

SPONSOR SUBMISSION CHECKLIST

Include the following with all submissions:	
	Protocol Information Form
	Billing Information Form
	Copy of Protocol and any applicable amendments
	Copy of proposed informed consent (Note: Be sure consent has a version date. This consent must also be submitted in electronic format to info@libertyirb.com, the Liberty IRB project manager or through the secure portal. Receive your username and password from your project manager.)

For Drug Studies, include the following:	
	Most current version of Investigator Brochure
	FDA Letter granting IND approval

For Device studies, include the following:	
	FDA Letter granting IDE approval; or
	Letter from study sponsor stating why study is non-significant risk; or
	Letter explaining why device is exempt from IDE requirements

For DHHS funded research, include the following with all submissions:	
	The DHHS- approved sample informed consent document (when one exists).
	The complete DHHS-approved protocol (when one exists).
	Any relevant grant applications.

<u>Multi-site studies</u>	
Each Investigator should complete the following forms:	
	Principal Investigator Information Form
	Submission letter signed by Principal Investigator
	Investigator Declaration signed by the PI
	Additional Research location Form (<i>if indicated</i>)
	Current Curriculum Vitae for Principal Investigator (<i>signed and dated</i>)
	Copy of Medical License for Principal Investigator
	Copy of Board Certification (if applicable)

LIBERTY_{IRB}

An Independent Central IRB

	Current Curriculum Vitae for all Sub-Investigators <i>(signed and dated)</i>
	Copy of Medical License for all Sub-Investigators Advertisement Submission Form <i>(if indicated)</i>
	Copy of all advertisements to be used in this study
	Copy of Form 1572 signed by Principal Investigator <i>(Drug study only)</i>