

GENERAL GUIDANCE FOR SUCCESSFUL GULF WAR VETERAN OUTREACH

Summary

Successful Gulf War Veteran subject recruitment for Gulf War Illness (GWI) biomedical research is a multifaceted effort. Success has proven to be contingent on adequate and realistic planning. The following guidance was developed in collaboration with Veterans who served in the 1990-91 Persian Gulf War (Operations Desert Shield and Desert Storm).

To establish an effective and sustainable outreach and recruitment plan, applicants are **strongly encouraged** to consider these best practices before preparing applications to the Congressionally Directed Medical Research Programs (CDMRP) Gulf War Illness Research Program (GWIRP). Researchers should consider including details in the following areas for applications requiring access to Gulf War Veterans to facilitate review and overall success of the project.

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1. MATCH COHORT FEATURES TO THE EXPERIMENTAL TREATMENT OR MARKER

GWII is a complex disorder. Investigators should carefully consider **stratified and targeted approaches** to cohort composition based on common underlying biology and/or symptom sets.

2. USE ESTABLISHED GULF WAR VETERAN COHORTS

Recruit from an existing cohort of Gulf War Veterans

- Consider recruiting from existing Gulf War cohorts whenever possible, given the known recruitment challenges.
- Tap into a GWIRP-supported cohorts, listed in the “Research Resources” section linked from the main GWIRP webpage (cdmrp.army.mil/GWIRP).

Collaborate with a Department of Defense (DoD) or Department of Veterans Affairs (VA) investigator who may have access to his/her own unique cohort

Researchers seeking GWIRP funding are encouraged to collaborate with DoD and/or VA personnel, including DoD/VA civilian employees and those in military service.

Potential benefits of collaboration are:

- Facilitating access to cohorts of veterans, including Veterans at VA’s War Related Illness and Injury Centers (WRIISCs) and others.
- Facilitating access to DoD or VA research databases.
- Facilitating access to DoD or VA databases of Gulf War Veterans.
- Facilitating access to DoD or VA repositories.
- Enriching studies through collaboration or in other ways.

Finding DoD/VA researchers: Applicants can visit Federal RePORTER to identify actively funded DoD or VA investigators and their areas of interest (federalreporter.nih.gov).

Getting a DoD/VA support letter: Researchers planning to access DoD or VA resources (e.g., databases) or study subjects should *include a letter of support with the application* (signed by the lowest ranking person in the agency with approval authority).

Using a DoD/VA site location: While a large majority of Gulf War Veterans get their healthcare outside of the VA, study site locations near or within a VA or DoD facility may aid in recruitment and, given the proximity, may:

- Aid in subject retention.
- Boost recruitment of healthy controls, including healthy Gulf War Veterans still active in the Service.

Consider messaging to target healthcare providers at a military healthcare facility, or targeting the local military community. To find a military hospitals or clinics near you visit <https://tricare.mil/mtf/>

3. CONSIDER A MULTI-SITE OR NATIONWIDE DESIGN

Consider a multi-site study design to reach recruitment goals. For example, recruiting 100 Veterans with GWI may be easier at five sites in different geographic areas than in just one site, particularly if there are other GWI studies ongoing in a particular geographic area that may be competing for study subjects.

During study design, consider what may be needed to overcome multi-site limits and complications, such as:

- Regulatory compliance and IRB approval at each site.
- Staff training at each site.
- The need for extensive assessments to ensure comparability in patient treatment and endpoint measurement at the various sites.
- Availability of sophisticated treatment or assessment modalities.
- Whether nationwide or region-wide commercial labs may be a viable option for standard laboratory analyses.
- Whether nationwide or region-wide commercial facilities may be a viable option for standardized performance, behavioral, quality of life, or similar assessments.
- Whether collaboration with one or more Gulf War Illness Clinical Trials and Interventions Consortium (GWICTIC) sites may be helpful. The multi-site GWICTIC, funded and actively overseen by the GWIRP, is now operational for designing and executing multiple clinical trials. Researchers may wish to make use of the GWICTIC infrastructure, including accessing established recruitment networks.
- Whether collaboration with the Boston Biorepository, Recruitment, and Integrative Network sites may be an option.
- Whether collaboration with VA (such as the WRIISC's) or DoD facilities may be an option.

4. RECRUIT GULF WAR VETERANS WHERE THEY ARE

Advertising costs associated with subject recruitment are allowable expenses that can be budgeted in your GWIRP research application.

All advertisements and recruitment materials must be approved by the respective Institutional Review Board (IRB) or Ethics Committee (EC) prior to use. Local IRB/EC approval at the time of application submission is not required.

Post recruitment materials in VA facilities

Many ill Gulf War Veterans seek treatment at VA facilities. Therefore, following IRB approval for each item and following prior written facility approval for posting/dissemination, consider:

- Determining if the facility has pre-designated mechanisms for dissemination of study recruitment materials.
- Posting flyers on bulletin boards.

- Providing flyers or other written materials to specific clinics or individual providers within facilities.
- Leaving flyers or pamphlets in waiting rooms.
- Disseminating a video through the facility’s video kiosks.

Reach out through social media

Use social media to connect with Gulf War Veterans (see more about [under 6. Use Effective Choices of Recruitment Materials](#)).

Posting IRB-approved materials on social media sites specifically targeted to Veterans can be a powerful way to leverage a minimal investment.

Gulf War Veteran-specific websites that have agreed to publish ready-made recruitment materials include:

- The 91outcomes.com website (email: admin@91outcomes.com).
- The “Gulf War Illnesses” Facebook page (email: usmc1one@gmail.com).

Consider using:

- Facebook,
- Twitter,
- Instagram, and
- Other social media.

Reach out to local Veterans organizations

Consider contact with local Veteran Service Organizations (VSOs) to:

- Provide IRB-approved outreach materials to potential subjects at public or private Veteran-oriented events. These could include regular local meetings or other events, such as Veteran’s Day celebrations and certain commemoration or dedication ceremonies.
- Post IRB-approved recruitment materials at VSO buildings.
- Publish IRB-approved recruitment materials in printed organization magazines or newsletters. This may include paid advertising.
- Participate in a VSO events by securing a slot on the event agenda to publicly present the purpose of the study and the need for subjects. Other options could include staffing a booth, kiosk, or table, or even “working the crowd.”

The State Veterans Commission

Some states and locales have broad commissions or other bodies composed of representatives from multiple VSOs. Even a short presentation to such a body may have a ripple effect in reaching many veterans. Come prepared with IRB-approved materials to distribute and website information to share.

Reach out to treating clinicians

Try reaching out to treating clinicians (VA and non-VA facilities) to make them aware of the purpose of the study and the need for research subjects. Consider the following:

- Healthcare providers may not pay much attention to flyers and kiosk presentations posted at their institutions, so direct awareness campaigns that include emails and short presentations at staff gatherings may be effective.
- Target healthcare professionals outside of the VA specializing in disorders related to the specific GWI symptoms addressed in a proposed study. For example, a study involving fatigue may garner subjects from a medical practice group specializing in chronic fatigue syndrome.
- Reach out to providers at military healthcare facilities to inform them about the study and ask if they might provide specific recruitment materials to potentially eligible subjects and healthy Gulf War Veterans as controls.

Consider out-of-state recruitment activities

Experience has shown that some Veterans suffering from GWI are willing to travel cross-country to participate in research studies, provided adequate reimbursement and incentives are included.

Investigators should consider the potential benefits and costs of recruitment outside of the usual catchment of the clinical research facility.

See *Consider Compensation, Incentives, and Other Accommodations Section*, below.

Reach out to your state-level Veterans Department/Agency

The government of each State, Territory, and the District of Columbia has its own state-level department, agency, commission, office, or similar entity tasked with state-level Veterans Affairs' duties.

Researchers may wish to reach out to the state-level entity to see how IRB-approved materials related to clinical trials and other human studies might be able to be included in its communications materials or notices.

The National Association of State Directors of Veterans Affairs (NASDVA) website provides links to each of these for every State and Territory (nasdva.us/links.aspx).

Bring them to you: Host an event

One established GWI research institution successfully garnered interest by hosting its own annual "Open House" event timed near Veterans Day. This event includes short presentations providing overviews of the state of the science and of studies that are currently enrolling and potentially enrolling in the near future on site; interaction with the researchers; facility tours; refreshments; and a boxed lunch. Such annual events are well publicized by local media reporting, posting flyers, and inviting local elected officials to attend to help raise visibility. Researchers may also consider posting IRB-approved advertising materials in printed organization magazines or newsletters.

5. EMPLOY AVAILABLE EXPERTISE

Make use of your institution's publicity division

Most universities, research organizations, and large hospitals have a public affairs or public relations office. This entity may, with or without cost, be able to assist funded researchers to:

- Author press releases or other publicity related to research awards, studies, and publications.
- Solicit/elicit press coverage.
- Prepare or otherwise assist with advertisements and similar marketing efforts.

Get inside knowledge

- **Create a Veteran advisory panel.** Some GWIRP-funded researchers have succeeded by establishing an ad hoc Veteran advisory panel to advise on study recruitment and other matters related to the funded study.
- **Hire a Veteran consultant.** Some GWIRP-funded researchers have hired a Veteran to assist with study recruitment and other matters related to the funded study. Such a consultant should be able to identify the appropriate Veteran audience and should know where and how to reach them and what sorts of messages and incentives would be most likely to create interest and engagement.
- **Look to Veterans' Organizations for nominations.** Local or national Veterans' organizations, particularly those focused on Veterans' health, can be tapped for nominations of suitable individuals.

Make use of commercial contractors

Some GWIRP-supported investigators have reported great success employing a commercial study subject recruitment firm to identify and recruit prospective Gulf War Veteran study subjects. These services may be costly but have produced worthwhile results.

An internet search for phrases like "help for subject recruitment" will produce results including both "tricks and tips" webpages and vendors specializing in clinical study recruitment. **Note:** The GWIRP does not endorse particular commercial vendors.

6. USE EFFECTIVE CHOICES OF RECRUITMENT MATERIALS

Use a variety of materials

Remember that only IRB-approved recruitment materials may be disseminated for recruitment purposes. Consider:

- Employing multiple forms of publicity to reach a broader audience.
- Targeting not only potential Gulf War Veteran study subjects but also those who may know such a Veteran and can carry the message to him or her.
- Materials should be standalone pieces and separated from whatever else you're disseminating.

Information should include (at a minimum):

- The study name, purpose, or other identifier;
- The study location (e.g., city and state – remember, these study materials may travel far and wide);
- A point of contact and relevant contact information (e.g., phone number, email address);
- Whether travel reimbursement is provided;
- Whether compensation or other participation incentives are provided (compensation should not be over-emphasized);
- Any specific study benefits to study participants; and
- A website address for more information.

As a best practice, consider creating each of the following materials:

- **Website** or sub-website and/or Facebook page created specifically for the study media (e.g., Facebook, Twitter) that ideally will go viral to help you recruit in ever-expanding circles of contacts. Remember that it needs to be readily shareable, easily readable, be standalone with all necessary information. It should contain all relevant information and should not rely on embedded hyperlinks so that it can be spread as a visual meme (i.e. image). It should be easily readable in the size that will be shared on social media.
- **Printed materials** for your study team or volunteers to post at locations where Veterans and those who know them may see them. Consider including tear-off tabs at the bottom of the flyer with sufficient information to ensure contact with the study is possible, but also ensure all necessary information is contained on the full flyer itself after all tabs have been taken.

Some GWIRP-funded investigators have also created the following but their effectiveness has not been documented:

- Audio/video materials for video kiosks or broadcast (video, audio, slideshows).
- Event swag with study logo/information (pens, notepads, embroidered hats, etc.).
- Banners, billboards, etc.

Use commercial media to reach Gulf War Veterans

Consider using the following media:

- **Broadcast media** (radio or television). While the cost of advertising on broadcast media may be high, some local media outlets may allow public service announcements for free.
- **Billboards**. Some researchers have reported success using billboards in Veteran-dense rural areas.
- **Newspaper advertising** may be effective in some communities.

7. USE EFFECTIVE MESSAGING

Develop an effective messaging for recruiting Veterans with GWI

While recruitment materials must accurately reflect the study and not be coercive or offer undue inducements, including a clear message or theme may help elicit interest in study participation. Suggested recruitment themes include the following:

- “Participation may help you better understand and cope with your own illness.”
- “As many as 250,000 Veterans of the 1990-1991 Gulf War continue to suffer from Gulf War Illness. Your participation will help them.”
- “You served your country in 1991. You’ve been suffering ever since. Now there’s a way you can get help and help others too.”
- “Your participation may help veterans from later conflicts with similar toxic exposures.”

Develop effective messaging for recruiting healthy Veteran controls

Healthy people have little motivation to participate as controls, so an incentive for recruitment of healthy controls (i.e., healthy 1990-91 Gulf War Veterans, healthy Gulf War Era Veterans) may improve recruitment outcomes. As with recruiting ill study subjects, a clear message or theme may help elicit interest in study participation. Suggested recruitment themes include the following:

- “As many as 250,000 Veterans of the 1990-1991 Gulf War continue to suffer from Gulf War Illness. Your participation will help them.”
- “You served together in 1991. They’ve been suffering ever since. Now there’s a way you can help.”
- “Your participation may help veterans from later conflicts with similar toxic exposures.”

Affirm GWIRP Involvement

Many Veterans suffering from GWI are reluctant to participate in research funded by Government agencies. Many Veterans have suggested that strongly identifying the research as a Congressionally directed GWIRP effort may encourage participation.

8. CONSIDER COMPENSATION, INCENTIVES, AND OTHER ACCOMMODATIONS

Researchers should adequately consider travel reimbursement and study participation incentives prior to research proposal submission. Failure to do so may result in barriers to participation for substantial number of study subjects, whether ill or controls.

Considerations should include covering travel costs expenses related to travel to study sites and the potential impact of a lack of accommodations for study subjects. Note that many of these ill Veterans are unemployed, may be experiencing continued denials of their disability claims, and may be on very limited incomes due to their illnesses. Remember that IRB approval will be required to determine whether the amount and schedule of each type of

proposed payment is ethically acceptable. Compensation should not be excessive so as to appear an undue inducement or coercive. It should also be in line with local financial expectations and similar to other like research activities.

Budget for sufficient travel reimbursements and incentives

Budget up front for sufficient travel cost reimbursement in order to avoid barriers to study participation by Veterans outside of the local area. Many GWIRP-funded researchers have found it necessary to recruit study participants from outside the area local to the study site in order to reach recruitment targets even for study sites in major metropolitan areas. Reimbursement of travel costs is a strongly and frequently repeated recommendation by numerous Gulf War Veterans.

At a minimum, consideration should be given to the following areas:

- **Travel costs.** (airfare, bus fare, driving costs).
- **Overnight lodging.** Remember that ill Gulf War Veterans typically have debilitating fatigue and other symptoms that may sharply limit the number of hours in a day they can perform activities, including study participation and travel.
- **Meals.** Consider providing meals, meal vouchers, or per diem or other meal compensation.

Budget for sufficient study participation incentives

Consider incentives for study participation relevant to all types of study subjects, including Veterans with GWI and healthy controls. Consider providing:

- **Meal(s).** Consider providing meals, meal vouchers, or per diem or other meal compensation even for studies that do not require travel.
- **Fair incentives** for participation based on study activities. Consider the level of incentive for studies where the participation is more invasive, arduous, involved, or long in duration.

Physical and logistical accommodation of subjects

- Plan ahead to ensure Veteran study participants are made to feel comfortable during the entire study participation process.
- Veteran subjects may be unfamiliar with the trial facility and may need assistance finding or obtaining transportation to the facility. Subjects may also need directions for navigating within the facility.
- Once they arrive, they may need special logistical assistance.
- Ill subjects can tire easily and may need wheelchair transportation.
- It is important for subjects to be assigned to a specific personal point of contact, such as a readily available staff member who can answer questions or provide assistance as needed.

9. CONSIDER STUDY EXCLUSION CRITERIA

Finding a sufficient number of Veteran study subject participants suffering from GWI – including ones who are free from exclusionary conditions and/or lifestyle practices can be a significant challenge. Furthermore, stringent eligibility requirements may prove a greater barrier to accrual of a sufficient number of study subjects than the already-significant challenge of study subject recruitment. When planning exclusion criteria, consider:

- The effects of exclusion criteria on subject accrual.
- The frequency of comorbid conditions is increasing due to an aging 1990-91 Gulf War population.
- Attempting to balance the elimination of confounding/comorbid conditions with the need to recruit an adequate number of subjects.
- That in some cases, it may be more practical to control for conditions than to exclude them.

10. ENSURE YOUR STAFF IS PROPERLY TRAINED

The subjects' experience during the study is important for inspiring engagement. Consider and plan for the following:

- Gulf War Veteran subjects participating in research are likely to be burdened with pain, fatigue, and other chronic symptoms related to their illness prior to starting a clinical research study. In some cases, these pre-existing symptoms may be intensified by participation in a study. To ensure continued participation, Veterans should be attentively treated and given courtesy.
- Recruitment staff and staff on site should embody a strong customer service orientation.
- Study personnel should have ready answers to frequently asked questions. Providing staff with set “scripts” is one method of assuring that study participants are given consistent answers.
- Staff should be trained to escalate queries or requests to higher or more knowledgeable personnel when the need arises.
- Investigators should ensure study team responses are consistent and timely. Veteran study subjects are likely to be acutely cognizant that they are donating of their personal time and limited energy. Responses that are not timely or appropriate may be expected to result in the loss of the prospective study subject. As such, staff should make every effort to respond to queries and requests rapidly and make the most of the time the subject or recruit will invest in the study.

11. ENSURE STUDY RESULTS GET BACK TO THE SUBJECTS AND THE VETERAN COMMUNITY

Complaint by participants in some past studies include, “I participated in that study but I have no idea what happened with it.” Veterans who communicate these messages may be less likely to participate in future research and may serve to discourage others from doing so. Thus, it is a best practice to ensure that research study participants are considered as valued individual people, not just as subjects aggregated to produce published outcomes.

To ensure study subjects feel valued in their participation in your research study, consider:

- Providing a copy of the lay abstract of the study proposal to each study participant at the conclusion of their study participation so they can understand the “big picture” regarding the study.
- Providing individual test results where possible, and if necessary, a key to their interpretation. Informing participants of their individual results, as well as the aggregate, final study results, acknowledges their contribution and shows respect. It is likely that most Veterans will understand if you need to hold this information until after the study is completed (and unblinded, if applicable).

Note: Providing results of assessments may be inappropriate in some cases because research activities/tests may not be completed with the same rigor as activities/tests for clinical purposes. The need to provide information to subjects should be balanced with the ethical considerations of providing data or test results that may be research based.

- Providing a written statement or record for any diagnoses made, including the “diagnosis” of Gulf War Illness if that has been made by a clinician for the individual Veteran. Documentation of test results concluding with a rationale or checklist demonstrating how the results show that a Veteran fits the Centers for Disease Control and Prevention or Kansas (or both) definitions for GWI would be a tangible benefit to many ill Veterans.
- Providing an emailed copy of the final publication of the study’s outcomes to each study participant may fulfil the requirement of informing participants of study results; however, additionally providing a more lay-accessible summary would provide much greater benefit to most Veterans.
- Researchers should developing a plan for dissemination of study results as part of initial study design and budget resources for this task.