

Tools for QA/QI

Regulatory Documentation

No Action Indicated

Voluntary Action Indicated

Directed Action Indicated

Is the most recent approved protocol on file? No Yes

Are there previous versions of the protocol? No Yes

If yes, are all previous versions on file? List below.

Is this an FDA regulated study? No Yes

Is there a signed 1572 on file? No Yes

Is there a signed 1571 on file (when PI is IND sponsor)? No Yes

Are there 1571s on file for the following:

Original No Yes

All amendments No Yes

Annual Reports No Yes

Is there a subject enrollment log? No Yes

If yes, is the enrollment log complete? No Yes

Is/will the site (be) monitored? No Yes

How often? _____

Is there a monitoring log? No Yes

If yes, is the log complete? No Yes

Is there a monitoring plan in the approved protocol? No Yes

If yes, has plan been followed? No Yes

Is there a DSMB for this study? No Yes

If yes, is a DSMB report or indication of DSMB review and/or recommendations on file? No Yes

Have all KSP completed human subjects training? No Yes

Is there an investigational drug or device? (Drug Device) No Yes

If yes, is product information on file? No Yes

Are lab tests required? No Yes

Is the lab internal or external/commercial? Int Ext

Are normal lab values on file? No Yes

Is lab certification on file? No Yes

Is the lab director's CV on file? No Yes