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Quick Links

UHHS

Center For Clinical Research

Office of Research Compliance
(Coming Soon!)

UHC IRB

UHC Grants and Contracts

Quick Question:

What is the most common missing item from the Regulatory Binder?
Let us know!

Contact Us

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Lakeside 1400
11100 Euclid Avenue
Cleveland, Ohio 44106
216.844.5576
E-mail us!

Regulatory Binder: Definition and Content

A Regulatory Binder is a binder containing protocol specific information such as IRB documentation, submissions and approvals, Data and Safety Monitoring Board Reports, and sponsor correspondence. All IRB approved studies, including those which are not industry sponsored, should have a Regulatory Binder in order to maintain regulatory compliance and adherence to high standards of research conduct. Specifically, the Regulatory Binder should contain:

1. Original protocol and amended versions;
2. Signed and dated CV's of investigators and all study staff;
3. Pre-screening and enrollment logs and staff signature logs;
4. All IRB correspondence including submissions, approvals, and written correspondence;
5. Original copies of all IRB approved versions of Informed Consent documents (original through current);
6. Investigatory Brochure/ Device Manual / Package Insert (most recent version);
7. Laboratory certification (e.g., CLIA, CAP) and normal laboratory/reference values;
8. Drug or device accountability records including dispensing log, shipping and receiving records;
9. Blank set of Case Report Forms / data collection sheets / IRB-approved questionnaires;
10. FDA required forms (1571 and / or 1572, Financial Disclosure FDA 3455) and correspondence;
11. NIH / Sponsor correspondence; and
12. Data and Safety Monitoring Board Reports.

Many industry-sponsored studies are provided with a binder with pre-labeled tabs indicating the content of the binder. Study staff for Investigator initiated or non-sponsored projects should create a Regulatory Binder to maintain their official records. The binders should be kept in a secure area. If you would like assistance organizing your Regulatory Binder, or would like a review of your Regulatory Binder to ensure proper content, please contact the [Office of Research Compliance](#). The UHC Research Compliance team will review your binder and provide assistance and feedback as necessary.

Helpful Tip: Human Tissues and Histology Services

The Human Tissue Procurement Facility (HTPF) and its Histology component are available to researchers to prospectively collect discarded human tissue samples according to individual requirements, and to offer custom histology services for both human and animal tissues. If you are interested in learning more about these services, please visit our Webpage at: <http://cancer.cwru.edu/>, click on Shared Resources (located in the bar under the Title: CASE Comprehensive Cancer Center), and then Tissue Procurement & Histology. Please note that these facilities have recently been combined and Dr. Greg MacLennan is the Director of the new Core. The main HTPF Website is: <http://www.cwru.edu/med/pathology/tissue>. Please contact Bob Wyza, Director of Operations, at 216-844-5389 (Robert.Wyza@case.edu) to discuss your tissue procurement needs. Nancy Edgehouse is Manager of the histology services and can be reached at 216-368-1388 (Nancy.Edgehouse@case.edu).