WE-HEAL
THE WOUND ETIOLOGY AND HEALING STUDY

Why is the WE-HEAL Study being done?

Patients are seen every day in the Center for Wound Healing with wounds and ulcers that will not heal. The Wound Etiology and Healing study or WE-HEAL study has been developed to help researchers study the reasons why some patients heal quickly and others have problems healing wounds. This research will help doctors to better understand and treat certain diseases in the future.

Who is being asked to participate in the WE-HEAL Study?

All patients seen at the Georgetown University Hospital in the Center for Wound Healing with an open wound are being asked whether they would be willing to participate in this study.

What is involved in the WE-HEAL Study?

If you agree to participate the WE-HEAL researchers will arrange the following:

- Recording of wound and health information in the WE-HEAL database
- Retention of the following samples for use in research:
  - Tissue left over after surgery
  - Wound fluid that would otherwise be discarded
  - Left over blood/ serum samples

In many hospitals, after a diagnosis has been made, excess blood, fluid and tissue samples are thrown away. However, researchers recognize these specimens can be useful in understanding why some patients heal quickly and others heal slowly. We have developed the WE-HEAL study to allow consenting patients to donate their left over samples to our human tissue bank and database so that they may be used for research purposes instead of being discarded.

The WE-HEAL Study requires no additional medical procedures or time commitment from participants. The tissue, wound fluid, and blood samples are collected only after your doctor has ordered them as part of your routine medical care. The samples will always be used for diagnosis purposes first. If samples remain after diagnosis, and you have agreed to release them, then they can be donated to the WE-HEAL study for research. Participants can choose to only participate in part of the study by choosing what they wish to donate when signing the consent form.
What happens to my tissue and blood samples if I do not participate?

During any surgery, tissue samples removed for treatment and diagnostic purposes are sent to the pathology laboratory, where a trained doctor (a pathologist) looks at your tissue with a microscope in order to help your doctors understand what is causing your wound. After a diagnosis is made, the microscope slides are saved. Often, a piece of your tissue is also saved in case it is needed for more tests. Samples may include cells, blood, bodily fluids, cartilage, muscle, or any part of any organ that is removed during surgery.

Other samples collected during routine clinical care include blood samples and fluid samples from vacuum devices used to suck excess fluid out of wounds after surgery. Left over blood samples and fluid collected in wound vacuum devices are usually discarded after testing.

What is the Human Tissue Bank?

The Georgetown University Hospital Human Tissue Bank is a storage facility that includes computer databases, freezer storage, and cabinets to preserve tissue and other medical samples. All samples and health information will be coded with a unique identifier which will allow the samples to be linked to data from health records in the WE-HEAL database, but will not allow researchers to otherwise link samples back to individual patients.

What type of Research will be done with my samples?

Many different kinds of research use tissue and health information so there is no way to tell you exactly what research will be done using the samples and health information you donate. Some studies may involve the development of new tests to find diseases; others may focus on cures for diseases. In some cases, the research may help to develop new products such as tests and drugs that may have commercial value. The research may look at different parts of your tissue and the cells that make up the tissue.

- The researchers may implant your tissue onto an experimental animal to study wounds in-depth.
- The researchers may do a number of tests on your tissue, including genetic testing to study how diseases are passed on in families or to understand the role that genes play in disease.
- The investigators may study genetic information that may predict whether a person will be susceptible to diseases like cancer or autoimmune diseases.
- Research using tissue can also answer other health questions and may focus on the causes of diseases like autoimmune diseases, cancer, diabetes or heart disease.

Participants will never find out the results of research performed on the samples donated. Materials obtained from you in the WE-HEAL study will only be used in research and will not be sold. The research
may help to develop new products in the future with commercial value but you will not be provided with any financial compensation should this occur.

**Why participate in the WE-HEAL Study?**

- There is no additional time commitment from you.
- Samples are only obtained during routine medical procedures as deemed necessary by your doctor and only samples that would otherwise be discarded will be donated.
- With your help new products, tests, and discoveries may be found.
- Information gained from your participation will help researchers and doctors better understand how to prevent and treat certain diseases in the future.

**Links**

**Georgetown Hospital Center for Wound Healing**
[http://www.georgetownuniversityhospital.org/body_dept_home.cfm?id=513](http://www.georgetownuniversityhospital.org/body_dept_home.cfm?id=513)

**Victoria Shanmugam, MD**
[http://georgetownuniversityhospital.org/body_fw.cfm?id=8&action=detail&ref=3310](http://georgetownuniversityhospital.org/body_fw.cfm?id=8&action=detail&ref=3310)

**Publications**

**How do I contact the WE-HEAL Study?**

If you wish to contact the WE-HEAL Study for further information, please contact:

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