

IRB *NEW* Application Submission Checklist

CHECKLIST for COMPLETE APPLICATION

YES	NO	N/A	
			This is a CHRMC IRB application.
			Have all applicable questions been answered?
			Have all attachments been included?
			Do all research team members have Human Subjects Training?
			Documentation is attached for all Human Subjects Training obtained outside of CHRMC, UW, FHCRC, and CITI.
			Conflict of interest disclosed?
			If the research is funded by a grant, is the grant application attached? <i>If you are attaching the grant application, include the grant face-page.</i> <i>NOTE: In the case of no funding, application may be forwarded to VP for Research for approval (depending on type of study).</i>
			Does the research involve foster children or wards of the state?
			Is a special population involved in the study?
			If special population is involved, is a consultant needed?
			Is CHRMC the coordinating center for this study?

CHECKLIST for COMPLETE CONSENT and ASSENT FORMS

YES	NO	N/A	
			Did you use the CHRMC consent/assent template(s)?
			Have you addressed whether one or two parent signatures are required?

CHECKLIST for NEED OF MATERIAL TRANSFER AGREEMENT

YES	NO	N/A	
			Does the study involve the transfer of materials outside of CHRMC?
			Is the material being transferred to a for-profit entity?

CHECKLIST for HIPAA

YES	NO	N/A	
			Will Private Health Information be shared inside or outside of CHRMC?

ATTACHMENTS CHECKLIST

YES	N/A	
		Section 7 Copy of grant application(s)/funding listed (public, private, non-profit, or corporate)
		Section 8.5 Citation list of all work noted (attach as appendix to application)
		Section 10.6 Letters of cooperation
		Section 11.1 Copies of all recruitment materials (flyers, advertisements, approach letters, brochures, telephone scripts, etc.)
		Section 11.11 HIPAA Authorization Form
		Section 12.1 Flow chart of study procedures
		Section 12.1.B Data collection forms
		Section 12.1.C Copies of surveys and/or questionnaires
		Section 13.3.A Investigator’s Brochure (for investigational drugs) or package inserts
		Section 13.4 Manufacturer’s Notebook (for investigational medical devices)
		Section 19 Appendices for the Pediatric Clinical Research Center
		Research Protocol. Required for multi-center trials, investigator initiated medical research studies, industry sponsored trials, and studies establishing a research repository.

