



## A Patient's Story

# Healthy participant sees trial as a chance to stand up to dementia



Dora Winston knows the ravages of memory loss all too well.

She spent five years caring for her older sister, Bernice and watched her painful, slow decline.

“Bernice started hallucinating when she was about 79,” Dora says. “That’s when I picked her up in Mississippi and moved her into my home in Chicago. It was devastating to watch her decline.”

“As Bernice regressed, she was unable to dress or feed herself,” Dora recalls. “As I watched my sister decline, I realized that I did not want to go that route and if there were anything I could possibly do to prevent it, I was willing to do it.”

So when Dora, 75, heard a radio announcement in June 2011 that Rush University Medical Center was recruiting seniors for a study to see if aspirin could help prevent dementia and promote general well being, she immediately called to find out more.

The Aspirin in Reducing Events in the Elderly (ASPREE) study is intended to determine whether aspirin can enhance quality of life by reducing physical disability and/or vascular dementia for healthy older adults and whether those potential benefits outweigh the risks.

Zach Hill, a research assistant at Rush, visited Dora twice at home to conduct an in-depth medical history and determine whether she was eligible to participate in the study. The two hit it off right away.

When Zach arrived for a third visit, during which he planned to draw blood and to conduct a series of memory and cognitive tests, he found Dora anxiously tending Bernice. Fearing her sister had had a stroke; Dora was struggling to get Bernice to the hospital.

Dora recalls, “Zach came and he was so patient and kind. He didn’t really know me or Bernice, but he helped me carry her to the car and kept asking if I was OK to drive her and he sent a

card afterward asking how she was doing. You just don’t expect that kind of kindness out of people.”

The memory of her helplessness and Zach’s compassion reinforced Dora’s determination to participate in the trial. When Zach called to reschedule their screening visit, she was eager to get started.

“The tests were like games,” Dora remembers. “He had me memorize a list of words. He read me a story and had me tell it back to him and he showed me a picture and then I had to draw it myself.”

Dora knows that aspirin can have negative side effects, such as bleeding, but her doctor had already prescribed low-dose aspirin therapy for her prior to the trial. “I wasn’t worried about taking aspirin because I was already doing it,” she says. Still, she shared the results from her blood work with her doctor and told him about her plans to participate in the trial. “He was OK with the idea,” she says.

Researchers visit participants in the ASPREE study every year to conduct memory and health assessments. They also call participants every three months between visits to stay in touch, provide support and find out if there have been any changes in their health or lives.

Dora doesn’t know if she’s taking a 100 mg dose of aspirin or a placebo, but the uncertainty doesn’t bother her.

“The trial’s a good thing,” she says. “Maybe it will help me and maybe it won’t, but it might help somebody else.”

Rush’s ASPREE coordinator Joanny Gonzalez estimates the majority of the participants in the trial share Dora’s motivation. “Probably 90 percent of them participate because they have a family member or someone close to them that has been diagnosed with Alzheimer’s or they have a family history of dementia. The other 10 percent feel that that they have a lot to offer. They have a lot to give and their age isn’t stopping them from contributing. They want to do something for future generations.”



# What to Do When Things Go Wrong

**A**lthough there are cases where things have gone wrong during clinical trials, the majority of clinical trials are conducted safely and ethically. There are many professionals and procedures in place to ensure that your rights are protected and that the risk of participation is minimized.

## What You Can Do

In situations where you feel that your safety and ethical treatment are in jeopardy, your best guide is the informed consent form. It is your bill of rights. If you feel, for example, that you have been subjected to unreasonable risk, that your concerns and wishes are not being respected or that you have witnessed unethical behavior, you need to contact the institutional review board (IRB) immediately. A contact number for the IRB or patient advocate is provided with your informed consent form. The study staff can also provide this information for you at any time.

If you are not satisfied after talking with your IRB or patient advocate, or if it appears that the IRB and the study staff are unable to help, then you need to contact the FDA or OHRP, directly.

### If you wish to consult with the FDA

**For studies of biologics**, including gene therapy and vaccine studies, you should contact the Division of Communication and Consumer Affairs in the Center for Biologics Evaluation and Research.

- Telephone (301) 827-2000

**For drug studies**, the FDA contact is the Division of Scientific Investigations in the Office of Medical Policy at the Center for Drug Evaluation and Research.

- Telephone (301) 594-0020

**For medical device studies**, the contact is the Division of Bioresearch Monitoring in the Office of Compliance at the Center for Devices and Radiological Health.

- Telephone (301) 594-4718

### If you wish to consult with the Office for Human Research Protections

- Telephone (240) 453-6900 or (toll-free) (866) 447-4777
- Mailing Address  
Office for Human Research Protections  
Department of Health and Human Services  
The Tower Building  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852  
Email [ohrp@osophs.dhhs.gov](mailto:ohrp@osophs.dhhs.gov)

You might also try the Office of Inspector General, Department of Health and Human Services (HHS).

- Telephone (800) 447-8477
- Mailing Address  
Office of Inspector General  
The U.S. Department of Health and Human Services  
Attn: HOTLINE  
330 Independence Avenue, SW  
Washington, D.C. 20201  
Email [HHSTips@oig.hhs.gov](mailto:HHSTips@oig.hhs.gov)

Although this may not address immediate concerns about safety and ethical treatment, you can play a more active role in the future by joining or participating in an IRB. This experience will help you increase your network of support.

### Some suggested steps that you can take to better protect yourself

- Ask who wrote the study protocol and what qualified that person to do so.
- Call the IRB to learn about how much time was spent reviewing the study protocol and what specific areas, if any, gave members cause for discussion or concern.
- Find out if there is or has been professional debate about the risks associated with the study drug. If so, ask for referrals to medical publications where these risks are discussed.
- Request that the study staff speak to you in plain English (or Spanish, French, sign language, etc.)—or find someone who can.
- Quiz the researcher and study coordinator about how many adverse events and deaths have been reported during trials of this study drug—whether or not they were actually attributed to the drug. If they don't know, call the IRB. If the IRB doesn't know, call the pharmaceutical company.
- Ask the researchers if they would advise you to enroll in the trial if you were a member of their family.
- Gather as much information as you can from published reports and news coverage about your study medication.
- If possible, go to another research center conducting the same clinical trial. Go through the same set of questions and see if you get the same answers. Seek explanations for inconsistencies.
- Share everything you learned with your family doctor and other friends and family within your support network before enrolling.