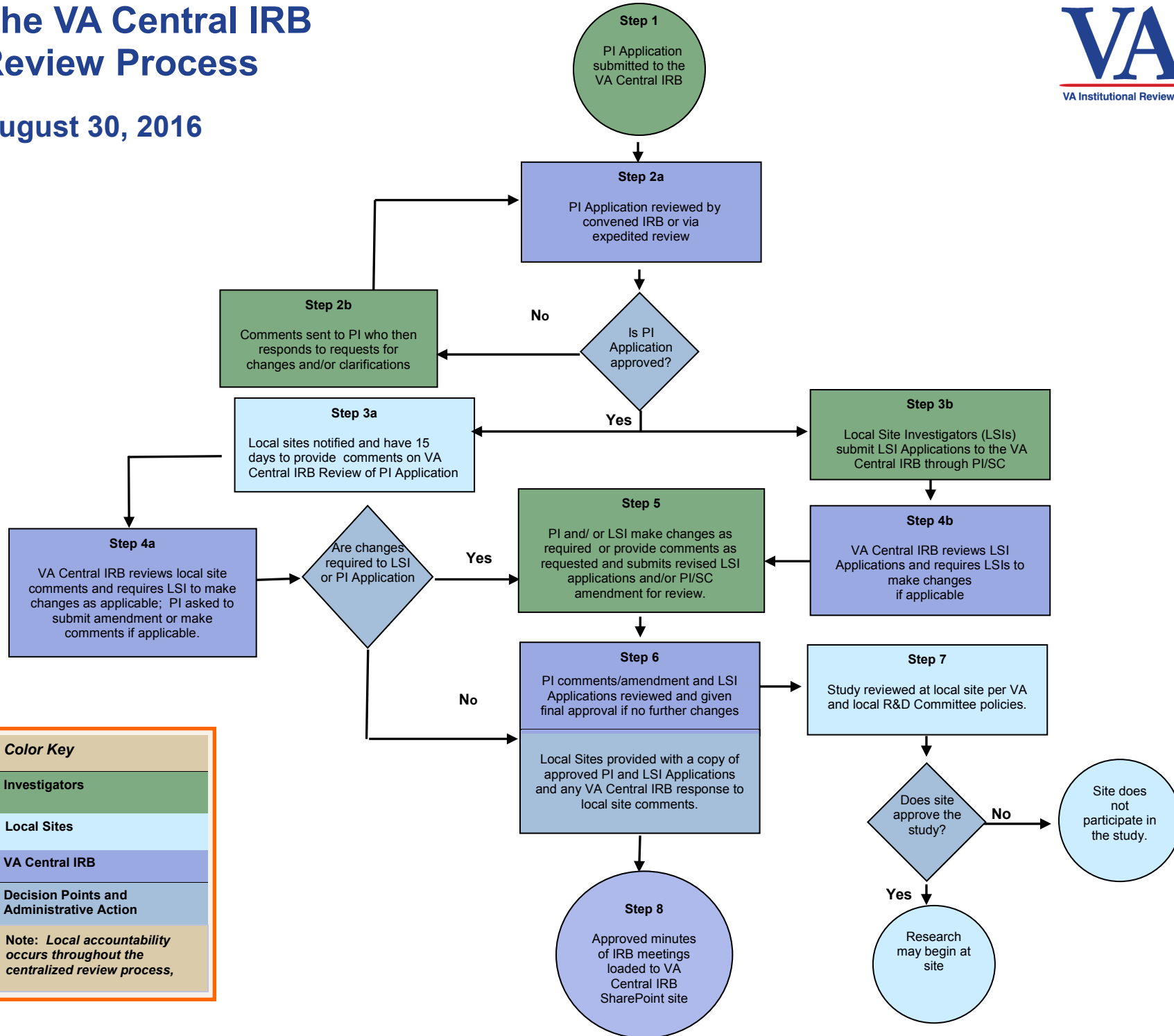


The VA Central IRB Review Process

August 30, 2016



Color Key
Investigators
Local Sites
VA Central IRB
Decision Points and Administrative Action
Note: Local accountability occurs throughout the centralized review process,

Key Steps in the VA Central IRB Review Process

August 30, 2016



Note: A study cannot begin until it is approved by the VA Central IRB and the local VA facility has complied with the requirements of VHA Handbook 1200.01.

Step 1. The Principal Investigator of a multi-site study, after review concurrence of the VA Central IRB Administrator, submits a PI/SC Application with all applicable documents to the VA Central IRB.

The PI Application includes the following as applicable:

- Co-PI/SC and Coordinating Center Supplements
- Model Informed Consent Form and HIPAA Authorization
- Waiver Requests (HIPAA/Informed Consent)
- Vulnerable Population Supplements
- CVs and Conflict of Interest Statements for PI
- Model Recruitment Materials
- Protocol (*VA Central IRB has optional template*)
- Other documents as per study design

Step 2. Review of the PI Application by the VA Central IRB at a convened meeting or by expedited review; if approved, the PI and participating local sites are informed.

Step 3. This step consists of 2 parts that take place simultaneously:

Step 3a. Local Site Review

Local sites have 15 calendar days to review the VA Central IRB approved PI/SC Application and submit comments to the VA Central IRB.

Step 3b. Local Site Investigator (LSI) Applications

LSIs may begin to submit LSI Applications to the VA Central IRB.

LSI Applications include the following as applicable:

- Local ACOS/R&D Concurrence
- Informed Consent Form/HIPAA Authorization
- CVs and COI Statements for investigators
- Recruitment materials to be used at local site
- Other documents as required per protocol

Step 4. VA Central IRB reviews Local Site comments and LSI Applications

Step 4a. Review of submitted local site comments; VA Central IRB may:

- Refer comments to PI/SC
- Require changes in PI/SC and/or LSI Applications
- Take no action

Step 4b. Review LSI Applications and include any change from step 4a if applicable.

Step 5. PI and/or LSI submits changes or provides comments as applicable. PI/SC may submit an amendment if required or desired in order to respond to VA Central IRB comments.

Step 6. VA Central IRB approves LSI Applications and all relevant materials sent to the Local Site, to include the approved PI/SC and the relevant LSI Application, as well as the VA Central IRB response to any local site comments.

Step 7. The Local Site reviews the IRB-approved package in accordance with its local R&D Committee policies and determines whether to approve the study to be conducted at the local site and whether all requirements to begin the study at the site have been met.

Step 8. Upon approval at a subsequent convened meeting and the signature of the VA Central IRB Co-Chairs, VA Central IRB meeting minutes are uploaded onto the VA Central IRB Share-Point site for access by Local Site Liaisons.