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Boston Public Health Commission

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Clinical trials:
Minority participation is vital

Tracey Sigler (left), shown with her son, Bryant, participated in a study to investigate risk factors associated with gestational diabetes, a rare disease that disproportionately impacts black women.

At one point in her life, Tracey Sigler admits, the mere mention of human medical experiments would have probably triggered an immediate reaction.

No way. No way was she going to be some sort of human guinea pig.

But she acknowledges that times have changed and so has she.

So when she saw an ad seeking volunteers for a study that could potentially help other women with a rare form of diabetes, she decided to sign up.

"I'm very comfortable," she says. "It will help others and increase awareness."

And that's the point.

"Today's standard treatments," Dr. Lidia Schapira explains, "are yesterday's clinical trials." Schapira is an oncologist at Massachusetts General Hospital and an assistant professor at Harvard Medical School.

> ***"Everyone should be included in a clinical trial. When a group is excluded, that group loses."***
>
> ***—Lidia Schapira, M.D.***

"Many of the treatments we take for granted are the results of clinical trials," she continued. One example is the treatment for breast cancer. Schapira pointed out that, prior to research, women who are now candidates for breast-conserving treatment were subjected to complete removal of the breast.

At their most basic, clinical trials are research studies conducted to find an improved way to prevent, diagnose or treat a disease or condition.

Most everyone understands the necessity. They also understand the risks. And that's when mistrust can enter the picture — often aimed not only at the research and its inherent risks, but also at those conducting the research.

It wasn't that long ago — 1997 to be exact — when President Bill Clinton apologized for the federal government's role in the Tuskegee experiment. Started in 1932, the 40-year study enlisted mostly illiterate sharecroppers in Alabama to participate in what they were told was a study on "bad blood."

In reality, the study was on the ravages of syphilis. The men were left to suffer its consequences even when a suitable treatment became available.

The lingering mistrust still looms large. A recent study undertaken by Dr. Neil R. Powe details the split between blacks and whites.

Powe, of Johns Hopkins Medical Institutions, and his associates found that only 27 percent of blacks surveyed expressed willingness to participate in a cardiovascular drug trial, compared to 39 percent of whites.

According to the study, more blacks said they believed that doctors would use them as guinea pigs without their consent, that they would be asked to participate in research even if it were harmful, and that doctors would not fully explain the research to them.

More troubling was that more than half of the black respondents said that doctors had previously experimented on them without their consent. Only one-fourth of whites had a similar response.

The researchers noted that, after controlling for perceived risk and distrust, willingness to participate was not significantly different between blacks and whites.

The numbers are clear. The National Cancer Institute, for instance, found that between Jan. 1, 2003 and June 30, 2005, only 8 percent of blacks participated in research studies supported by the institute. Yet, incidence and death rates of cancer in blacks far exceed those in whites.

The egregiousness of the Tuskegee study is not debatable. Much damage was done. But not participating in clinical trials could be equally damaging.

When research is conducted on whites only, medical experts argue, doctors are forced to assume that the results are transferable to all people. But that is not always a correct assumption.

In a recent study, doctors found that black women with advanced and recurrent cervical cancer tolerated platinum-based chemotherapy better than white women participating in the same study.

"Everyone should be included in a clinical trial," said Schapira. "When a group is excluded, that group loses."

That is exactly what Tracey Sigler was thinking.

Three years ago, she was pregnant and

Sigler, *continued to page 4*

The ins and outs of medical research

Ben Perkins, 43, is on a mission.

For years, he has worked as a community educator trying to raise awareness of the need for more African American involvement in HIV/AIDS research.

Perkins is also a bit of a maverick. He has participated in several clinical trials; as a gay black man, he says he believes that he owes it to the black and gay communities.

"It's one thing to talk about it, but another thing to actually roll up your sleeves," he said.

For Perkins, it's personal. Many of his friends are HIV-infected. "HIV has had a profound impact on me," said Perkins. "My childhood best friend died of AIDS."

Taking part in a clinical trial is voluntary. But participation has been highly skewed to include mostly whites, men and those with higher levels of income. Minorities, the elderly, women and those from rural areas are largely excluded.

There are reasons for the gap — chief among them the higher degree of mistrust among African Americans. But other barriers exist.

Ben Perkins, a project director at The Fenway Institute, was a volunteer in a clinical trial to develop a vaccine for HIV.

Insurance may not pay for the study; the requirements can be time-consuming and demand time away from work; transportation may not be available; language differences present a problem; and the study may be too complicated to understand.

For many, it is merely lack of awareness — people may not know that participation in a clinical trial is possible.

Part of the problem lies with the medical profession itself. Primary care physicians and those not affiliated with research institutions may not be aware of patient eligibility for clinical trials. Some physicians simply do not make referrals. More significantly, minority investigators, who may be more successful in attracting minority volunteers, are under-represented in research.

Programs are in the works to increase participation by minorities and women. On a national level, the National Institutes of Health now requires researchers to design strategies to include under-represented groups. Medicare authorized payment of routine costs back in 2000 for Medicare recipients who participated in clinical trials.

On the local level, community-based partnerships, including the Program to Eliminate Health Disparities at Harvard School of Public Health, are developing initiatives to increase awareness and understanding of clinical trials among blacks to improve their participation.

For the record, anyone can participate in a clinical trial if he or she meets the specific inclusion criteria, such as age, gender, extent or type of disease, previous treatment and other medical conditions.

The potential benefits are enormous. A person can play a more active role in his or her health care, have access to new treatment before it is made available to the general public, and obtain closely monitored expert medical care. And they can make a major contribution to science and help others.

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Clinical trials: Who pays the bill?

For those suffering from cancer or other life-threatening illnesses, there may come a time when conventional medicine is no longer an effective course of treatment. It then becomes important to understand what a clinical trial is and what your insurance company is required by law to cover. Massachusetts is one of 24 states and the District of Columbia that mandates coverage for certain clinical trials.

Lack of such health insurance is a major barrier to many patients who want to enroll in trials.

Phases

Clinical trials are the testing phases of a new drug or treatment option. For instance, when pharmaceutical companies want to introduce their drug to consumers, they must first test it to make sure the drug works. They accomplish this through clinical trials, which are conducted in phases.

For a new drug, Phase I consists of testing a small group of people to determine the safety of a drug, its proper dosage and to identify side effects. Phase II involves testing a larger group to further gauge the drug's safety as well as its effectiveness. Phase III includes the largest testing group, and continues to test the aspects covered in the previous phases. Its main purpose, however, is to determine if the treatment under study is better than the standard treatment. If Phase III is successful, the drug may become available to the public. At times Phase IV — which occurs after the drug has been marketed — is conducted in order to gauge the effects of long-term use.

Insured health plans in Massachusetts

In Massachusetts, health insurers — including commercial health insurers, Blue Cross and Blue Shield of Massachusetts Inc. and health maintenance organizations — are required by a 2002 law, Chapter 257 of the Acts of 2002 (Chapter 257), to cover "qualified clinical trials to the same extent as if the care was considered non-investigational." There are two parts to this law.

First, a clinical trial must be "qualified" and meet certain conditions:

- The trial is for the treatment of cancer;
- It is approved by certain agencies or organizations, such as the National Institutes of Health;
- It is administered by qualified personnel at a qualified facility;
- Phase I clinical trials can be conducted only at academic medical centers or an affiliated facility;
- There is reasonable expectation that the trial will provide benefits commensurate with the risks;
- The patient meets the selection criteria and has provided informed consent.

The second part of the law concerns the care covered. When you undergo a clinical trial, the professional services — doctor visits, radiology services, inpatient care and other standard medical procedures — will be covered, just as they would be if you were being treated with a conventional method. An exception to this rule is payment for an experimental drug. In most cases, the sponsor of the trial provides and pays for the drug being tested. Your plan will not pay for drugs and services that the investigator typically provides.

Self-insured health plans

These mandates do not cover all people who have employer-sponsored health insurance in Massachusetts. While insured health plans are common for small companies and individuals, larger companies are sometimes self-insured or self-funded and governed by the Employee Retirement Income Security Act of 1974 — commonly referred to as ERISA. ERISA is a federal law that protects the rights of employees covered under self-funded health plans in private industry. ERISA does not mandate coverage for clinical trials, so it is very possible your company's health plan does not provide for it. To know for sure, check with your department of human resources. If your company has a self-insured plan, there may be different coverage details.

It is important to note that the type of plan you have is dictated by your company. For instance, while you may have a Blue Cross Blue Shield of Massachusetts card, it is your company that decides whether it is an insured or self-insured plan. Check with your company to make sure.

Medicare

Chapter 257 applies only to Massachusetts insured plans. Medicare, on the other hand, is a federal health insurance plan for those 65 and older, people under the age of 65 with certain disabilities and those with end-stage renal disease (permanent kidney failure that requires transplantation or dialysis). In 2000, Medicare introduced guidelines for routine care for those volunteering for medical research.

If you have Medicare you will be covered for:

- Room and board for a hospital stay that Medicare would pay for even if you weren't in a clinical trial;
- An operation to implant an item that is being tested;
- Treatment of side effects and complications of the new care;
- Any other routine costs of items and services.

Medicare does not cover all expenses, however. It will not pay for any items that the study provides for free, or items or services that are only used to collect data and are not relevant to your personal health. For instance, if multiple CT scans are taken only to collect data, the service will not be reimbursed. Medicare will also not pay for out-of-pocket expenses such as coinsurance and deductibles that are always the responsibility of the patient.

Medicaid

Right now, Massachusetts' Medicaid program, or MassHealth, "does not pay for research or experimental treatment."

You should talk with your doctor about the best clinical trials for you. He or she will be able to recommend the most appropriate treatment facility for your condition.

Take the right steps

If you are interested in a clinical trial, take the right steps to find reliable information.

Talk to your doctor or call a local teaching hospital.

Look for ads in newspapers and search the Internet.

Meet with the research team monitoring the trial.

Contact your health insurance advisor to make sure the trial is covered.

Talk to your family about your decision.

Clinical trials

Questions & Answers

Lisa Michelle Owens, M.D.
Medical Director
Brigham Primary Physicians at Faulkner Hospital

1. Why is it important for blacks to participate in clinical trials?

Some medical therapies benefit one group more than another. It is important to include African Americans in clinical trials so that we know that the new breakthrough treatments or procedures will be equally beneficial, or more importantly, not harmful to blacks. So, in order to best apply these new treatments, we need to study them in blacks. Additionally, participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available and help others by contributing to medical research.

2. Do all clinical trials carry risk?

There are risks to participating in some clinical trials. There may be unpleasant, serious or even life-threatening side effects to experimental treatment. The experimental treatment may not be effective for the participant. The research plan or protocol may require more of their time and attention than would the standard treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements. There are some clinical trials — quality-of-life trials — that pose little or no risk.

3. What mechanisms protect the safety of volunteers in medical research?

The ethical and legal guidelines of medical practice also apply to clinical trials. Most clinical research is conducted according to federal regulations, which contain built-in safeguards to protect the participants. The trial follows a carefully controlled protocol — a study plan which explains what the researchers will do in the study. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals and to various government agencies.

4. If an individual agrees to participate in research, does that mean that he or she is committed for the entire length of the study?

No. An individual can withdrawal from a clinical trial at any time. It is important for the individual to let the researchers know the reason why they are leaving the study.

5. Who sponsors clinical trials?

Clinical trials are sponsored or funded by various organizations or individuals, such as physicians, medical institutions, foundations, voluntary groups and pharmaceutical companies. Federal or governmental agencies, such as the National Institutes of Health, the Department of Defense, and the Department of Veterans Affairs also sponsor clinical trials. Trials can take place in a variety of locations — hospitals, universities, doctors' offices or community clinics.

6. What are the different types of clinical trials?

Treatment trials test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy. Prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These studies may include medicines, vaccines, vitamins, minerals or lifestyle changes.

Diagnostic trials are conducted to find better tests or procedures for diagnosing a particular disease or condition. Screening trials look for the best way to initially detect certain diseases or health conditions.

Quality-of-life trials (or supportive care trials) look at ways to improve comfort and the quality of life for individuals with a certain ongoing illness.

7. Why are some people reluctant to volunteer for clinical research?

Some individuals are reluctant to volunteer to participate in clinical trials because in the past there were not always strict ethical, medical and legal guidelines in place to protect the safety of the volunteers. Others are reluctant because they know more about the risks and less about the potential benefits of participating in clinical research. Lastly, some people do not realize that by participating in clinical research they are helping researchers to learn about new potential treatments or procedures.

8. If your primary care physician does not offer you a clinical trial, what is the best way to find one?

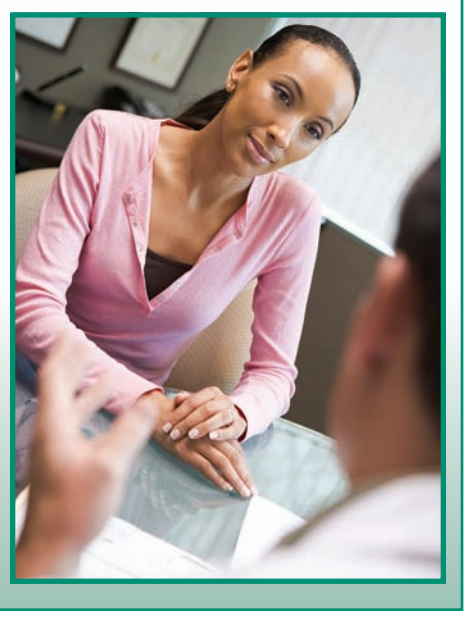
Access to information on available clinical trials is available online, or through teaching hospitals or medical centers.

9. Who pays for medical research?

Medical research is paid for by grants which can be funded through governmental agencies, such as the National Institutes of Health and the Department of Defense, private foundations, pharmaceutical companies and medical institutions.

A closer look

Clinical trials are medical research studies to find an improved way to treat, prevent or diagnose an illness. Volunteers are required to prove the efficacy of the new approach. Historically, African Americans and other minorities, as well as women and the elderly, have not been well represented among those participating in clinical trials. Some African Americans are distrustful of the health care system in general and clinical trials in particular, and choose not to volunteer. Yet it has been shown that medicines can affect people differently. Depending on the protocol, researchers seek a wide range of volunteers to understand the impact of the new treatment on everyone.



The right decision

Volunteering for a clinical trial is a personal decision. You should not participate if you are uncomfortable with the trial or feel that it is not right for you. There are questions you might ask yourself …

- **Am I able to take the time for extra trips to the doctor that might be required?**
- **Am I comfortable receiving a treatment the risks and benefits of which are not completely known?**
- **Am I able to handle the side effects?**
- **Can I afford it if my insurance company does not cover the treatment?**
- **Is transportation a problem? Can I drive myself or take public transportation?**
- **Do I have a support system or caretaker who can help me through the side effects?**
- **Is it possible for me to miss work if necessary?**
- **What is it that concerns me about the study?**

Sigler

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developed gestational diabetes, a relatively rare disease that occurs in only about 4 percent of all pregnancies, and more frequently in women of color — blacks, Asians, Latinas and American Indian.

Although the exact cause of gestational diabetes is unknown, if left untreated or poorly controlled, it can cause long-term medical problems for both mother and child. Gestational diabetes increases the risk of heart disease after pregnancy.

Sigler was able to control her condition with diet; fortunately, she did not have to resort to insulin. But Sigler still had concerns. Though free of diabetes after the birth of her son, she was not completely out of danger — high blood pressure and other cardiovascular diseases run in her family.

Lidia Schapira, M.D.
Assistant Professor of Medicine
Harvard Medical School

For her, the decision to participate in the study conducted at Brigham and Women's Hospital was not hard.

For what she hoped to gain, Sigler said, the requirements were minimal.

She fasted the night before and spent about five hours the next day undergoing tests at the hospital. The study consisted of an oral glucose tolerance test, fasting blood tests and a non-invasive blood vessel study.

The only discomfort she experienced was a slight headache from a nitroglycerin pill she was asked to take, but even that subsided quickly.

Not all trials carry risks or even an interventional treatment. Quality of life trials seek to improve the comfort and quality of life of patients and their caregivers.

Take Carmiletta Teasley, for example. Teasley, 49, volunteered for a 20-week program studying the impact of human touch on cancer survivors.

Yes — massage therapy.

She heard about the study through The Wellness Community, a support group at The Dimock Center, where it was described as a "unique opportunity for people with cancer and their caregivers."

Sponsored by the National Cancer Institute, the study was designed to determine if caregivers could be taught simple touch and massage techniques to alleviate the discomfort suffered by cancer patients.

The massage "aroused my curiosity," Teasley said. "It could be a gold mine."

Her mind raced with excitement.

"If massage worked on my side effects of cancer, it might help diabetes as well," she said. "My curiosity overcame any reservation I had."

Teasley is still under treatment for sarcoma and melanoma.

In spite of her medical conditions, Teasley considers herself blessed.

The study required a caretaker to work with her, and she requested that to be her best friend — a cancer survivor herself.

Her friend could relate to many of the things Teasley was going through, which is why she agreed to work with her.

Carmiletta Teasley plans to enter a study for her cancer that is not responding to traditional treatment.

For the first part of the experiment, her caretaker read the Bible to her. "Both of us are very spiritual," Teasley said. "Many people turn to their faith to see it through."

After four weeks of reading the Bible, the massage sessions began. Her caretaker massaged her hands, feet and legs.

According to Teasley, head massages did the trick.

"Especially on a bald head," she said.

For Teasley, the trial was a good thing. "I now have a means of alleviating many of the side effects of my illness," Teasley said. "Now I know there is something that works."

Even now she still resorts to massages to ease her discomfort.

Teasley is not through with clinical trials. The chemotherapy is not working and she is looking for other research at Dana-Farber Cancer Institute. She found another trial, but the decision was not easy.

"It's a painstaking process," she said, noting that she fully understands the risks involved with the new trial. "You need to understand the guidelines. You have to know what you're willing and not willing to do."

She also stressed the fact that a person has the right to pick and choose.

"It's a personal journey," she explained. "The decision can mean life or death. I'm not sure if I have an alternative."

Lebaron Brown, 50, figured he had nothing to lose.

"For a lot of years," he confessed, "I've felt lousy."

But he ignored a slew of symptoms, even remaining in denial about the lump on his neck that continued to grow.

Lebaron Brown credits his survival to a clinical trial for his Stage IV colon cancer.

Finally, he went to the clinic for a check up, and, to say the least, it didn't go well — he had Stage IV colon cancer and it had spread to his liver, lungs, kidney and brain.

That's when his doctors at Boston Medical Center offered Brown a clinical trial.

"They explained everything," he said. "They did an excellent job in making me understand. They warned me that, because of the extent of my cancer, they were going to hit me with a very powerful, fast working drug."

He is still able to tick off the possible side effects — loss of appetite, nausea, vomiting, rash, hair loss, chills and fever.

He had them all.

But Brown is not complaining. His lump has disappeared.

"That was the first to go," he said. "I was sick as a dog but it was working."

Brown said he never had an issue with mistrust.

"I looked in their eyes," he recalled. "They were sincere and concerned to help me. I trusted them. They laid it out to me and I signed."

And as far as Brown is concerned, it was a good decision.

"I'm still here," he exclaimed. "I feel better than I have in 15 or 20 years."

Will it work for you?

Make sure you understand and are comfortable with a clinical trial if offered to you. A research team will oversee the study. Ask a few questions …

- What is the purpose of the study?
- Has it been tested before? If so, what were the results?
- What kinds of tests and experimental treatments are involved?
- How do the possible risks, side effects and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Will hospitalization be required?
- Who will pay for the experimental treatment? If my insurance will not pay, can I still be in the study?
- Will I be reimbursed for other expenses?
- What type of long-term follow up care is part of this study?
- Will results of the trials be provided to me?
- Who will be in charge of my care?
- Who is sponsoring the study?
- If someone else in the study has an unexpected side effect, will you tell me?
- Can I withdraw from the study?
- Is it possible that I will be given a placebo instead of the drug under study?

Source: National Institutes of Health, Dana-Farber Cancer Institute

Where to look for help

- **RSVP for Health (Partners HealthCare System, Inc.)**
  866-391-7030
  www.rsvpforhealth.partners.org
- **US National Institutes of Health**
  www.clinicaltrials.gov
- **The Center for Information & Study on Clinical Research Participation**
  888-247-2773
  www.ciscrp.org
- **CenterWatch Clinical Trials Listing Service**
  617- 948-5100
  www.centerwatch.com
- **Coalition of Cancer Cooperative Groups**
  877-520-4457
  www.cancertrialshelp.org
- **National Heart, Lung, and Blood Institute**
  www.nhlbi.nih.gov/studies/index.htm

Perkins

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But there are risks as well. Unpleasant side effects — some potentially life-threatening — are always a possibility. Worse, the experimental treatment may not be effective.

"I understand people's hesitation," Perkins said. "It's a big deal. You're putting your body on the line."

Clinical trials are conducted in four sequential phases. Phase I trials test the safety of a new treatment, while Phase II trials test the effectiveness of that treatment.

If the results of the first two phases look promising, Phase III trials then determine whether the experimental treatment is better than the current standard treatment. If successful, the research team can request approval by the Food and Drug Administration to make the treatment available to the public.

In some instances, a Phase IV is added to continue to monitor the long-term effect on people who use the experimental treatment even after federal approval.

Stringent guidelines for clinical trials are in place to protect the safety of volunteers. The Data Safety Monitoring Board oversees safety data and warns researchers and participants if they notice a trend towards excessive risk. The research plan — or protocol — is reviewed by the federally mandated Institutional Review Board (IRB), a group of health professionals, statisticians and laypersons.

The IRB monitors the progress of the trials, checks for side effects and can request periodic modifications. Most important, the board can terminate the trial if preliminary results are not satisfactory.

Such was the case with the latest protocol to which Perkins had consented.

Sponsored by the National Institute of Allergy and Infectious Disease and Merck & Co., Inc., the Step study was designed to evaluate the safety and effectiveness of an investigational vaccine for HIV. The Step study was a Phase 11b clinical trial that enrolled HIV-negative volunteers to receive either the study vaccine or a placebo, an inactive substance.

"It was important to me to find a cure or a vaccine," Perkins said. "I wanted to make a difference and contribute to the body of knowledge to decrease the incidence of HIV."

Perkins admits that he was a bit apprehensive about receiving injections of an unknown substance. But he is just as quick to point out that the potential benefits greatly outweighed any minor psychological anxiety.

Unfortunately, the study was terminated early. The results were not promising, the researchers determined, and their objectives were unlikely to be met.

Though the vaccine did not perform as intended, Perkins is still involved with the trial. Every six months, he receives examinations to determine the long-term effects of the experimental drug.

Perkins is a project director at the Fenway Institute, an interdisciplinary center for research, training, education and policy development. The institute is part of Fenway Community Health Center.

Perkins is a bit philosophical when it comes to clinical trials.

"I look at it," he explains, "as an act of love — for oneself, the community and for those who come behind."

Comments on Be Healthy? Contact Karen Miller at kmiller@bannerpub.com.