

# Research Study Assessing New Device for Life-Threatening Bleeding

The University of Cincinnati's Department of Surgery, Division of Trauma and Critical Care in collaboration with the Department of Emergency Medicine is part of a national study called REVIVE sponsored by Arsenal Medical, Inc. and funded by the Department of Defense. REVIVE is testing whether people who have life-threatening abdominal bleeding improve when a new device called ResQFoam is used. Due to the emergent nature of the medical condition of the subjects in this study, the U.S. Food and Drug Administration (FDA) has granted this research study an exception from informed consent (in accordance with Federal Regulations under 21 CFR 50.24). We know you may have concerns or questions about this study and so we have provided answers to some frequently asked questions below. Please feel free to ask any others you may have.

## What does REVIVE stand for?

REVIVE stands for Reducing Exsanguination Via In-Vivo Expandable Foam.

## What is the REVIVE study?

REVIVE is a multi-center study taking place at Level 1 trauma centers across North America. The purpose of the study is to determine whether a new device called ResQFoam improves outcomes of patients with life-threatening abdominal bleeding.

## Why is the REVIVE study important?

The knowledge gained from the REVIVE study will allow us to study a potentially lifesaving device in trauma patients, helping us determine if the study device improves patient outcomes and decreases mortality.

## What is a research study?

A research study (sometimes called "medical research", "clinical research study" or "clinical trial") is a carefully planned test to learn about health, diseases, medicines and new treatments. Research studies contribute important information to improve healthcare. Without research, doctors cannot know how best to treat adults and children.

## What is trauma?

Trauma is the leading cause of death in people under the age of 45 and refers to "a body wound or shock produced by sudden physical injury, as from violence or accidents". People who have suffered trauma may need specialized care, including emergency treatment to stop internal bleeding.

## Is ResQFoam safe?

ResQFoam has been extensively tested in short- and long-term animal studies. These studies indicate that ResQFoam is a safe and life-saving device in animals. ResQFoam has not been tested in humans.

## How are patients selected for this study?

After a patient is brought to the emergency department, the trauma physician on call will examine and review information about the patient to determine whether he or she is eligible to be enrolled in this study. This information includes blood pressure, ultrasound, and a variety of other measurements to support the physician's judgment.

Any person 18 years or older may be eligible to participate in REVIVE if:

- Have an emergent and confirmed hemorrhage in the abdomen that results in advanced hemorrhagic shock
- Receive an emergent laparotomy procedure

## What does "exception from informed consent" mean?

The consent process is when a person is asked for their permission to participate in a research study. Normally, before you decide whether or not to participate, you must be fully "informed" of what is involved in the study. Some of the information provided in the informed consent process includes: participation is voluntary, what the researchers want to accomplish, what will be done during the study, how long it will take, the risks and benefits of the study and other treatments available. However, patients in the REVIVE study may be unable to consent due to their emergent condition. Because of this, they may be entered into the study without providing informed consent. The trauma physician taking care of the patient will determine whether or not they are eligible to participate. Every attempt will be made to obtain consent from the legal representative and/or family member so that they may decide if the patient joins, continues or refuses participation in the study. Enrolled patients will be informed of the study as soon as it is possible.

## How can I "opt-out" of this study?

Members of the community may opt-out if they do not wish to be in the study. A colored, plastic bracelet with the word "RESQFOAM Ø" on it will be available for those who do not want to participate in this study. If a patient arrives to the emergency department with this bracelet on, they will not be screened or enrolled in REVIVE. If you would like to opt-out of the study, please call the number listed below.

## How can I find out more about the REVIVE study?

For more information, call **513-558-6332** or email **REVIVE@uc.edu**