

**ACCUTE Study****Principal Investigator:** Joseph Rappold M.D.**Electronic Consent Guidelines (MyTrus)****Study Title: ACCUTE (AB103 Clinical Composite Endpoint Study in Necrotizing Soft Tissue Infections).**

"Hello, my name is (*research personnel*). I am calling from *Maine Medical Center* about a research study. I am trying to reach (*name of LAR*)? I was given your phone number from (*contact source*), is this a good time to talk? I expect this call will take about (*30 minutes*)".

- **If LAR is not available, arrange to leave a message, or ask for a good time to call back.**

"I am calling because your friend/relative (*name of patient*) may be eligible to participate in a research study and I would like to ask your permission for (*name of patient*) to participate in this clinical trial. He/she is eligible because they are being admitted to the trauma/surgical service at Maine Medical Center and they are scheduled for an urgent surgical debridement. A debridement is the removal of dead, damaged, infected tissue that MAY be a necrotizing soft tissue infection. This is a rare but severe bacterial infection that can destroy the muscles, skin and underlying tissue. Necrotizing refers to something that causes tissue death. We are studying the effects of a drug called AB103. The purpose of this research study is to learn more about AB103, to see if it helps patients with necrotizing soft tissue infections. In order for (*patient name*) to participate in this study, we must obtain informed consent. Maine Medical Center is using a web based program called MyTrus for this process. This will allow you to review and sign the consent form electronically from a computer, smart phone or tablet. There are 5 steps required for this process:

1. First, a photo ID must be confirmed by scanning, fax or smartphone  
**IMPORTANT: MUST OCCUR BEFORE SENDING ACCESS CODE TO LAR,**
2. Once valid ID is confirmed, I will provide you with a web address and access code in order to access the MyTrus site.
3. You must register on MyTrus by creating an account with unique user name and password.
4. You must read details about participating in the study, I will remain on the line with you while you review the consent to answer any questions that you may have.
5. Finally, you will electronically sign the consent form.

May I send you the web address and access code?"

- **IF LAR DECLINES RECEIPT OF CONSENT DURING TELEPHONE CALL-DISCONTINUE, THE PATIENT IS NO LONGER ELIGIBLE.**
- **Stay on the phone with LAR while the consent form is being signed.**
- **Inform LAR using their unique user name and password combination, they will be able to log into the portal at any time to print a copy of the informed consent document with appropriate timestamps.**
- **Once consent has been obtained:**
  1. **A separate consent process enrollment note needs to be documented in EPIC.**
  2. **Print a copy of the consent for the patient's chart**
- **Subject MUST be re-consented if/when they are able to do so.**