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What is a RegulatoryBinder?

- Paperwork required to keep updated on studies where patients are being consented or animals used for research.
- Can be contained within paper or electronic format.
- Examples: IRB documentation, training of staff, etc…….

Why Bother?

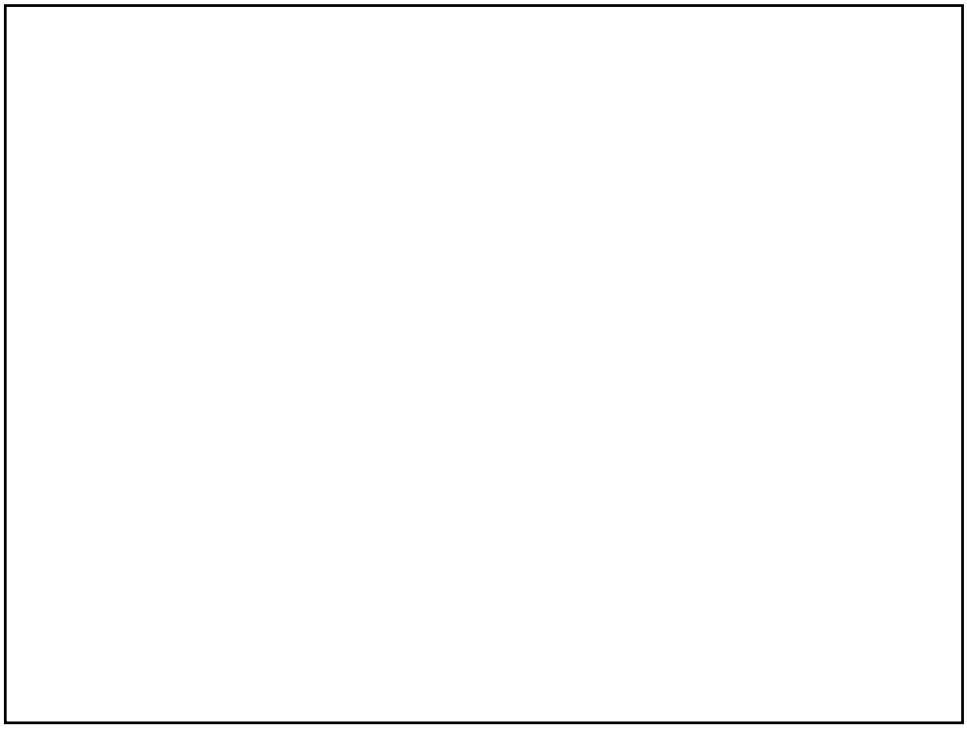
- IRB requirement. If audited—need this information to be organized and accessible.
- Excellent way to organize study, reports, procedures, consents etc.

Binder: Table

Delegation of Responsibility, CREC, COI, UH Credentials Log

Print Name	Signature	Title	Responsibilities							

3. Screening & Enrollment



6. Investigatory, IRB Brochures

- IRB approved study brochures/Information sheets

7. Laboratory Certification

- Certification forms
- Normal lab values for each lab

Or Box.Com

5HJXODWRU\ %LQGHU 7HPSODWH
7DEOH RI &RQWHQWV
'RXJODV /LSVRQ

,5% 3URWRFROV $PHQGPHQWV
D $GGHQGD
E 2UJLQDO,V%R[RQEP$SSURYDO
F)250 ,5% SURWRFRO,V%&KDQJHV\WSHUUXPHQWV LQV
DPHQGPHQWV LQIRUPHG FRQVHQW YHUVLRQV
G)250 ± 3URWRFRO 'HYLDWLRQ /RJ

&9V /LFHQVXUH H6LJQDWXUHV I 'RS7RQDVLQEOLQJ/R\J/R
D &9V XSGDWHG VLJQHG GDWHG HYHU\ \HDUV
E 3URIHVVLRQDO OLFHQVHV
F 6LJQDWXUHV HOHFWURQLF
G)250 'HOHJDWLRQ/LOWHVSRQVLEOH&RQ 8UDW &5
&UHGHQWLDOV
H)250 7UDLQLQJ ORJ

6FUHHQLQJ (QUROOPHQW /RJV

Department	What to maintain	How	How long
DHHS (Department of Health and			

ICH GCP GCP E6 4.9.5, 5.5.11 and 5.5.12	x Trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by applicable regulatory requirement (s).	x Recorded, handled, and stored in a w that allows accurate reporting, interpretation, and verification	x Should take measures to prevent accidental or premature destruction of these documents x 2 years after last approval of marketing application a until there are no pending or contemplated marketing applications OR x At least 2 years have elapsed since the formal discontinuation of clinical development of investigational product x Retained longer if required by applicable regulatory requirements or by agreement wu Sponsor requirem

x Records associated with a

UHCMC IRB