Pending or Deferred?

ICD = Informed Consent Document  
LAR = Legally Authorized Representative

Does IRB request substantive modification or clarification to the protocol or ICDs that is directly relevant to any of the following criteria from 45 CFR 46.111 (DHHS) and 21 CFR 56.111 (FDA)? If yes, check all that apply:

- Risks must be minimized
- Risks must be reasonable in relation to benefits, if any, and importance of knowledge to be gained
- Selection of subjects must be equitable
- IC must be sought from each subject/LAR or waived
- IC must be documented or waiver granted
- Data will be monitored if appropriate for subject safety
- Privacy & confidentiality must be adequately safeguarded

OR, if appropriate to the study, directly relevant to the following additional criteria from 45 CFR 46.111 and 21 CFR 56.111?

- Additional safeguards for subjects who are vulnerable to coercion or undue influence (vulnerable populations) must be adequate

If any box is checked, go to “Yes”  
If no boxes are checked, go to “No”

Are the changes required limited to:

- Minor revisions to protocol or ICDs?
- Simple concurrence with a clearly stated IRB assumption?
- Submission of a missing ancillary approval?