention was	☐	☐	☐	☐
13. I am sure of our ability to evaluate the impact of prevention initiatives in our community	☐	☐	☐	☐
14. Regularly evaluating the impact of our prevention initiatives will make us more effective in preventing secretive problems than our current approach to prevention did	☐	☐	☐	☐

[1 year follow-up]

Definition

- “Secretive problems” means spouse abuse, child maltreatment, suicidality, alcohol/drug problems
- “Prevention framework” means the prevention procedures and strategies that your IDS *will be applying* in response to the 2003 Community Assessment

	Strongly Disagree	Disagree	Agree	Strongly Agree
15. My community's prevention framework is effective	☐	☐	☐	☐
16. The results of my community's prevention framework will be desirable	☐	☐	☐	☐
17. I am sure of our ability to use data from the 2003 Community Assessment to plan community-based prevention efforts	☐	☐	☐	☐
18. Using data from the 2003 Community Assessment will improve the effectiveness of our efforts to prevent secretive problems	☐	☐	☐	☐
19. I am sure of our ability to conduct science-based community prevention	☐	☐	☐	☐
20. A science-based approach to community prevention will be more effective in preventing secretive problems than our previous approach to prevention was	☐	☐	☐	☐
21. I am sure of our ability to use a risk- and protective-factor focused prevention approach	☐	☐	☐	☐
22. Focusing on risk and protective factors in our community prevention initiatives will be more effective in preventing secretive problems than our previous approach to prevention was	☐	☐	☐	☐
23. I am sure of our ability to identify empirically-supported prevention initiatives to use in our community	☐	☐	☐	☐
24. Knowing about empirically supported prevention initiatives will make us more effective in preventing secretive problems than our previous approach to prevention did	☐	☐	☐	☐
25. I am sure of our ability to implement empirically-supported prevention initiatives in our community	☐	☐	☐	☐
26. Empirically supported prevention will be more effective in preventing secretive problems than our previous approach to prevention was	☐	☐	☐	☐
27. I am sure of our ability to evaluate the impact of prevention initiatives in our community	☐	☐	☐	☐
28. Regularly evaluating the impact of our prevention initiatives will make us more effective in preventing secretive problems than our previous approach to prevention did	☐	☐	☐	☐

[Training Test Questions]

1. What is a risk factor?
 - a. A factor whose presence is related to an increased probability in a problem being present or developing
 - b. A factor whose presence is related to an decreased probability in a problem being present or developing
 - c. A factor that causes a problem to be present or develop
 - d. A factor that causes a problem to be absent or not develop
2. What is a protective factor?
 - a. A factor whose presence is related to an increased probability in a problem being present or developing
 - b. A factor whose presence is related to an decreased probability in a problem being present or developing
 - c. A factor that causes a problem to be present or develop
 - d. A factor that causes a problem to be absent or not develop
3. What is an empirically-supported program?
 - a. A program that is well-funded by a society
 - b. A program that has been scientifically evaluated and found to be effective
 - c. A program that was developed based on the scientific literature
 - d. A program that has been found to be well-liked by participants
4. What should guide the selection of risk factors to target for prevention?
 - a. The strength of the association between the factor and the problem
 - b. The existence of empirically supported programs for that problem
 - c. Community Assessment data showing that our community is higher on the risk factor than most communities
 - d. All of the above
5. True or False: Use of empirically-supported programs is scientifically supported only if they are carried out as originally described.
 - a. True
 - b. False
6. A community is using an empirically supported program for social isolation, in an IDS-guided effort to reduce the prevalence of partner abuse, suicidality, and alcohol problems. Which of the following should the IDS be tracking as its primary variable to see if the program is working?
 - a. Partner abuse
 - b. Suicidality
 - c. Alcohol Problems
 - d. Social isolation
7. The Community Assessment reveals that in Community X, financial stress, exercise habits, and community cohesion are each modestly and independently related to drug use. Which of the following would likely be most effective in reducing the community's rate of drug use?
 - a. Increase publicity about ADAPT services available on base.
 - b. Implement three community-based strategies, one targeting financial stress, one targeting exercise, and one targeting community cohesion.
 - c. Implement three community-based strategies all targeting community cohesion.
 - d. Distribute fliers reminding members that drug use is against regulations.

[Satisfaction with NORTH STAR]

How satisfied were you with	Neither				
	Extremely Dissatisfied	Dissatisfied	Satisfied Nor Dissatisfied	Satisfied	Extremely Satisfied
1. NORTH STAR approach to prevention	☐	☐	☐	☐	☐
2. NORTH STAR training	☐	☐	☐	☐	☐
3. NORTH STAR materials	☐	☐	☐	☐	☐
4. (Post-test only) NORTH STAR support systems (phone consultation, listservs, newsletters, etc.)	☐	☐	☐	☐	☐



**Wilford Hall Medical Center
Institutional Review Board (IRB)**

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2200 Bergquist Dr, Bldg 4430
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Federal Wide Assurance #FWA00001750 and DoD Assurance #50007

NOTICE OF ACTION REGARDING IRB REVIEW

Date: 28 Nov 07

TO: Individual(s) Indicated Below

Your **STATUS REPORT** was reviewed and approved by the Commander, Clinical Research Squadron on behalf of the WHMC IRB on the date indicated below. They were available for review by the other Board members as appropriate at the 27 Nov 07 meeting. The Board unanimously approved your protocol for continuation for another 12 months.

FWH20030121E, "A Prospective Study of Suicide Prevention in the USAF," **PI: Col G. Wayne Talcott/AFMOA/SGZF BROOKS** [Approved on: 14 Nov 07]

FWH20030126E, "Innovative Surveillance and Risk Reduction Systems for Family Maltreatment, Suicidality, and Substance Problems in the USAF Protocol 2 NORTH STAR Process Evaluation; Family Maltreatment, Substance Problems, and Suicidality: Randomized Prevention," **PI: Maj David Linkh/AFMOA/GOFF Pentagon** [Approved on: 13 Nov 07]

FWH20030134E, "Identification of Respiratory Viruses by Enzyme Immunoassay (EIA), Polymerase Chain Reaction (PCR) and Microarray Assays on Nasal Wash Specimens," **PI: LTC Samuel Livingstone/59 MDW/CM** [Approved on: 13 Nov 07]

FWH20050113E, "Myometrial invasion and its correlation with CD44 isoform immunohistochemical expression in endometriod carcinoma endometrial biopsy specimens," **PI: LTC Brian Kendall/SGULP** [Joint BAMC/WHMC] [Approved on: 2 Nov 07]

FWH20060184E, "Angiotensin converting enzyme inhibitors and risk of anaphylaxis in patients allergic to insect venom," **PI: Capt Kevin White/SGMDA** [Approved on: 15 Nov 07]

FWH20070022E, "Incidence and Risk Factors for AIDS-Defining and Non-AIDS Defining Cancers in an HIV-infected Cohort," **PI: CDR Brad Hale/Navy Medical Center San Diego** [Joint BAMC/WHMC] [Approved on: 2 Nov 07]

FWH20070057E, "Pediatric resuscitation simulation to improve outcomes of pediatric resuscitations," **PI: Maj Phil Spinella/MMNP** [Approved on: 15 Nov 07]

Name of Official
MARIA E. DOMINGUEZ

Title/Office Symbol/Phone
Protocol Assistant/SGRS (Protocol Office)/2-6095

Signature

File this and any other IRB correspondence in your study binder