Essential Documentation Binder – Instructions

Binder

Dividers (5 packs of 8 tab dividers)

Printed Divider Tabs. There are 2 different sheets, A and B. A is the first sheet.

*Patient Binder Contents Sheet

Forms for Patient Binders:

*Informed Consent Checklist
*Investigational Product Accountability Log
*Documentation of Subject Unblinding
*Adverse Event Log

Printed Section Descriptions

Forms for Binder Sections:

**Screening and Enrollment Log
**Delegation of Responsibility Log
**Biological Specimen Tracking Log (De-Identified)
**Biological Specimen Tracking Log (Identifiable)
**Protocol Deviations/Violations Log.
**Unanticipated Problems Log

1. Get all the supplies and print everything listed above. All the documents are in the following location: O:\IRB-2\Quality Improvement\Essential Documents\Website Documents. NOTE: All of the most recent documents are now in one folder: Website Documents. Print the most recent Word version of each document.

2. 3 hole punch the printed documents.

3. The 5 patient documents* go first in the binder.

4. Put the printed divider tabs in the dividers. There are 2 different sheets, A and B. A is the first sheet. Keep the dividers in the same order as printed.
5. Put the dividers in the binder, inserting the section descriptions behind the matching dividers. There are a few sections (e.g. correspondence) that don’t have section description papers. While doing the dividers and descriptions, insert the 4 binder section documents** behind the matching dividers. Put sticky notes on the tops of the 4 binder section documents** so the study teams know where they are. When you get to the last full set of dividers, try to form a full set of 8 out of the leftovers.

6. Order more supplies when they get low.