

**REGULATORY ANALYST - IRB *NEW* Application
PRE-REVIEW 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? If you are attaching the grant application, include the grant face-page.
			If no funding involved, forward application to VP for Research for approval (refer to CHRMC IRB policy #33 to determine type of study requiring this approval).
			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 APPLICATION - REGULATORY COMPLIANCE

YES	NO	N/A	
			PI's responses comply with federal regulations, state law, and CHRMC's policies?
			Are the attachments complete, appropriate and compliant with federal regulations, state law, and CHRMC's policies?
			Management notified if conflict of interest is disclosed.
			If the research is funded by a grant, the grant is reviewed for consistency between grant proposal and IRB application.
			If wards of the state are involved, all application materials will be reviewed for compliance with federal regulations, state law, and CHRMC's policies.
			If special populations – prisoners, pregnant women, fetuses, persons with diminished decision-making capacity - are involved in the study, all application materials will be reviewed for compliance with federal regulations, state law, and CHRMC's policies.

			If CHRMC is the coordinating center for this study, confirm IRB assurances are in place and can accrue.
			Confirm status of biohazards.
			Confirm status of radiation safety.

CHECKLIST - COMPLETE CONSENT FORMS

YES	NO	N/A	
			Was the CHRMC consent template used?
			Was the issue addressed of whether one or two parent signature(s) required?

CHECKLIST for CONSENT FORM - REGULATORY COMPLIANCE

YES	NO	N/A	
			Refer to Informed Consent Checklist (45 CFR 46.116).
			If specimens are identified, is the information regarding destruction and timeframe included in the Consent Form?
			If the patient withdraws, will their specimens be destroyed?

CHECKLIST for COMPLETE ASSENT FORMS

YES	NO	N/A	
			Was the CHRMC assent template used?
			Was the issue addressed of whether one or two parent signature(s) required?

CHECKLIST for ASSENT FORM REGULATORY COMPLIANCE

YES	NO	N/A	
			Refer to Informed Assent Checklist (45 CFR 46.116).

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?
			Does the consent address the sharing of materials outside of CHRMC?

CHECKLIST FOR HIPAA

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

CHECKLIST FOR HIPAA REGULATORY COMPLIANCE

YES	NO	N/A	
			Is HIPAA authorization required?
			Is HIPAA authorization being waived?
			Are all participating sites properly disclosed?
			Are identifiers written on specimens? If so, will specimens be sent to outside labs?
			Is an Oath of Confidentiality needed?
			Do all treatment schedules match up?
			Is there an adequate plan for the destruction of identifiers? If so, what is the time frame?
			Does the consent form disclose how Private Health Information will be accessed and used?

REGULATORY COMPLIANCE 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 multicenter trials, investigator initiated medical research studies, industry sponsored trials, and studies establishing a research repository.
		All attachments will be reviewed for compliance with federal regulations, state law, and CHRMC's policies.

ADMINISTRATIVE TASKS

YES	N/A	
		Compose pre-review memo.
		E-mail pre-review memo to PI.
		Pre-review memo saved to IRB shared drive.
		In the case of no funding, verify VP for Research approval has been received.

ADMINISTRATIVE NOTES
