

# HUMAN SUBJECTS RESEARCH REGULATORY BINDER

PROJECT TITLE (example): **"An Example of the Regulatory Binder for Non-Medical Human Subjects Research"**

Principal Investigator:

Individuals Authorized by the IRB  
to Conduct Research and Obtain  
Informed Consent:

**ALL RECORDS ARE UNIVERSITY PROPERTY. THEY MUST BE KEPT WITHIN THE UNIVERSITY FACILITIES.**

**Affix below the label provided by the Office of Research Compliance. The label provides the start and end of the project.**

**If research is to continue past the expiration date, the research needs to be reviewed as a continuing review by the IRB for approval for another specified period.**

**If the project has expired, new submission is required for the initiation or continuation of the project.**

## Table of contents

**Include ONLY final IRB approved versions of each of the documents listed below. File these documents in the order that is listed below.**

1. Project Submission Transmittal Form
2. Conflict of Interest Form
3. Human Protocol Processing Form
4. Protocol Summary Outline Form
5. Collaborative or site agreements (letters from schools/other facilities) and approval letters from outside IRBs if the project has been reviewed by another IRB
6. Research Proposal/Narrative Portions of the grant application such as the hypothesis, purpose, specific aims, experimental methods and analysis or Masters or Doctoral research proposal
7. Data collection instrument (generally surveys and analysis of data require this instrument)
8. An original copy of the of the approved and stamped Informed Consent Form
9. approved and stamped Assent Form (if children are recruited)
10. Consent Waiver (if applicable)
11. Internal Indemnification form
12. HIPPA Waiver of Authorization form (if required)
13. Copies of signed consent forms with original signatures from the subject. (Instruction: Make two copies of the approved consent form for subjects consent and signature. Provide one signed copy to the subject and retain the other signed copy and file in this section)
14. Signed copy of the assent form (follow the same instruction for obtaining and filing consent forms)
15. Copies of data collection /survey instruments which has been completed by research subjects. If this is a large file, these instruments can be kept in a different file, but document where those records have been kept.
16. If subjects are audio- or videotaped keep information on where those tapes have been securely kept
17. Amendments
18. Adverse Events
19. Publication
20. University Guidelines. The Policies and Procedures Manual for medical and non-medical IRBs must be kept in this section. If your project is non-medical, down load the non-medical guidelines or if it is medical, down load the medical guidelines from the Office of Research Website [www.research.drexel.edu](http://www.research.drexel.edu).