



# LIBERTY IRB

An Independent Central IRB



## Sponsor Submission Checklist

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

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

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

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

<b><u>Multi-site studies</u></b>	
<b>Each Investigator should complete the following forms:</b>	
	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> )



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	Copy of Medical License for Principal Investigator
	Copy of Board Certification (if applicable)
	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>