



AWARE for All in a Box:

**A patient education kit to organize
clinical research education events
in your community**

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ABSTRACT

Does your organization focus on short-term public education for the purpose of meeting clinical trial enrollment targets?

Medical researchers say that the lack of clinical research volunteers is reaching crisis proportions and is rapidly becoming a major healthcare issue.

The Center for Information and Study on Clinical Research Participation (CISCRP) is an independent non-profit organization dedicated to educating and empowering people to make informed decisions regarding participation in clinical research. CISCRP's educational outreach model known as AWARE responds to this severe shortage of volunteers by addressing the public's lack of fundamental knowledge about clinical research and low level of trust. AWARE offers a significant improvement over traditional public education that is short-term; it offers an educational tool that is driven by the premise that awareness, realizing the value of participation, and ongoing engagement are the keys to generating public support and attracting more clinical research volunteers.

AWARE for All in a Box is an easy to use kit to educate your patients and local communities about the importance of clinical research participation. It is your opportunity to host an *AWARE for All: Clinical Research Education Event* (big or small) in your community! Your event (s) will be co-branded with your logo and the CISCRP logo. *AWARE for All in a Box* includes a DVD including a presentation delivered by a diverse panel of experts entitled "What Clinical Research Means to You" and a Library of Patient Testimonials covering a wide range of diseases and conditions; a CD-Rom featuring AWARE instruction guide, templates and sample materials, Also included are Education Before Participation Brochures, and Medical Heroes Membership Packets . Your registration fee also includes a webpage on the *AWARE* website featuring your organization's logo, event details and contact information. *AWARE for All in a Box* costs \$500.

The results of hosting programs using *AWARE for All in a Box* will be:

- Focused positive attention on your organization's role in advancing public health while increasing public understanding of the clinical research process
- Increased health literacy for your community
- A community of individuals who begin to take an active role in their healthcare
- Meaningful community engagement and increased interest in your clinical research program

AWARE for All: Clinical Research Education Events

Background:

The Center for Information and Study on Clinical Research Participation (CISCRP) is an independent non-profit organization dedicated to educating and empowering people to make informed decisions regarding participation in clinical research. CISCRP's most effective outreach and educational tool is *AWARE for All: Clinical Research Education Events*, which is described in more detail below.

CISCRP is working hard to resolve a number of major healthcare issues by getting to the root of one of the system's most significant problems: the severe shortage of volunteers to participate in the clinical research trials that are vital to any new medications reaching the people who need them. Surveys have shown that even though 94% of the public recognizes that participation in clinical research is very important to advance medical science, 74% say they have no real knowledge of the clinical research process. In addition, 98% do not know where and how to identify and evaluate appropriate clinical studies for patients diagnosed with cancer and other chronic diseases. So it is clear that a major reason for the shortage of volunteers is the public's lack of knowledge about what clinical research is and how they can and should participate in it.

Overall participation in clinical trials among all minority groups remains low. A 2002 study by the Robert Wood Johnson Foundation found that African Americans and Latinos are far less likely than whites to participate in HIV research trials, although these groups account for nearly half of HIV/AIDS patients. Far more data are available on minority participation in trials specifically for cancer. Blacks, for instance, are represented in small (less than 3%) but roughly proportional numbers with whites on clinical trials sponsored by the National Cancer Institute. And that's important, given that black people are more prone to have colorectal, prostate, and lung cancer than white people. But blacks are clearly under-represented on prevention studies needing people free of the disease.

There is a need for general education about the clinical research process, including the risks, benefits, and rights of participants. Patients typically learn about the risks and benefits for the first time when asked to sign an informed consent document. This is not an ideal time for such education because the person or loved one may be under great stress due to illness. In fact, a recent survey showed that 35% of people who signed consent forms said they did not understand what they signed and another 10% claimed never to have read the document at all. The purpose of *AWARE for All* is to address this lack of fundamental knowledge.

In addition to a significant knowledge gap, a general lack of trust about clinical research exists. According to several surveys by Harris Interactive and Research!America, the public views the research professionals who oversee clinical trials with distrust. They also distrust the pharmaceutical companies and government agencies responsible for patient safety. Some African Americans still remember past abuses like the Tuskegee Experiment in which syphilis treatment was withheld from a group of African American men for many years. They wonder if something like that could happen today. They are not familiar with the Federal guidelines and codes of ethics designed to protect clinical research volunteers from harm. Nor do they know about the panel of professionals and community members

responsible for monitoring study safety and safeguarding volunteer rights in every clinical trial.

It is this lack of trust and this knowledge shortfall that can be addressed through a unique public educational initiative known as *AWARE for All* -- which aims to increase the number of citizens of all ages, genders, races and ethnicities who are willing to help advance medical science and improve public health.

Making the connection

Just as the clinical research enterprise seeks to find innovative treatments to treat unmet medical needs, CISCRP seeks to find innovative solutions to the industry's patient recruitment challenges and increase participation in clinical research. The *AWARE* program provides greater understanding among the public which leads to a larger number of volunteers so that researchers can advance medical knowledge and help improve individuals' longevity and quality of life.

Medical researchers say that the lack of clinical research volunteers is reaching crisis proportions and is rapidly becoming a major healthcare issue. *AWARE for All* goes to the root cause of this problem by educating the public about participation so that they are willing to help advance medical and pharmaceutical science in its quest to treat and cure a range of diseases. By partnering with CISCRP, your organization will contribute to solving this problem and receive significant positive exposure by doing so.

Target audience

AWARE's target audience includes all potential participants in clinical research and their loved ones who help with decision making, the medical/research communities so they are better able to explain clinical research to their patients, and the media and policy makers who can promote the value of volunteering in clinical trials.

In particular, your organization may consider marketing this program to minority and underserved communities because they are severely under-represented in most clinical research trials. This can be accomplished through grassroots advertising and focused outreach through your organization and the local community groups and/or disease specific advocacy groups that you already work with.

AWARE for All in a Box

As a nonprofit organization that does not recruit for clinical trials and does not conduct clinical trials, CISCRP is the public's trusted source for education about clinical research participation and is positioned to educate the public in a neutral fashion. Over the past five years of offering *AWARE* in communities across the country, we have packaged the "best of *AWARE*" as *AWARE for All in a Box*. *AWARE for All in a Box* is a way to bring the best fundamental principles of the *AWARE* program to your community in a streamlined and user-friendly process.

AWARE for All in a Box includes a DVD, CD-Rom, Education Before Participation Brochures, and Medical Heroes Membership Packets. Your registration fee also includes a webpage on the *AWARE* website featuring your organization's logo, event details and contact information.

The DVD begins with a presentation entitled “What Clinical Research Means to You”. A diverse panel of experts delivers key messages and information about clinical research to the public. They will answer questions that patients and the public should ask themselves before deciding to participate in clinical research:

- What is a clinical trial and how does it work?
- Why do we need clinical research?
- What do you need to know about informed consent?
- Is clinical research safe? What are the risks? Should I participate? How can I become more AWARE as a volunteer?
- What questions should I ask before participating?

The DVD also includes a library of patient testimonials. We have selected the most captivating and moving stories of patients across the country who are the true medical heroes participating in clinical research. Patients share their compelling stories about clinical research and insights about participation. They share:

- A little bit about themselves personally and their experience with clinical trials
- What prompted their interest in participating
- Any obstacles or challenges they encountered with friends & family when they told them about their participation
- How they decided between standard of care treatment versus the clinical trial
- Advice they have about participating
- Would they do it again and why

AWARE for All in a Box includes a CD-Rom featuring AWARE Instruction Guide, Templates and Sample Materials. Some of the resources included are as follows:

- AWARE instruction guide
- Sample public relations tools such as press release and event alert
- Template certificate of appreciation for clinical research volunteers
- Customizable flyers and posters co-branded with CISCRP’s logo (plug in your logo and event details)
- Outcomes research study (pre-test, post-test, answer sheets, instructions for implementation)
- 32-page educational resource that complements the DVD. This may be printed and copied for distribution to patients and/or event participants.

AWARE for All in a Box includes 25 copies of Education Before Participation and 25 Medical Heroes Membership Packets.

Additional tools are available at an additional cost as a complement to *AWARE for All – Clinical Research Education Events*. These tools help you educate and inform the public about clinical research participation. A complete list with costs is included at the CISCRP store.

AWARE for All in a Box is available for a \$500 registration fee.

Getting Started

AWARE for All in a Box will be utilized to *implement AWARE for All: Clinical Research Education Events*. The first step to delivering a program is to determine the format of your event.

Step 1: Select a Format

We'd like to provide you a few examples of how you can participate in *AWARE for All – Clinical Research Education Day*. Don't forget, *AWARE for All in a Box* gives you the flexibility to use the tools to offer multiple events, so why not start out with a simple event and then progress to a more complete event!

➤ Option 1: Keeping it Simple

- ✚ Small groups such as disease advocacy support groups, senior centers, local libraries and churches may choose to host *AWARE for All – Clinical Research Education Events*. Simply use the pre-recorded DVD to play for your participants. All you need is a master of ceremonies to welcome participants and hit play on the DVD.
- ✚ Individuals who already understand the vital importance of participation in clinical research may choose to host a "house party". Simply invite friends and family to watch the DVD in the comforts of their own home.
- ✚ Consider hosting a lunch and learn for your institution's staff that is not already knowledgeable about clinical research.

➤ Option 2: Plan an Event

- ✚ Plan an event for the community. Identify a space that will enable you to host an audience to view the DVD. Invite your own clinical research coordinators and/or principal investigators to talk about clinical research going on in your community and also answer any questions that arise from the DVD. You may even include health screenings, a free meal, and exhibitors (community organizations such as disease advocacy groups, etc).
- ✚ Consider hosting a dinner meeting at a local restaurant or special location. We had one organization in 2010 that hosted a dinner meeting at a local winery! What a great draw for the public to enjoy a night out and get educated at the same time.
- ✚ Team up with a local health fair. Either set up a table about clinical research participation and play the DVD on a computer or laptop. Or ask if you can have a room set aside for a special presentation for the public to participate. You can pick one or two times throughout the health fair to play the DVD and answer questions.

➤ Option 3: Get Creative

- ✚ Think outside the box about ways to utilize the tools that CISCRP has made available to deliver a Clinical Research Education Day that is customized for your community. What would drive your community to attend an event like this? What resources do you have available that are unique?
- ✚ CISCRP would be happy to think through unique ideas of delivering *AWARE for All – Clinical Research Education Day* in your community. We hope you'll take advantage of the credibility that CISCRP brings to your program as a non-profit organization whose sole purpose is to educate the public about clinical research participation.

Step 2: Select a Date

- Consider collaborating with an event that is already being organized/publicized – choose their date!
- Consider other community activities that might compete with your event – avoid these dates!
- Piggy back CISCRP's National AWARE for All: Clinical Research Education Day - Saturday, October 27, 2012
- *Whatever date you choose, it goes on the CISCRP website with your institution's contact information!*

Step 3: Get Registered

- Visit the CISCRP website to register by credit card at:
http://www.ciscrp.org/professional/store/aware_main.html
- CISCRP will ship you AWARE for All in a Box so you can get started planning your AWARE for All: Clinical Research Education Event!

Evaluation/Metrics

At every *AWARE*, we gather basic socioeconomic data about the participants and conduct pre- and post-event surveys on the usefulness of the information, the likelihood of their volunteering for a clinical research study, and other factors. These data continue to help us improve the program and reach more people with important information about medical research. Consistently, our data have shown that *AWARE* participants are more likely to volunteer for a clinical research study after they have attended our program.

Overall *AWARE* attendees rate the program as good or excellent. National averages reveal, prior to *AWARE*, only 39% of respondents had participated in a clinical trial. After asking participants some of their key concerns about participating in clinical research, 99% of respondents reported that *AWARE* addressed their concerns about participating in clinical research. Following *AWARE*, 92% of respondents indicated that they are likely to look for ways to participate in a clinical trial; 99% of respondents are likely to tell their friends or family what they learned at *AWARE*; and the final evidence of *AWARE*'s efficacy is that 91% of respondents are likely to participate in a trial if invited by their physician.

AWARE for All in a Box includes an optional outcomes research study. The outcomes study may be conducted to evaluate the educational effectiveness of the *AWARE* program. Change in participant knowledge will be assessed by administering a pretest and posttest which will contain the same ten knowledge based questions about clinical research. The pretest, posttest and instructions for implementation will be provided to all registered sites. All registered sites who agree to provide CISCRP one set of outcomes data from one of your *AWARE* events become eligible for a 6 month license to duplicate the DVD included in the *AWARE for All in a Box*. Duplicated DVDs are a great idea as a giveaway at a health fair, something to give patients while they are going through the informed consent process or even something to send to patients whom may call on the phone to inquire about specific clinical trial opportunities.

Conclusion

AWARE for All – Clinical Research Education Events ensure that the public become more educated about clinical research. *AWARE* increases public awareness and health literacy

ultimately empowering patients to take a more active role in their own healthcare thus aiding in the reduction of health disparities all too prevalent in our society.

Utilizing this program will focus positive attention on your organization's role in advancing public health while increasing the public's understanding of clinical research and creating a community of active and informed participants in the clinical research process. We invite your organization to register and purchase *AWARE for All in a Box* so you may host an *AWARE for All: Clinical Research Education Event* in your community.