

Checklist for IRB Submission and Classification

Submission Requirements: Information that must be submitted before an application can be evaluated

Application form	<input type="checkbox"/> Yes	<input type="checkbox"/> No	All items completed	
Proposal/protocol				
Consent/Assent Form(s)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Unless implied consent	
Data collection instruments	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Survey/interview questions	
Supporting documents				
Institutional approval	<input type="checkbox"/> Yes	<input type="checkbox"/> Not Applicable	<input type="checkbox"/> No	If at another institution
Training certificates	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> No	All investigators & approval advisor

Required Protocol Elements: Characteristics/Procedures that must be described/explained in detail before evaluation by the IRB Office

Population	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Minors/vulnerable populations
Recruitment	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Pressure/concealment
Consent	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Informed/voluntary
Procedures/experiences for subjects	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Informed/voluntary
Data collection	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Sensitive topics
Risk/benefit	<input type="checkbox"/> Yes	<input type="checkbox"/> No	More than minimal risk
Recording	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Written/audio/video/online
Confidentiality	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Identification/storage

Classification Criteria: Criteria used for classification as Exempt, Expedited, or Full Review

Full Review if ANY of the following are present

Risk	<input type="checkbox"/> Yes	<input type="checkbox"/> No	More than minimal risk
Minors	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Any subjects younger than 18
Vulnerable subjects	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Selected from these groups
Pressure or coercion	<input type="checkbox"/> Yes	<input type="checkbox"/> No	In selecting or recruiting subjects
Concealment or deception	<input type="checkbox"/> Yes	<input type="checkbox"/> No	In research procedures
Invasive procedures	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Adequate protection

Expedited Review if ANY of the following are present (and Full Review is not needed)

Subject identification is possible	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Unless no harm if revealed
Sensitive topics	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Treated properly
Recordings	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Audio or video

Exempt from IRB Review if NONE of the criteria for Full or Expedited Review are present

Project Name _____

Researcher _____

IRB Approval Signature _____

IRB Classification

Exempt from IRB Review

Expedited Review - Approved

 If Expedited: Please describe below or on the back of this sheet how the three areas under Expedited Review above (Subject identification, Sensitive topics, and Recordings) have been dealt with satisfactorily.

Full Review