Tip Sheet #1

How to Open CANVAS

In order to open this study at your site, please complete the following steps:

- ✓ **Notify Alliance Foundation Trials (AFT) that your site is interested in opening the CANVAS Trial (AFT-28) by emailing CANVAS@AllianceFoundationTrials.org.**

- ✓ **AFT will send you a start-up package that will include information on the following:**
  - **Protocol and Protocol Signature page**
  - **Model Informed Consent Form**
  - **FDA Form 1572 template**
  - **REDCap user agreement (used for all study Case Report Forms)**
  - **Information about your Site Zone account (used for regulatory documents)**
  - **Links to the virtual Site Initiation Visit (SIV) video**

- ✓ **Obtain IRB Approval. This can be done in one of two ways:**
  - **Option 1: Use the Central IRB [Quorum] as your site's IRB of record**
  - **Option 2: Submit this protocol to your site's local IRB**

- ✓ **Upload all of the required regulatory forms into your Site Zone account**

- ✓ **Once all requirements above have been met, your site will receive a Site Activation Memo. Your site cannot consent and enroll patients into the CANVAS (AFT-28) study without this memo.**

If you have questions about this process, please contact CANVAS@AllianceFoundationTrials.org.

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