

KUSM-W Human Subjects Committee 2 Submission Requirements

All IRB/HSC forms can be found at: <http://wichita.kumc.edu/compliance/forms.html>

Please collate material in order listed if more than 1 copy is required

Please do not staple any portion of the original submission

Copies may be stapled

FULL COMMITTEE NEW	Original	No. of Copies
Full Committee Application	1 Signed Original	12 Copies
Scientific Merit Review Checklist	1 Signed Original	12 Copies
Consent Form(s)	1 Original	12 Copies
Protocol	1 Original	2 Copies
Sponsor's Consent Template (if applicable)	1 Original	2 Copies
Investigator's Brochure (if applicable)	1 Original	2 Copies
Advertisements, Flyers (if applicable)	1 Original	2 Copies
Grant Application (if applicable)	1 Original	2 Copies

FULL COMMITTEE AMENDMENT	Original	No. of Copies
Request for Amendment Form	1 Signed Original	12 Copies
Revised Consent Form(s)	1 Original	12 Copies
Revised Protocol	1 Original	2 Copies
Revised Investigator's Brochure (if applicable)	1 Original	2 Copies
Other Revised Documents	1 Original	2 Copies

NEW EXPEDITED STUDY	Original	
Expedited Application	1 Signed Original	
Scientific Merit Review Checklist	1 Signed Original	
Consent Form(s)	1 Original	
Protocol	1 Original	
Data Collection Sheet, Survey Instrument, etc	1 Original	
Grant Application (if applicable)	1 Original	

NEW EXEMPT	Original	
Exempt Application	1 Signed Original	
Protocol	1 Original	
HIPAA Waiver (for retrospective chart reviews)	1 Signed Original	
Data collection sheet	1 Original	

RECERTIFICATION/CONTINUING REVIEWS	Original	No. of Copies
Continuing Review Form	1 Signed Original	12 Copies
Current stamped consent form(s)	1 Original	12 Copies
Clean copy of consent form(s) – not stamped	1 Original	12 Copies
Protocol Summary	1 Original	12 Copies
Protocol	1 Original	2 Copies
Other documents (if applicable) – DSMB report, FDA report, etc.	1 Original	2 Copies

MINOR, EXPEDITED AMENDMENT REQUESTS		
Request for Amendment Form	1 Signed Original	
Revised Protocol (if applicable)	1 Original	
Revised Consent (if applicable)	1 Original	
Other amended documents	1 Original	

PROBLEM REPORTS, CLOSURES

Corresponding HSC Form	1 Signed Original	
Supporting documents	1 Original	

RESPONSE TO PROVISOS**Original**

Letter/Memo outlining changes	1 Signed Original	
Revised Protocol	1 Original	
Revised Consent Form(s) with changes highlighted	1 Original	
Clean copy of revised consent form(s)	1 Original	
Other revised documents	1 Original	