Attachment 1. The Quality of Life Inventory

Quality of Life Difficulties (QOL)

For each of the following conditions, select the item that best describes your condition within the last thirty (30) days.

1. Headaches
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

2. Irritable Bowel Syndrome
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

3. Arthritis
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

4. Premenstrual Syndrome
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

5. Recurring Sinus Infections
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

6. Tension Fatigue Syndrome
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

7. Recurrent Anxiety
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

8. Recurrent Depression
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

9. Insomnia
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

10. Low Self Esteem
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

11. Binge Eating
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

12. Chronic Tension
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

13. Lack of Energy
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

14. Food Allergies
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

15. Feeling Under Stress
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

16. Cancer
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

17. Prostate Problems
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

18. Overeating
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

19. Stomach Pain
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

20. Back Pain
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

21. Pain in Arms, Legs or Joints
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

22. Menstrual Pain or Problems
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

23. Chest Pain
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

24. Dizziness
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

25. Diarrhea
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

26. Irregular Heartbeat
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

27. Shortness of Breath
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

28. Constipation
- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

29. Stomach Gas or Indigestion

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

30. Feeling Weak

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

31. Eating Too Rapidly

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

32. Eating After Being Full

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

33. Embarrassed About Overeating

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

34. Depressed Over Eating Habits

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

35. Depressed About My Weight

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

36. Difficult to Stop Eating

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

37. Worrying About the Future

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

38. Unable to Concentrate

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

39. Forgetfulness

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

40. Bad Temper or Quick to Anger

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

41. Indigestion

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

42. Diabetes

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

43. Vomiting

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

44. Heartburn

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

45. Esophageal Reflux

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

46. Control Over My Appetite

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

47. Ability to Relax

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

48. Heart Disease

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

49. Fibromyalgia

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

50. Difficulty in Falling Asleep

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

51. Awakening During the Night

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

52. Feeling Sad

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

53. Waking Up Too Early

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

54. Sleeping Too Much

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

55. Unintentional Weight Gain

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

56. Unintentional Weight Loss

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

57. Inability to Concentrate

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

58. Satisfied With My Life

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

59. Sleepy Throughout the Day

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

60. Difficulty in Making Decisions

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

61. Feeling Restless

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

62. Getting More Tired Than Usual

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

63. Blaming Myself Too Often

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

64. Causing Problems for Others

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

65. Worrying About My Faults

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

66. Wondering If Life is Worth Living

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

67. Suicidal Thoughts and Worries

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

68. Decreasing Interest in People

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

69. Decreasing Interest in Activities

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

70. Difficulty in Sitting or Standing Still

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

71. Often Fidgety

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

72. More Tired Than Usual

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

73. Generalized Depression

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

74. Difficulty in Finishing Activities

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

75. Feeling Sad Too Much of the Time

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

76. Dieting Too Often

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

77. Difficulty in Staying With a Diet

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

78. Difficulty in Getting Up in the Morning

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

79. Eating Too Much Between Meals

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

80. Eating Too Much During Meals

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

81. Getting Tired Too Often

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

82. Preoccupied with Gloomy Thoughts

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

83. Thinking Too Much About Death

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

84. Slowing Down of My Thinking

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

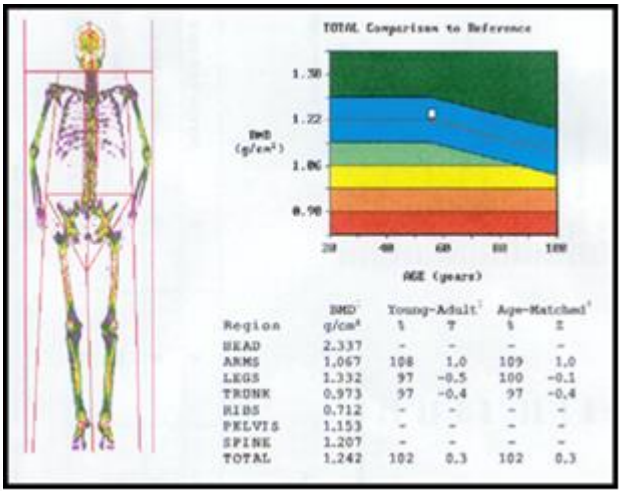
85. Unhappy Too Much of the Time

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

86. Difficult to Stop Eating Once I Start

- ○ Not a problem
- ○ A minor problem
- ○ A major problem
- ○ A severe problem

Attachment 2. The DEXA Total Body Test



Is There a Fracture in Your Future?

By Michael F. Roizen, MD & Mehmet C. Oz, MD

"Osteoporosis is often called the Rottweiler disease because it chews up your bones fast. And it's sneaky. You won't have a clue that your bones have been quietly getting brittle until you trip over the dog's water bowl and break your wrist or fracture your hip.

Getting a clue early enough to do something about it is the whole point of having something called a bone mineral density test, which checks out the sturdiness of your skeleton. Who should have one of these, and when? Age, sex, family, and "it depends" are part of the answer. (Aren't they always?)

If bones that snap like toothpicks run in your family (or if you're underweight or you overdo alcohol), ***you should get your skeleton scanned by age 50 or earlier****. If not, docs urge women to have the test around menopause and definitely by 65.* ***Men should get it by then, too****; osteoporosis doesn't know from sexual discrimination.*

No worries about the process. As medical tests go, this one's a gem: It's fast, painless, very safe, and doesn't cost the moon. Figure about 15 minutes for a DXA scan… (DXA or DEXA stands for Dual Energy X-ray Absorptiometry if you like to know these things). DXA scans are the gold standard for assessing your bones' mineral content and bone density, the most frequently used measure for bone strength. If your insurance doesn't cover DXA, it will run about $200."

What is a Bone Density Scan (DXA)?

The following information has been reviewed by a physician with expertise in DEXA testing and was further reviewed by committees from the American College of Radiology (ACR) and the Radiological Society of North America (RSNA) by physicians with expertise in several radiologic areas.

Bone density scanning, also called dual-energy x-ray absorptiometry (DXA) or bone densitometry, is an enhanced form of x-ray technology that is used to measure bone loss. DXA is today's established standard for measuring bone mineral density (BMD). An x-ray (radiograph) is a noninvasive medical test that helps physicians diagnose and treat medical conditions. Imaging with x-rays involves exposing a part of the body to a small dose of ionizing radiation to produce pictures of the inside of the body. X-rays are the oldest and most frequently used form of medical imaging.

DXA is most often performed on the lower spine and hips. **In children and some adults, the whole body is sometimes scanned.** Peripheral devices that use x-ray or ultrasound are sometimes used to screen for low bone mass. In some communities, a CT scan with special software can also be used to diagnose or monitor low bone mass (QCT). This is accurate but less commonly used than DXA scanning.

What are some common uses of the procedure?

DXA is most often used to diagnose osteoporosis, a condition that often affects women after menopause but may also be found in men. Osteoporosis involves a gradual loss of calcium, as well as structural changes, causing the bones to become thinner, more fragile and more likely to break. DXA is also effective in tracking the effects of treatment for osteoporosis and other conditions that cause bone loss.

The DXA test can also assess an individual's risk for developing fractures. The risk of fracture is affected by age, body weight, history of prior fracture, family history of osteoporotic fractures and life style issues such as cigarette smoking and excessive alcohol consumption. These factors are taken into consideration when deciding if a patient needs therapy.

Bone density testing is strongly recommended if you:

- are a post-menopausal woman and not taking estrogen.
- have a personal or maternal history of hip fracture or smoking.
- are a post-menopausal woman who is tall (over 5 feet 7 in) or thin (less than 125 pounds).
- are a man with clinical conditions associated with bone loss.
- use medications that are known to cause bone loss, including corticosteroids such as Prednisone, various anti-seizure medications such as Dilantin and certain barbiturates, or high-dose thyroid replacement drugs.
- have type 1 (formerly called juvenile or insulin-dependent) diabetes, liver disease, kidney disease or a family history of osteoporosis.
- have high bone turnover, which shows up in the form of excessive collagen in urine
- have a thyroid condition, such as hyperthyroidism.
- have a parathyroid condition, such as hyperparathyroidism.
- have experienced a fracture after only mild trauma.
- have had x-ray evidence of vertebral fracture or other signs of osteoporosis.

How should I prepare?

On the day of the exam you may eat normally. You should not take calcium supplements for at least 24 hours before your exam. You should wear loose, comfortable clothing, avoiding garments that have zippers, belts or buttons made of metal. Objects such as keys or wallets that would be in the area being scanned should be removed.

You may be asked to remove some or all of your clothes and to wear a gown during the exam. You may also be asked to remove jewelry, eye glasses and any metal objects or clothing that might interfere with the x-ray images.

Inform your physician if you recently had a barium examination or have been injected with a contrast material for a computed tomography (CT) scan or radioisotope scan. You may have to wait 10 to 14 days before undergoing a DXA test.

Women should always inform their physician or x-ray technologist if there is any possibility that they are pregnant. Many imaging tests are not performed during pregnancy so as not to expose the fetus to radiation. If an x-ray is necessary, precautions will be taken to minimize radiation exposure to the baby.

How does the procedure work?

The DXA machine sends a thin, invisible beam of low-dose x-rays with two distinct energy peaks through the bones being examined. One peak is absorbed mainly by soft tissue and the other by bone. The soft tissue amount can be subtracted from the total and what remains is a patient's bone mineral density. DXA machines feature special software that compute and display the bone density measurements on a computer monitor.

How is the procedure performed?

This examination is usually done on an outpatient basis. In the Central DXA examination, which measures bone density in the hip and spine, the patient lies on a padded table. An x-ray generator is located below the patient and an imaging device, or detector, is positioned above.

Test results will be in the form of two scores:

T score — This number shows the amount of bone you have compared with a young adult of the same gender with peak bone mass. A score above -1 is considered normal. A score between -1 and -2.5 is classified as osteopenia (low bone mass). A score below -2.5 is defined as osteoporosis. The T score is used to estimate your risk of developing a fracture.

Z score — This number reflects the amount of bone you have compared with other people in your age group and of the same size and gender. If this score is unusually high or low, it may indicate a need for further medical tests. Small changes may normally be observed between scans due to differences in positioning and usually are not significant.

What are the benefits vs. risks?

Benefits

- DXA bone densitometry is a simple, quick and noninvasive procedure.
- No anesthesia is required.
- The amount of radiation used is extremely small—less than one-tenth the dose of a standard chest x-ray, and less than a day's exposure to natural radiation.
- DXA bone density testing is the most accurate method available for the diagnosis of osteoporosis and is also considered an accurate estimator of fracture risk.
- DXA equipment is widely available making DXA bone densitometry testing convenient for patients and physicians alike.
- No radiation remains in a patient's body after an x-ray examination.
- X-rays usually have no side effects in the diagnostic range

Risks

There is always a slight chance of cancer from excessive exposure to radiation. However, the benefit of an accurate diagnosis far outweighs the risk. The effective radiation dose from this procedure is about 0.01 mSv, which is about the same as the average person receives from background radiation in one day. Women should always inform their physician or x-ray technologist if there is any possibility that they are pregnant. No complications are expected with the DXA procedure.

A Word About Minimizing Radiation Exposure

Special care is taken during x-ray examinations to use the lowest radiation dose possible while producing the best images for evaluation. National and international radiology protection councils continually review and update the technique standards used by radiology professionals.

State-of-the-art x-ray systems have tightly controlled x-ray beams with significant filtration and dose control methods to minimize stray or scatter radiation. This ensures that those parts of a patient's body not being imaged receive minimal radiation exposure.

What are the limitations of DXA Bone Densitometry?

A DXA test cannot predict who will experience a fracture but can provide indications of relative risk. Despite its effectiveness as a method of measuring bone density, DXA is of limited use in people with a spinal deformity or those who have had previous spinal surgery. The presence of vertebral compression fractures or osteoarthritis may interfere with the accuracy of the test; in such instances, CT scans may be more useful. Central DXA devices are more sensitive than pDXA devices but they are also somewhat more expensive.

A test done on a peripheral location, such as the heel or wrist, may help predict the risk of fracture in the spine or hip. These tests are not helpful in following response to treatment, however, and if they indicate that drug therapy is needed, a baseline central DXA scan should be obtained.

Attachment 3: Bio Impedance Assessment (BIA)

How Safe Is Bioelectrical Impedance Analysis (BIA)?

Bioelectrical Impedance Analysis(BIA) in Body Composition Measurement
National Institutes of Health
Technology Assessment Conference Statement

Users of the BIA procedure consider it safe because of several factors.. One factor is that currents at a frequency of 50 kHz are reported to be unlikely to stimulate electrically excitable tissues, such as nerves or cardiac muscle. Another is the absence of any reports of untoward events induced by BIA, even in the course of thousands of individuals undergoing measurement. A third factor is that relatively small current magnitudes are involved, less than 1 mA, which are less than the threshold of perception. Furthermore, the use of batteries or low-voltage power sources greatly diminishes risks from macro-shock. At the same time, not all safety issues have been explicitly or formally evaluated, particularly issues that might arise when additional devices are involved (such as an implanted cardiac defibrillator) or in a hospital environment where electrical interference is more likely. In addition, so far as the panel is aware, there exist no formal safety standards for BIA instruments. Also, introduced current in the BIA procedure is larger in magnitude than are leakage currents allowed for some other medical devices, such as electrocardiograph machines (although that leakage involves the 60-Hz power-line frequency, which is thought to have more intrinsic risk).

The panel neither heard nor identified any particular reason why the BIA measurement is other than safe. However, the panel thought that a more systematic assessment of all safety-related issues would be in order in view of the obvious public interest in this issue and because the panel was not advised of any comprehensive assessment that has presently been completed. Furthermore, a review of issues of electro-magnetic compatibility may also be in order, in regard to both interferences with the BIA measurement and interference by the BIA measurement with other devices that might be in the vicinity. It is wise to advise anyone with an implanted defibrillator to avoid BIA evaluation until this issue has been reviewed, because even small currents could potentially provoke an incorrect defibrillator response.

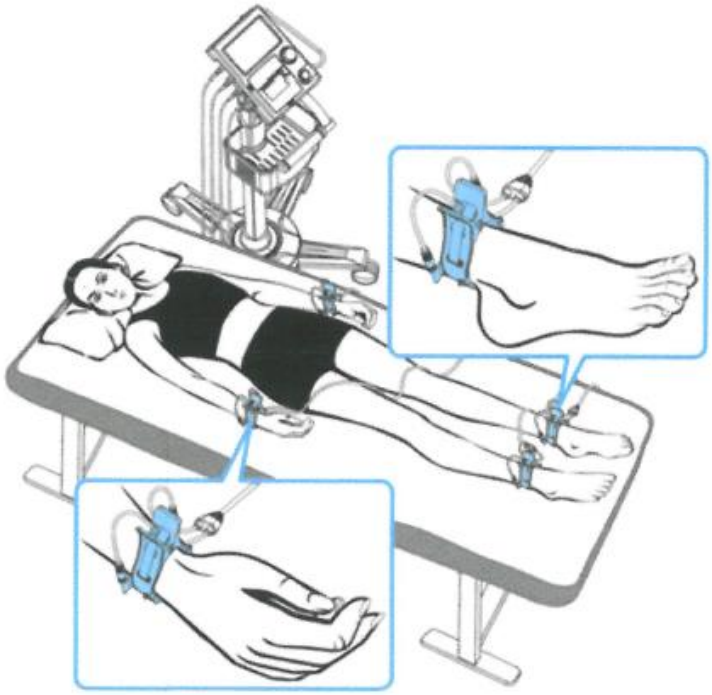
InBody370

InBody S10

SUPINE

TANITA MC780U

Cozy 930	X-SCAN PLUS 970	X-CONTACT 357S
		
for patients	high-end	middle-end
50 spine posture	standing posture	



Attachment 4: How Clinical Research Studies Benefit Subjects

Source Newsroom: Penn State Milton S. Hershey Medical Center
Newswise — Clinical research studies are the reason medical care has improved leaps and bounds in the past few decades. Without these carefully-designed tests for new drugs, procedures or devices, treatments for diseases would not progress. These studies should be viewed as opportunities, although some people may view them negatively. "We need to change the view from researching on people to providing opportunities for people to participate in research," said Dr. Neal Thomas, associate dean of clinical research at Penn State College of Medicine. "Clinical research is necessary to advance medical care and is all about trying to further discoveries to find the best cure for a diseases." Here is what the public should know about clinical studies:

Volunteers do not have to have a specific disease. "You don't have to be sick to be in a clinical research study," said Terry Novchich, director of Penn State Hershey's Clinical Trials Office. "We look for healthy volunteers for various studies depending on where we are in the development stage of that drug." For example, Novchich said a new drug may be given to healthy volunteers before it's given to individuals who have that particular disease to test their reactions, or someone healthy could be studied to compare to someone with a disease.

Clinical studies offer crucial access for patients to cutting edge research. In addition to providing scientists with information, clinical research studies often allow patients at academic medical centers like Penn State Hershey access to new and developing therapies that are not otherwise available. "A small percentage of the patients in the United States are treated at places like Penn State Hershey," Thomas said. "A lot of things that we do here are not offered at places that are not academic and don't have an active research program."

Not all studies are the same. Sometimes studies involve a medication, but others involve a device or new therapy. Some may be merely observational. "We do a lot of research here where the patient never receives anything," Thomas said. "They either just give information or they give samples of tissue or blood that allow scientists to help discover why things happen and then try to target therapies to that specific reason."
A lot of the research studies conducted at the college are not trials at all but studies that lead to discovery.

There's a reason for the experiments. People may fear they or their loved one will be "experimented on." Novchich and Thomas often hear potential study participants or their parents say they don't want to be a 'guinea pig.' "Part of our job is to explain that it's not experimenting on someone just to experiment. It really is trying to find the best possible treatment for their specific disease," Thomas said. At a teaching hospital, each case is looked at as a learning opportunity to advance treatment and care for the next patient. "A lot of people say even if this won't help my child, if it could help the next generation of children that come through with this problem, then it's worth it."

Safety of participants is paramount. According to Novchich, an independent institutional review board (IRB) ensures human subject protection during all studies. Patients always must consent to being part of a study, a process that is monitored locally by the Penn State Hershey IRB and overseen by federal regulations. The potential risks and the benefits are outlined for each volunteer during a comprehensive consent process by members of the study team prior to participating in the research study. Additionally, before a drug can be tested on humans, it often goes through years of development and any studies have to be approved by the Food and Drug Administration. "They can be assured that the research is being done to answer an important scientific question and not being done just because we want to do research," Thomas said. "The overarching goal is to improve the care of the patients that we treat, whether that's the individual patient who is recruited for the research study or future patients with the same disease process."