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]:

		No	n/a	Yes
1.	Does the proposal involve special concerns?	__	___	___
2.	Should the proposal be exempt from IRB review?	__	___	___
3.	Is the proposal eligible for expedited review?	__	___	___
4.	Should the IRB waive informed consent or some required elements?	__	___	___
5.	Should the IRB waive requirements to document informed consent?	__	___	___

		Yes	n/a	No
6.	Are procedures adequate for confidentiality, anonymity, security, privacy?	___	___	__
7.	Are all necessary elements of informed consent included?	___	___	__
8.	Are procedures adequate to inform and negotiate consent?	___	___	__
9.	Are procedures adequate to administer informed consent?	___	___	__
10.	If the research is > minimal risk, does scientific merit outweigh risk, and are benefits maximized & risks minimized?	___	___	__

		No	n/a	Yes
11.	Does the research involve children and > minimal risk?	___	___	__

		Yes	n/a	No
12.	Does the research meet requirements and recommendations for trials?	___	___	__
13.	Are all appropriate documents from other IRB(s) included?	___	___	__
14.	Will the researchers comply with Privacy Act?	___	___	__
15.	Will the researchers comply with IHS and tribal procedures?	___	___	__

		No	n/a	Yes
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 <u>exempt</u> from IRB review? *[45 CFR 46.101(b)]* <u>Present</u>

Research subjects/volunteers are involved in <u>only</u> one or more of the following methods.

[.101(b)(4)] A. Use only <u>existing</u> 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 <u>service/care programs</u>, *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], <u>observe</u> public behavior (including participatory observation), or do <u>interviews</u> or <u>surveys</u> or <u>educational tests</u>: ____
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
[.101(b)(3)] 3) federal statute(s) completely protect all subjects' confidentiality; (__)
or
4) all respondents are elected, appointed, or candidates for public officials. (__)

[.101(b)(1)] D. In educational settings, research or evaluate <u>normal educational practices</u>. ____

[.101(b)(6)] E. For research not involving vulnerable volunteers [see "C." above], do <u>food research</u> 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. (__)

	<u>Yes</u>	<u>n/a</u>	<u>No</u>
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 <u>also</u> meet 3 criteria:			
A) If potentially exempt because subjects cannot be identified, the research <u>indeed</u> 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 <u>expedited review</u>, not by the full IRB? *[46.110]* <u>Present</u>

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 (__)
  <u>If from IHS records or specimens, Privacy Act may apply; see #14, last page.</u>

- 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 (__)

	<u>Yes</u>	<u>n/a</u>	<u>No</u>
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, <u>i.e.</u>, checklist must be filled out.

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

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

- The research could <u>not feasibly be carried out without the waiver</u>: (__)

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. (__)

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

B. If waiver of some or all informed consent elements is permitted, <u>Yes</u> <u>No</u>
should the IRB still require the project to obtain full informed consent? ___ __

5. Should the IRB <u>waive requirements to document</u> informed consent? *[46.117(c)]* <u>Present</u>

A. Is either characteristic present in this project that permit waiver of the requirement of <u>documenting</u> 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, <u>Yes</u> <u>No</u>
should the project still *either*

1) document fully informed consent? ___ __

or

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

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

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

B. If sensitive identifiable data, is there a <u>Certificate of Confidentiality</u>? ___ ___ __

C. Do the procedures protect against the risks sufficiently? ___ ___ __

7. Are all necessary elements of informed consent included?

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

			Yes	n/a	No
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</u> and <u>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? *If <u>yes</u>, the research by definition is "more than minimal risk."*	___	___	__
	B.	Is the research <u>more than minimal risk</u>?	___	___	__
	C.	*If <u>yes</u>,* are <u>benefits maximized</u> and <u>risks minimized</u>?	___	___	__
[(a)(1)&(2)]	D.	*If <u>yes</u>,* does the research's scientific merit outweigh its risks?	___	___	__
11.	**If research involves <u>children</u> (age < 18) and <u>> minimal risk</u>:** *[46.405-408]*				
[.405]	A.	Does the research <u>present the prospect of direct benefit to child</u>? *If yes, local IRB may approve. If no, go to "B."*	___	___	__
[.406]	B.	Is it *both* <u>only a minor increase</u> over minimal risk, *and* will it give **<u>vitally important</u>** <u>knowledge about child's disorder</u>? *If yes, local IRB may approve. If no, go to "C."*	___	___	__
[.407]	C.	Does it present opportunity to understand, alleviate, or prevent a ***<u>serious</u>*** <u>problem affecting children</u>? *If <u>A.</u> and <u>B.</u> are "no" but <u>C</u> is "yes," protocol must be sent to OPRR for review. If <u>A</u>, <u>B</u>, & <u>C</u> are "no," it is not approvable.*	___	___	__

		Yes	n/a	No
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 *controlled* 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?	___	___	__
	If "yes," does the protocol have			
	A. Form 596 or letter with MPA #, effective date, and conditions?	___	___	__
	and			
	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>?

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:

a) determined that the use or disclosure does not violate law or policy;
b) determined that the research 1) could not be accomplished without providing records with individual identifiers; & 2) warrants the risk to privacy;
c) required the receiving researcher to
  1) establish reasonable administrative, technical, & physical security of all data,
  2) remove or destroy the identifiers of the individual at the earliest possible time, and
  3) make no non-emergency use/disclosure of the data or information without approval;
d) secured a written statement by the researcher that she/he understands and will abide by the provisions a) through c) above.

Does the Privacy Act apply?	___	___	__
If "yes,"			
A. Has the researcher complied with the Privacy Act?	___	___	__

		Yes	n/a	No
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?	___	___	__

		No	Yes
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? *(This assessment is necessary for annual reviews.)*	__	___