

# Key Steps in the VA Central IRB Review Process



February 2011

**Step 1.** The Principal Investigator of a VA Office of Research and Development (ORD)-funded study submits a PI Application with all applicable documents to the VA Central IRB. The PI

Application includes the following as applicable:

- Co-PI 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
- 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 or approved contingent upon minor modifications, 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 30 days to review the VA Central IRB approved PI 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:

- Informed Consent Form
- CVs and Conflict of Interest Statements for LSIs
- Recruitment materials to be used at local site
- Other documents as applicable

**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
- Require changes in PI and/or LSI Applications
- Take no action

**Step 4b.** Review LSI Applications and include any changes from step 4a.

**Step 5.** PI and/or LSI submits changes or provides comments.

**Step 6.** VA Central IRB makes final approval decision and all relevant materials sent to the Local Site, to include the approved PI and the relevant LSI Application and the VA Central IRB response to any local site comments, so the Local Site can determine whether or not it will participate in the project.

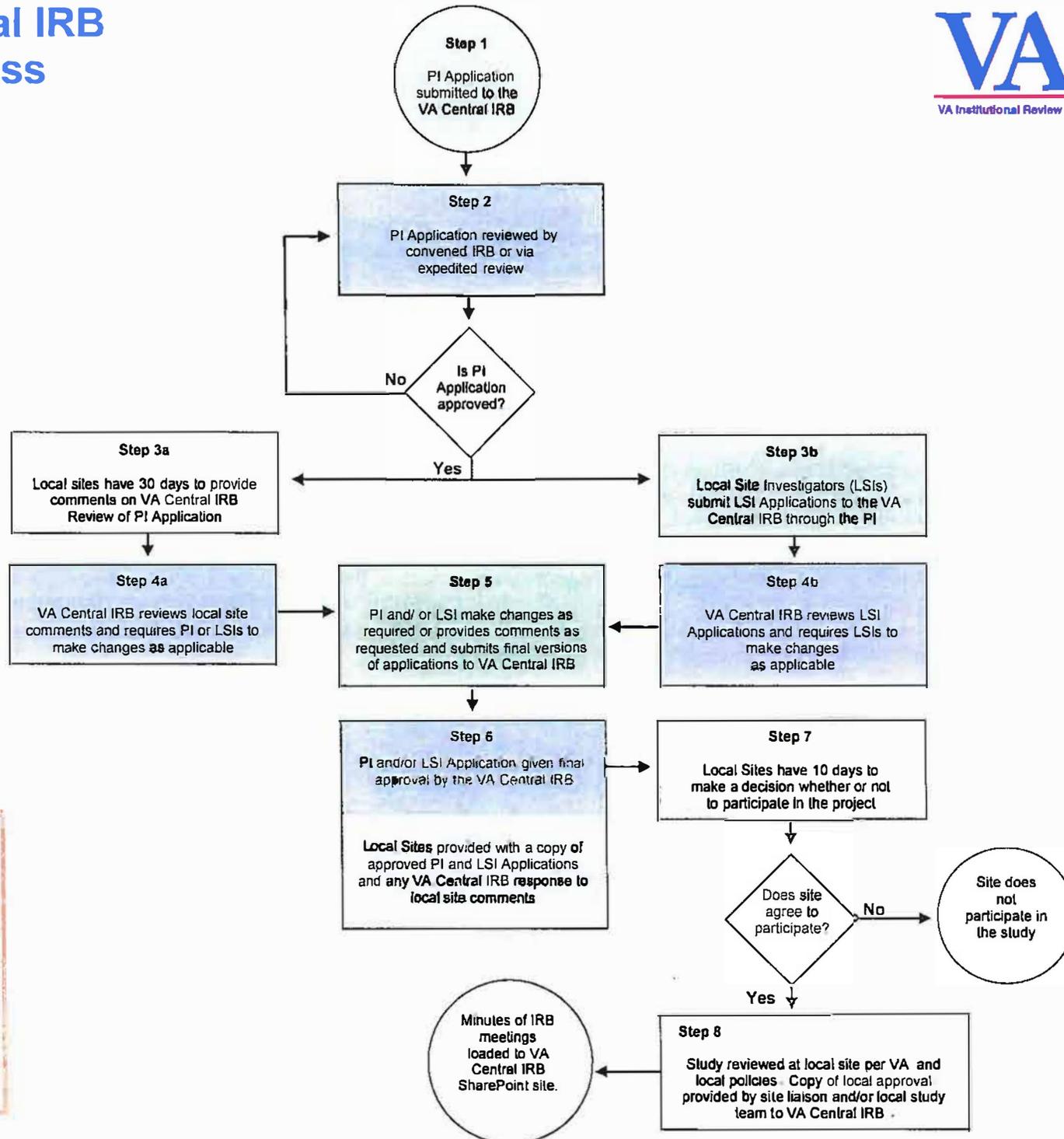
**Step 7.** The Local Site has 10 days to decide whether or not it will participate in the study and to submit a participation decision to the VA Central IRB.

**Step 8.** The Local Site processes the study in accordance with VA and local requirements. Meeting minutes are loaded onto the VA Central IRB SharePoint site for access by local site Liaisons.

*Note:* A VA study cannot begin at a given local VA facility until the PI and LSI applications have been approved by the VA Central IRB, and the local VA facility has complied with the requirements of VHA Handbook 1200.01.

# The VA Central IRB Review Process

December 2011



<b>Color Key</b>
Investigators
Local Sites
VA Central IRB
Decision Points and Administrative Action
<i>Note: Local accountability occurs throughout the centralized review process.</i>