



INVESTIGATOR SUBMISSION CHECKLIST

INCLUDE THE FOLLOWING WITH ALL SUBMISSIONS:	
	Submission letter signed by Principal Investigator
	Protocol Information Sheet
	Principal Investigator Information Form
	Investigator Declaration signed by the PI
	Additional Research Location Form (<i>if indicated</i>)
	Billing Information Form
	Current Curriculum Vitae for Principal Investigator (<i>signed and dated</i>)
	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
	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)
	Advertisement Submission Form (<i>if indicated</i>)
	Copy of all advertisements to be used in this study
	For DHHS Studies, include the sample approved Informed Consent document, complete DHHS approved protocol, and any relevant grant applications.



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FOR DRUG STUDIES, INCLUDE THE FOLLOWING:	
	Most current version of Investigator Brochure
	Copy of Form 1572 signed by Principal Investigator
	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