

Idiopathic Pulmonary Fibrosis Job Exposure Study Site File

Contents

The local site file contains:

1. site delegation log (statement of activities document may be used)
2. CVs and GCP certificates for research personnel listed in the delegation log
3. study approvals
4. study protocol
5. study standard operating procedure
6. study recruitment bundle (participant information sheet, consent form, job history sheet, case report form)
7. study training log (ipfjes-tlog.docx)
8. participation (screening) log (ipfjes-plog.xlsx)
9. sample log (ipfjes-slog.xlsx)
10. adverse event log (ipfjes-alog.xlsx)
11. general notes (ipfjes-general-notes.docx)
12. signed consent forms

It is acceptable for some or all of these to be stored electronically.