

IHS Institutional Review Board (IRB) Checklist

P.I.: _____ **Institution:** _____

Title: _____

Primary Reviewer: _____ **Date:** ___ / ___ / ___

4 Basic Steps of IRB Review:

1. **Understand the protocol:** science & methods, and medico-psycho-socio-cultural impacts.
2. **Minimize potential risks:** biological, medical, psychological, social, and cultural harms.
3. **Maximize potential benefits:** to the individual, and to the society [research knowledge].
4. **Ensure that the consent process fully informs potential research participants.**

Summary of findings and recommendations [fill out after completing review]:

	<u>No</u>	<u>n/a</u>	<u>Yes</u>
1. Does the proposal involve <u>special concerns</u> ?	—	—	—
2. Should the proposal be <u>exempt</u> from IRB review?	—	—	—
3. Is the proposal eligible for <u>expedited review</u> ?	—	—	—
4. Should the IRB <u>waive informed consent</u> or <u>some required elements</u> ?	—	—	—
5. Should the IRB <u>waive requirements to document</u> informed consent?	—	—	—
	<u>Yes</u>	<u>n/a</u>	<u>No</u>
6. Are procedures adequate for <u>confidentiality, anonymity, security, privacy</u> ?	—	—	—
7. Are all <u>necessary elements of informed consent</u> included?	—	—	—
8. Are procedures adequate to <u>inform and negotiate consent</u> ?	—	—	—
9. Are procedures adequate to <u>administer informed consent</u> ?	—	—	—
10. If the research is > minimal risk, does <u>scientific merit outweigh risk</u> , and are <u>benefits maximized & risks minimized</u> ?	—	—	—
	<u>No</u>	<u>n/a</u>	<u>Yes</u>
11. Does the research involve <u>children</u> and <u>≥ minimal risk</u> ?	—	—	—
	<u>Yes</u>	<u>n/a</u>	<u>No</u>
12. Does the research meet requirements and recommendations for <u>trials</u> ?	—	—	—
13. Are all appropriate <u>documents from other IRB(s)</u> included?	—	—	—
14. Will the researchers <u>comply with Privacy Act</u> ?	—	—	—
15. Will the researchers <u>comply with IHS and tribal procedures</u> ?	—	—	—
	<u>No</u>	<u>n/a</u>	<u>Yes</u>
16. Additional IRB Decisions:			
A. Should the IRB receive reports from and review this project at intervals shorter than annually?	—	—	—
B. Should the IRB validate reports of compliance from sources additional to the principal investigator [PI]?	—	—	—

- 1. Does the proposal involve special concerns?** Present
- A. Vulnerable potential research volunteers with special protections:
 - 1) Children **[Read Subpart D** if research is greater than minimal risk] _____
Both assent of child and permission of parents required. Exemptions from IRB review apply except for observational research (if researcher is a participant), surveys, or interviews. Research with more than minimal risk but no direct benefit to the child is restricted.
 - 2) Fetuses (and pregnant women) **[Read Subpart B!]** _____
(Pregnant women are not vulnerable.) Research is severely restricted. The IRB must assure appropriate process to select, inform, and obtain consent of volunteers; the father's consent is usually required.
 - 3) Prisoners **[Read Subpart C!, & 28 CFR 512 for Fed. Bureau of Prisons]** _____
Research severely restricted; OPRR must review if > minimal risk; IRB must have a prisoner or prisoner-representative.
 - 4) People with mental impairment [no special regulations] _____
Because informed consent is problematic and the people vulnerable even if ambulatory, this type of research should be limited.
 - B. Influence or possible coercion that unduly entices consent (e.g., excessive compensation, unequal relationship [provider-patient, employer-employee]). _____
 - C. Sensitive information--e.g., child abuse; violence; some infectious diseases; drug abuse; condition could affect insurability, compensation, or litigation. _____
Research records are not medical records, and can be subpoenaed; they can be protected by a Certificate of Confidentiality.
 - D. Screening or diagnosis of diseases with significant potential for loss of insurance or other services, stigmatization, or self-stigmatization. _____
Screen for, e.g., carrier of an incurable genetic disease, HIV.
 - E. The research presents more than "minimal risks." _____
"Risk" means both the magnitude of harms, and the probability of incurring them. "Minimal" risks means risks a person ordinarily encounters in daily life and in routine medical, dental, or psychological exams. For research with more than minimal risk, the IRB should ensure that the research's benefits are maximized and risks minimized, and compare its scientific merit with its risk.
 - F. Genetic research, and research using blood and other body tissues. _____
Risks of genetic research include stigmatization, self-stigmatization, family or community disruption, loss of insurance, discovered misattributed paternity, etc. The protocol must [1] omit identifiers, or [a] inform volunteers of all risks and [b] discard the blood/tissue without testing beyond the protocol; and [2] either not grow perpetual cell lines or report that prospect in consent.
 - G. Deception: major (e.g., mislead volunteers about their health status, the researchers, or research purpose); minor (e.g., incompletely disclose some purpose of the study to avoid biasing the results). _____
 - H. Radiation: may require approval by a Radiation Safety Committee; not permitted in studies of healthy children with no benefit to them. _____

Yes n/a No

Does the project address all special concerns adequately? _____

If "No," explain. _____

_____.

2. Should the proposal be exempt from IRB review? [45 CFR 46.101(b)] Present
 Research subjects/volunteers are involved in only one or more of the following methods.

- [.101(b)(4)] A. Use only existing data, documents, records, or specimens properly obtained: _____
and either
 1) "the information is recorded by the investigator [so that] subjects cannot be identified" in the research data directly or statistically, and no-one can trace back from research data to identify a subject; ()
or
 2) the sources are publicly available. ()
- [.101(b)(5)] B. Research or demonstration service/care programs, e.g., health care delivery: _____
and
 1) the research/demonstration is directly conducted or approved by the head of a US Govt. department or agency, e.g., Director of the IHS; ()
and
 2) it concerns only issues under usual administrative control (48 Fed Reg 9268-9), e.g., regulations, eligibility, services, or delivery systems; ()
and
 3) its evaluation methods (if any) also are exempt from IRB review. ()
- [.101(b)(2)] C. For research not involving vulnerable subjects [prisoner, pregnancy, children, fetus, or mentally impaired], observe public behavior (including participatory observation), or do interviews or surveys or educational tests: _____
and either
 1) the subjects cannot be identified, directly or statistically; ()
or
 2) the responses/observations could not harm the subjects if made public; ()
or
 3) federal statute(s) completely protect all subjects' confidentiality; ()
or
 4) all respondents are elected, appointed, or candidates for public officials. ()
- [.101(b)(3)] D. In educational settings, research or evaluate normal educational practices. _____
- [.101(b)(1)] E. For research not involving vulnerable volunteers [see "C." above], do food research to evaluate quality, taste, or consumer acceptance: *and either*
 1) the food has no additives; ()
or
 2) the food is certified safe by the USDA, FDA, or EPA. ()

Yes n/a No

If not exempt now, can the protocol be made exempt by minor changes? _____
 (If so, consider asking the PI to make those changes.)

For the IRB not to review it, the research must also meet 3 criteria:

- A) If potentially exempt because subjects cannot be identified, the research indeed protects anonymity [see section "6." below]; _____
and
 B) If volunteers give information about others, inadvertent disclosure presents no more than minimal risk to those others. _____
and
 C) If a survey, interview, ed. test, or food research is done in an IHS facility, the information sheet has the IHS disclaimer [section 8.S.]. _____

3. Is the proposal eligible for expedited review, not by the full IRB? [46.110] Present

Expedited review (by the Chair and 1 IRB member) if the protocol is, or includes, only:

either

(per FDA) A. emergency use of an IND therapy for non-research care to a patient; _____

or

B. minor changes in previously approved research within the approved period; _____

or

C. research *both* is not greater than minimal risk *and* involves only: _____

- *continuing review*, and _____ ()

either research found by full IRB to be not greater than minimal risk _____

or enrollment finished & all interventions completed & only long-term f/u _____

or no subjects have been enrolled & no new risks found, *or* only data analysis _____

- existing data, documents, records, specimens originally for nonresearch purposes _____ ()

If from IHS records or specimens, Privacy Act may apply: see #14, last page.

- non-exempt research on individual/group behavior or characteristics by surveys, interviews, focus groups, oral histories, program evaluations, human factors evaluation, or studies of quality assurance methods _____ ()

- collect data of adult/child by noninvasive clinical procedure, *e.g.*, weight, hearing _____ ()

- collect data by clinical non-radiating devices (MRI, EKG, EEG, ultrasound, infrared, echocardiogram, thermogram, doppler blood flow, measure natural radiation) _____ ()

- moderate testing of/by exercise, muscle strength, flexibility, or body composition _____ ()

- research on drugs or devices not needing IND drug or IDE device application _____ ()

- venipuncture/fingerstick blood < = 2x/wk: healthy non-pregnant adult > 109 lbs (< = 550ml / 8 wks); healthy adult < 110 lbs or child (< = 3 ml/kg or 50ml) _____ ()

- noninvasively collect hair, nail clippings, deciduous or permanent teeth, gingival dental plaque/calculus, sweat, saliva, amniotic fluid, sputum, placenta [*cultural issues?*], skin/mucosal/buccal cells (*See detailed list for acceptable methods.*) _____ ()

- collect data from voice, video, digital, or image recordings made for research _____ ()

Yes n/a No

If not expeditable now, can it be made expeditable by minor changes? _____ _____ _____

(If so, consider asking the PI to make those changes.)

NOTE: 'expedited' protocols must meet all IRB requirements, i.e., checklist must be filled out.

4. Should the IRB waive the requirement to obtain informed consent, or waive some or all elements of informed consent? [46.116(c) or (d)] Present

A. Does this project qualify for possible waiver of requirements to obtain, or to include all essential elements of, informed consent? _____

- The research could not feasibly be carried out without the waiver: _____
and either

[.116(c)] 1) it is a research or demonstration project _____
that

(a) is directed or approved by state, local, or tribal governments, _____
and

(b) concerns only administrative/regulatory issues in service programs; _____

or

[.116(d)] 2) it is research (e.g., an activity for which consent usually not obtained, or involves deception of the research volunteer, etc.) _____

that

(a) involves no more than minimal risk, _____

and

(b) will give volunteers pertinent information at the end if appropriate; _____

and

(c) the waiver will not adversely affect volunteers' rights or welfare. _____

If IHS records/specimens are obtained, Privacy Act may apply; see #14, last page.

B. If waiver of some or all informed consent elements is permitted, Yes No
should the IRB still require the project to obtain full informed consent? _____

5. Should the IRB waive requirements to document informed consent? [46.117(c)] Present

A. Is either characteristic present in this project that permit waiver of the requirement of documenting informed consent? _____

either

[.117(c)(1)] 1) The existence of signed informed consent forms itself would place the research volunteer at major risk (e.g., potential loss of confidentiality or anonymity of people interviewed about extremely sensitive behavior). _____

or

[.117(c)(2)] 2) The research _____
both

(a) presents only minimal risk, _____

and

(b) involves no procedures which normally require written consent. _____

B. If a waiver of documenting informed consent is possible, Yes No
should the project still either

1) document fully informed consent? _____

or

[.117(c)] 2) offer each volunteer a written fact sheet? _____

6. Are confidentiality, anonymity, security, and privacy maintained? Yes n/a No

A. Are all computer & non-computer data be held in a secure manner? _____

B. If sensitive identifiable data, is there a Certificate of Confidentiality? _____

C. Do the procedures protect against the risks sufficiently? _____

7. Are all necessary elements of informed consent included?

@ Items <u>required by regulation</u> [45 CFR 46.116(a)]		Yes	n/a	No
@ [(a)(1)]	A. A clear statement that the study is " <u>research</u> "	___	___	___
@ [(a)(1)]	B. <u>All</u> the research <u>purposes</u> [i.e., protocol's <u>objectives</u>] clearly stated	___	___	___
[(b)(6)]	C. How, why, & how many prospective volunteers are <u>selected</u>	___	___	___
@ [(a)(1)]	D. Expected <u>duration</u> of the volunteer's involvement	___	___	___
@ [(a)(1)]	E. <u>Procedure(s) or treatment(s)</u> to be done	___	___	___
@ [(a)(3)]	F. Reasonably expected <u>benefits</u> to volunteer and others	___	___	___
@ [(a)(2)]	G. Reasonably foreseeable <u>discomfort and risks</u>	___	___	___
[(b)(1)]	H. Especially for experiments, a statement that the treatment(s) or procedure(s) "may involve risks that are currently unforeseeable"	___	___	___
@ [(a)(1)]	I. Which procedure(s) or treatment(s) are <u>experimental</u>	___	___	___
@ [(a)(4)]	J. The <u>alternatives</u> to the research's diagnostic method or treatment	___	___	___
[(b)(4)]	K. Procedure for the <u>orderly termination</u> of a volunteer's participation	___	___	___
[(b)(4)]	1) Consequences of a volunteer's <u>withdrawal</u> from the research	___	___	___
[(b)(2)]	2) When may the researcher <u>terminate</u> a volunteer's participation without the volunteer's consent	___	___	___
[(b)(5)]	L. Plans to <u>inform</u> volunteers of <u>significant research findings</u> during or after the study relevant to their continued participation or treatment	___	___	___
@ [(a)(6)]	M. If > minimal risk: " <u>In case of injury or severe adverse affect...</u> "	___	___	___
@	1) will <u>medical care for adverse affects</u> be given? who? where?	___	___	___
@	2) is <u>compensation for adverse affects</u> available? how?	___	___	___
@ [(a)(6)&(7)]	3) <u>whom</u> should a volunteer contact with injury or adverse affect?	___	___	___
@ [(a)(7)]	N. Who will answer <u>questions about the research itself</u> ?	___	___	___
@ [(a)(5)]	O. How <u>confidentiality</u> (___) or <u>anonymity</u> (___) are maintained	___	___	___
@ [(a)(7)]	P. Who on IRB will answer <u>other concerns, complaints, or grievances</u> ?	___	___	___
[(b)(3)]	Q. <u>Financial factors</u> (<u>extra costs of</u> , or compensation for, participation)	___	___	___
[(b)(3)]	R. <u>Other elements</u> a reasonable person would want to know	___	___	___
	S. If a <u>Certificate of Confidentiality</u> , an appropriate description	___	___	___
@ [(a)(8)]	T. <u>Non-coercion disclaimer</u> . E.G., " <u>Taking part is voluntary. You may refuse to take part without any penalty or loss of care or services by IHS or others. You may stop taking part at any time, without penalty or loss of care or services to which you are otherwise entitled.</u> "	___	___	___

		<u>Yes</u>	<u>n/a</u>	<u>No</u>
8.	Are the procedures adequate to <u>inform and negotiate consent</u>?			
	A. Does the project adequately describe the <u>process</u> of consent:			
	1) informing prospective volunteers (skilled negotiating, unhurried time, setting facilitates information transfer)	___	___	___
	2) assessing prospective volunteers' comprehension	___	___	___
	3) assessing prospective volunteers' autonomy (1A + 1B above)	___	___	___
	4) documenting the consent	___	___	___
	B. Is the consent form included?	___	___	___
	C. Are all other relevant documents included? (e.g., parental permission form___, assent script or form___, telephone script___, introduction or approach letter___, etc.)	___	___	___
9.	Are the procedures adequate to <u>administer informed consent</u>?			
@ [117(a)]	A. Give an information copy of the consent form to all volunteers	___	___	___
@ [408(b)]	B. For children age 0-17, a form and process of <u>parental permission</u>	___	___	___
@ [408(a)]	1) For minors old enough, a process of their <u>assent</u>	___	___	___
10.	If more than minimal risk, does <u>scientific merit outweigh risk</u>, and are <u>benefits maximized and risks minimized</u>? [46.111(a)]			
	A. Is the research " <u>indeterminate risk</u> ," e.g., Phase I, II, or III vaccine or Investigational New Drug/Device [IND] trials? <i>If yes, the research by definition is "more than minimal risk."</i>	___	___	___
	B. Is the research <u>more than minimal risk</u> ?	___	___	___
	C. <i>If yes</i> , are <u>benefits maximized</u> and <u>risks minimized</u> ?	___	___	___
[(a)(1)&(2)]	D. <i>If yes</i> , does the research's scientific merit outweigh its risks?	___	___	___
11.	If research involves <u>children (age < 18) and > minimal risk</u>: [46.405-408]			
[.405]	A. Does the research <u>present the prospect of direct benefit to child</u> ? <i>If yes, local IRB may approve. If no, go to "B."</i>	___	___	___
[.406]	B. Is it <u>both only a minor increase over minimal risk, and will it give vitally important knowledge about child's disorder</u> ? <i>If yes, local IRB may approve. If no, go to "C."</i>	___	___	___
[.407]	C. Does it present opportunity to understand, alleviate, or prevent a <u>serious problem affecting children</u> ? <i>If A. and B. are "no" but C is "yes," protocol must be sent to OPRR for review. If A, B, & C are "no," it is not approvable.</i>	___	___	___

		<u>Yes</u>	<u>n/a</u>	<u>No</u>	
12. Does the research meet requirements and IHS recommendations for <u>trials</u>?					
[.111(a)(6)]	A. A monitoring committee for safety (Phase II) or data (Phase III)?	___	___	___	
	B. If a <i>controlled</i> trial, will all eligible volunteers be offered the proven treatment after proof of effectiveness is obtained?	___	___	___	
13. Are all appropriate <u>documents from other IRB(s)</u> included?					
	Is an entity with an IRB (e.g., state, university, CDC, NIH) involved? <i>If "yes," does the protocol have</i>	___	___	___	
	A. Form 596 or letter with MPA #, effective date, and conditions? <i>and</i>	___	___	___	
	B. Is the approval still valid, i.e., effective date <u>< 1 year old</u> ?	___	___	___	
14. Will the researchers <u>comply with Privacy Act</u>?					
<i>The Privacy Act applies when a <u>non-federal government researcher</u> wants confidential <u>identifiable information</u> from government records [e.g., IHS medical records] <u>without consent</u> of the person. Such records may be disclosed for research, after DHHS:</i>					
<i>a) determined that the use or disclosure does not violate law or policy;</i>					
<i>b) determined that the research 1) could not be accomplished without providing records with individual identifiers; & 2) warrants the risk to privacy;</i>					
<i>c) required the receiving researcher to</i>					
<i>1) establish reasonable administrative, technical, & physical security of all data,</i>					
<i>2) remove or destroy the identifiers of the individual at the earliest possible time, and</i>					
<i>3) make no non-emergency use/disclosure of the data or information without approval;</i>					
<i>d) secured a written statement by the researcher that she/he understands and will abide by the provisions a) through c) above.</i>					
	Does the Privacy Act apply? <i>If "yes,"</i>	___	___	___	
	A. Has the researcher complied with the Privacy Act?	___	___	___	
15. Will the researchers <u>comply with tribal and IHS policies</u>?					
	A. Will OMB or the tribe(s) approve the questionnaire(s), if indicated?	___	___	___	
	B. Will the researchers report timely results to the tribe(s) and IHS?	___	___	___	
	C. Will the tribe(s) <u>and</u> RPC review and approve all publications?	___	___	___	
				<u>No</u>	<u>Yes</u>
16. Additional IRB decisions: [46.103(b)]					
[(b)(4)(ii)]	A. Should IRB require reports from this project sooner than annually?	___	___	___	
	If "Yes," reason(s): _____				
[(b)(4)(ii)]	B. Should IRB validate compliance reports from sources other than the PI?	___	___	___	
	If "Yes," reason(s): _____				
	C. Is this protocol greater than minimal risk? <i>(This assessment is necessary for annual reviews.)</i>	___	___	___	