IHS Institutional Review Board (IRB) Checklist

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

Title: _____

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

6 Basic Steps of IRB Review:

1. **Understand the research as written.**
   - **A. Science & methods**: type of research, scientific merit, risks & benefits.
   - **B. Study population**: definition, inclusion-exclusion, rationale, risks/benefits distribution.
   - **C. Influencing factors & contexts**: confidentiality & security, coercions on research team [e.g., type of compensation], conflicts of interest, Tribal/community involvement.
   - **D. Consent process**: capacity to consent, feasibility, compensation/coercion, waivers.
2. **Obtain additional information**: resolve contradictions, needed information not present.
3. **Minimize potential harms**: biological, medical, psychological, social, and cultural harms to individual, family, and community.
4. **Maximize potential benefits**: to individual, family, community, and society [knowledge].
5. **Ensure justice:** Is the intended population appropriate? Does it receive maximum benefits?
6. **Ensure that the consent process fully informs & freely consents potential participants**.

Summary [fill out after completing review]:
The check for the 'IRB-critical' answer is always in the far right column.

General:	No	n/a	Yes
1. Does the research involve special concerns?	__	___	___
2. Should the research be exempt from IRB review?	__	___	___
3. Does the research qualify for expedited review?	__	___	___
Context:	Yes	n/a	No
4. Are anonymity, security, confidentiality, and privacy maintained?	___	___	__
5. If research with children and > minimal risk, does it meet regulations?	___	___	__
6. Does the research meet requirements and recommendations for trials?	___	___	__
7. Are all appropriate documents from other IRB(s) included?	___	___	__
8. Will the research comply with best practices and government policies?	___	___	__
Risks, Benefits, and Justice:			
9. Does scientific merit outweigh risk? For individuals, communities, and families, are risks minimized, benefits maximized, and justice ensured?	___	___	__
Informed Consent:	No	n/a	Yes
10. Should the IRB waive all, or some elements of, informed consent?	__	___	___
11. Should the IRB waive requirements to document informed consent?	__	___	___
	Yes	n/a	No
12. Are procedures adequate to negotiate and administer full consent?	___	___	__
13. Are all necessary elements of informed consent included?	___	___	__
Additional IRB Decisions:		No	Yes
14A. Should the IRB seek reports of compliance from other than the PI?		__	___
14B. Should it review the research sooner than annually, or monitor the process?		__	___
14C. Is the research more than minimal risk? *(needed for 'Annual' Reviews)*		__	___

1. Does the research involve special concerns? Present

A. Vulnerable potential research volunteers with special protections:

1) Children [**Read Subpart D** if research is more than minimal risk] ____
Both assent of child and permission of parents required. Observational research (if researcher is a participant), surveys, and interviews are not exempt from IRB review. 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; OHRP 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. 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. "C" through "H" below are usually more than minimal risk.

C. Genetic research (and some research using blood and other body tissues). ____
Risks include: family and community disruption, self-stigmatization, external stigmatization, survivor guilt, loss of insurance, discovered misattributed paternity, etc. See the IHS policy on specimens.

D. Sensitive information that could affect insurability, compensation, litigation. ____
E.G., child abuse, violence, some infectious diseases, drug abuse. Research records are not medical records, and can be subpoenaed; they may be protected by a Certificate of Confidentiality.

E. Screening for, or diagnosis of, diseases with significant potential for loss of insurance or other services, stigmatization, or self-stigmatization. ____
E.G., screen for carrier of an incurable genetic disease, HIV.

F. Radiation *(may require approval by a Radiation Safety Committee; not permitted in studies of healthy children with no benefit to them).* ____

G. Possible coercion, on potential participant or on researcher, to entice consent. ____
E.G., high incentives to participants, unequal relationship [employer-employee], capitation payments to researchers to enroll people.

H. Deception: major *(e.g., mislead volunteers about their health status, the researchers, or research purpose)*; minor *(e.g., incompletely disclose a research purpose to avoid biasing the results).* ____

2. Should the research be exempt from IRB review? *[45 CFR 46.101(b)]* Present

*Research is exemptible when all research methods are **only** one or more of the following methods. If the research uses a method that is not one of the 5 categories below, the research is not exemptible from IRB review.*

[.101(b)(4)] A. Use only existing data, documents, records, or specimens properly obtained. ____

The research must also comply with one of the following:
either that
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 participant; (__)
or that
2) the sources are publicly available. (__)

[.101(b)(5)] B. Research or demonstration service/care programs, *e.g.*, health care delivery. ____

The research must also comply with all of the following:
that
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 that
2) it concerns only issues under usual administrative control (48 Fed Reg 9268-9), *e.g.*, regulations, eligibility, services, or delivery systems; (__)
and that
3) its research/evaluation methods are also exempt from IRB review. (__)

[.101(b)(2)] C. For research not involving vulnerable people [prisoner, fetus, pregnancy, children, or mentally impaired]: observe public behavior (including participatory observation), or do interviews or surveys or educational tests: ____

The research must also comply with one of the following:
either that
1) the participants cannot be identified, directly or statistically; (__)
or that
2) the responses/observations could not harm participants if made public; (__)
or that
[.101(b)(3)] 3) federal statute(s) completely protect all participants' confidentiality; (__)
or that
4) all respondents are elected, appointed, or candidates for public officials. (__)

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

[.101(b)(6)] E. For research not involving vulnerable volunteers [see "C." above], do food research to evaluate quality, taste, or consumer acceptance. Present
The research must also comply with one of the following:
either that
1) the food has no additives; (__)

or that

2) the food is certified safe by the USDA, FDA, or EPA. (__)

	Yes	n/a	No
If not exempt now, can the research be made exempt by minor changes? (If so, see if the PI will make those changes.)	___	___	__

For the IHS IRB to consider it Exempt, that is not to review it, the research must also meet all 4 criteria, below:

A)	It is in fact less than minimal risk to individuals, families, and communities;	___	___	__
	and that			
B)	if potentially exempt because participants cannot be identified, the research indeed protects anonymity *[see 4.A.]*;	___	___	__
	and that			
C)	if volunteers give information about others, inadvertent disclosure presents no more than minimal risk to those others;	___	___	__
	and that			
D)	if done in an IHS facility, info sheet has the IHS disclaimer *[13T]*	___	___	__

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3. Does the research qualify for expedited review, not by the full IRB? *[46.110]* Present

*Expedited review is by one IRB member and the Chair. It can be done only if all the research is **only** one or more of the following and "exempt" categories.*

The IRB review:

either is of

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

or it is of

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

or it is an

C. 'Annual' Continuing Review, and the research meets *one of the following* ____

- *either* had received expedited review initially *& has had no adverse events* (__)
- *or* was found by full IRB to be not > minimal risk *& has had no adverse events* (__)
- *or* finished enrollment, & completed all interventions, & has only long-term f/u (__)
- *or* has not yet enrolled any person, and has found no new risks for the research (__)
- *or* is doing only data analysis (__)

or it is of

D. new research that is not more than minimal risk, with all methods one or more of the following. *All methods must be one of the categories below, or an exemptible category -- otherwise the research is not expeditable.* ____

- existing data, documents, records, specimens originally for nonresearch purposes (__)
  If from IHS records or specimens, Privacy Act may apply; see 8.C.

- 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-radiation devices (MRI, EKG, EEG, ultrasound, doppler, echocardiogram, infrared, thermogram, 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 (<=550 ml / 8 wks); healthy adult <110 lbs or child (<=3 ml/kg or 50 ml) (__)

- noninvasively collect hair, nail clippings, deciduous or permanent teeth, gingival dental plaque/calculus, sweat, saliva, amniotic fluid, sputum, placenta, skin-mucosal-buccal cells *[But are there cultural harms in this research?]* (__)

- 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, see if the PI will make those changes.)	___	___	__

NOTE: expedited research must meet all IRB requirements, i.e., fill out checklist.

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4. Are anonymity, security, confidentiality, and privacy maintained?	Yes	n/a	No
A. If 'anonymous,' are all data in fact anonymous, e.g., no birthdates?	___	___	__
B. Are all computer & non-computer data held in a secure manner?	___	___	__
C. If 'confidential,' are confidentiality measures adequate?	___	___	__
D. If sensitive identifiable data, is there a Certificate of Confidentiality?	___	___	__
E. Do the procedures protect against the risks sufficiently?	___	___	__

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5. If the research involves children (age <18) and is greater than minimal

risk, does it meet the regulations? *[46.405-408]* Yes n/a No

[.405] A. Does the research present the prospect of direct benefit to child? ___ ___ __
If yes: IHS IRB may approve. If no, go to "B."

[.406] B. Is it *both* only a minor increase over minimal risk, *and* will it give **vitally important** knowledge about child's disorder? ___ ___ __
If yes: IHS IRB approval; both parents must permit. If no, go to "C."

[.407] C. Does it present opportunity to understand, alleviate, or prevent a ***serious*** problem affecting children? ___ ___ __
If A and B are "no" but C is "yes," send protocol to OHRP for review.
If A, B, & C are "no," it is not approvable.

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6. Does research meet requirements and recommendations for trials? Yes n/a No

[.111(a)(6)] A. A monitoring committee for safety (Phase II) or for data & safety (Phase III), especially for double-masked ('blind') trials? ___ ___ __

B. If a *controlled* trial, will all eligible volunteers be offered the proven effective treatment? *[see 9.E.(2)]* ___ ___ __

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7. Are all appropriate documents from other IRB(s) included? Yes n/a No

Is an entity with an IRB (*e.g.*, state, university, CDC, NIH) involved? ___ ___ __
If "yes," does the research have both
A. Form 596 or letter with MPA #, effective date, and conditions? ___ ___ __
and
B. Is the approval still valid, *i.e.*, effective date < 1 year old? ___ ___ __

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8. Will the research comply with best practices & government policies? Yes n/a No

A. Does it minimize harms and maximize benefits to the tribe(s) by Participatory Research (PR) *[see BMJ 1999; 319:774-778]*? ___ ___ __
Whether or not PR, does the research plan to:
1] work with communities to identify & minimize harms; and (___ ___ __
2] report timely results to the tribe(s), and to IHS; and (___ ___ __
3] have the tribe(s)--& IHS if relevant--review all publications? (___ ___ __

B. Will OMB or the tribe(s) approve the questionnaire(s), if indicated? ___ ___ __

C. Will the researchers comply with the Privacy Act? *It applies to non-federal-government research that wants confidential identifiable data from government*

records [e.g., medical] without consent of the person. DHHS or IHS must:
a) determine that the use or disclosure does not violate law or policy;
b) determine that the research 1) could not be accomplished without providing records with individual identifiers; & 2) warrants the risk to privacy;
c) require the receiving researchers to
1) have reasonable administrative, technical, & physical security of all data,
2) remove or destroy individual identifiers at the earliest possible time, and
3) make no non-emergency use/disclosure of data without prior approval; and
d) obtain a written statement by the researchers that they will abide by a-c) above.

1) If the Privacy Act applies, have the researchers complied with the Privacy Act? ___ ___ __

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9. Does scientific merit outweigh risk? Are risks minimized, benefits maximized, and justice ensured to individuals, families, communities? *[46.111(a)]* No n/a Yes

A. Is the research more than minimal risk? __ ___ ___
Phase I, II, or III trials of INDs-IDEs are 'indeterminate risk,' i.e., more than minimal risk [>MR]. Due to workload, this IRB usually only assesses risks, benefits, and science methods in >MR research.

Yes n/a No

[.111(a)(2)] B. *If >MR,* do its scientific methods and merit outweigh its risks? ___ ___ __

Does the research have the scientific methods that are essential for good quantitative and qualitative research?

1) For qua***nti***tative research, e.g.,:
(a) validated measures, ___ ___ __
(b) adequate sample size, ___ ___ __
(c) pretest, ___ ___ __
(d) controls, ___ ___ __
(e) other [_____]. ___ ___ __

2) For qua***li***tative research *[see: BMJ 2000; 320(1):50-52]*, e.g.,:
(a) respondent validation, ___ ___ __
(b) negative cases, ___ ___ __
(c) triangulation, ___ ___ __
(d) good methods to collect & analyze data, ___ ___ __
(e) fair dealing, ___ ___ __
(f) reflexivity, ___ ___ __
(g) other [_____]. ___ ___ __

If not, what should be changed? _____

_____?

[.111(a)(1)] C. *If >MR,* are potential harms minimized to individuals, families, and

communities? *[E.G., provide follow-up counseling to families and individuals. See ∎ 8.A. to minimize community harms.]* ___ ___ __

If not, what should be changed? _____

_____?

[.111(a)(2)] D. *If >MR,* are potential benefits maximized to individuals, families, & communities? *[E.G., newsletters to participants with the status of the research and meaning to individuals, families, and community of the results. See ∎ 8.A. to maximize community benefits.]* ___ ___ __

If not, what should be changed? _____

_____?

[.111(a)(3)] E. Is justice ensured to individuals, families, and communities? i.e.,:

1) The study population is suitable for research ___ ___ __

2) In RCTs, offer the treatment proven effective to individuals, families, and communities in the RCT ___ ___ __

3) Other [_____] ___ ___ __

If not, what should be changed? _____

_____?

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

A project can qualify for waiver of requirements to give all essential elements of informed consent, if it meets both conditions A) and B), below.

Both that

A) The research could not "practicably" [=feasibly] be done without the waiver. ____

and

B) The research is either 1) or 2), below: ____

Either it is

[.116(c)] 1) a research or demonstration project (__)

both that

(a) is directed or approved by state, local, or tribal governments, [_]

and that

(b) concerns only administrative/regulatory issues in service programs; [_]

or it is

[.116(d)] 2) a type of research (*e.g.*, an activity for which consent is usually not obtained, or research that involves deception of the volunteer

and thus cannot seek fully informed consent initially) (__)
meeting all of the following, that
(a) involves no more than minimal risk, [_]
and that
(b) will give volunteers pertinent information at the end if appropriate, [_]
and that
(c) the waiver will not adversely affect volunteers' rights or welfare. [_]

NOTE: If the research obtains IHS records or specimens, and if the IRB waives consent, the Privacy Act may apply; see 8.C. Yes No

C. If the research qualifies for waiver of informed consent, ***should the IRB still require the research to obtain full informed consent?*** ___ __

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

A project can qualify for waiver of written documentation that informed consent was obtained, if it meets either condition A) or condition B), below:

either that
[.117(c)(1)] A. the existence of signed informed consent forms itself would place the volunteer at major risk (*e.g.*, potential loss of confidentiality or anonymity of people interviewed about extremely sensitive behavior); ____
or that
[.117(c)(2)] B. the research ____
both
1) presents only minimal risk, (__)
and
2) involves no procedures which normally require written consent. (__)

C. If the research qualifies for waiver of documenting informed consent, ***should the project still require the research to*** Yes No
either to
1) document fully informed consent, ___ __
or to
[.117(c)] 2) offer each volunteer a written fact sheet? ___ __

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12. Are procedures adequate to negotiate and administer full consent? No n/a Yes

A. May *researcher* compensation [e.g., capitation payments] or other factors influence them to try too strongly to enroll participants? __ ___ ___

B. May the method or amount of *participant* compensation or other factors unduly influence or coerce them to 'consent'? __ ___ ___

			Yes	n/a	No
	C.	Does the project adequately describe the *all processes of consent*: *Both that*			
		1) inform prospective volunteers *(e.g., skilled negotiating, unhurried time, setting facilitates information transfer)*; *and that*	___	___	__
		2) offer time for prospective volunteer to discuss with family; *and that*	___	___	__
		3) assess prospective volunteers' comprehension; *and that*	___	___	__
		4) document the consent process.	___	___	__
	D.	Does the research have all relevant consent documents, including:			
		1) consent,	___	___	__
		2) assent script,	___	___	__
		3) parental permission,	___	___	__
		4) telephone script,	___	___	__
		5) soliciting advertisement,	___	___	__
		6) introduction/approach letter, and	___	___	__
		7) other [_____]?	___	___	__
@ *[.117(a)]*	E.	Give an information copy of the consent document to all volunteers.	___	___	__
@ *[.408(b)]*	F.	For children age 0-17, a form and process of parental permission.	___	___	__
@ *[.408(a)]*		1) For minors old enough, a process of their assent.	___	___	__

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13. Are all necessary elements of informed consent included?

[Explanation of item]

@ = *Items required by regulation [45 CFR 46.116(a)/(b)]*

			Yes	n/a	No
@ *[(a)(1)]*	A.	A clear statement that the study is "research" *[The word "research" should be early in document & not hidden]*	___	___	__
@ *[(a)(1)]*	B.	All the research purposes [*i.e.*, research objectives] clearly stated *[Check the document's list of purposes against the protocol's list]*	___	___	__
[(b)(6)]	C.	How and why prospective volunteers are selected	___	___	__
@ *[(a)(1)]*	D.	Expected duration of the volunteer's involvement *[Necessary if the duration is long, or is not obvious]*	___	___	__
@ *[(a)(1)]*	E.	Procedure(s) or treatment(s) to be done	___	___	__
@ *[(a)(3)]*	F.	Reasonably expected benefits to volunteer and others *[Do not overpromise--> thus, "possible benefits," "benefits may …"; state if no benefits to individual; "possible benefits to tribe …" is permissible; compensation is not in benefits but is separate--see OHRP]*	___	___	__

@ *[(a)(2)]*	G.	Reasonably foreseeable discomfort & risks--including all in protocol *[Check the document's list against the protocol's list]*	___	___	__
[(b)(1)]	H.	Especially for experiments, a statement that the treatment(s) or procedure(s) "may involve risks that are currently unforeseeable" *[Applicable most often in clinical trials of drugs or procedures]*	___	___	__
@ *[(a)(1)]*	I.	Which procedures-treatments are experimental--say "experimental" *[Applicable only to experimental research, not observational]*	___	___	__
@ *[(a)(4)]*	J.	The alternatives to the research's diagnostic method or treatment *[Applicable primarily to research of diagnosis or treatment. A boilerplate "the alternative not to take part" is seldom sufficient; rather, what are the real alternatives (e.g., routine care)?]*	___	___	__
[(b)(4)]	K.	Procedure for the orderly termination of a volunteer's participation *[K, K1, and K2 are applicable primarily to clinical trials, sometimes to compensation--if early termination will decrease compensation]*	___	___	__
[(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 *[Applicable primarily either to clinical trials, or to "deception" research in which debriefing at the end is a standard procedure]*	___	___	__
@ *[(a)(6)]*	M.	If > minimal risk: "In case of injury or severe adverse affect…" *[Per regulations, M is applicable only to greater-than-minimal-risk research. A not-greater-than-minimal-risk-research protocol may want to include M, M1, M2, or M3--or IRB may want them included]*	___	___	__
@		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? *[Usually the PI, with telephone #--collect call if long distance]*	___	___	__
@ *[(a)(5)]*	O.	How confidentiality (__) or anonymity (__) are maintained	___	___	__
@ *[(a)(7)]*	P.	Who will answer other concerns, complaints, or grievances? *[Regulations call this "subject rights"; usually the IRB, with telephone #--collect call if long distance]*	___	___	__

[(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 ___ ___ __
E.G., "**We have a Certificate of Confidentiality from IHS.** The Certificate means that no-one can make us give information about you to anyone outside the study without your consent, not even police or courts. We will not share anything you give us with anyone, except in one case. If you tell us that you or someone may be in danger of great harm, or of physical or sexual abuse, we will report it. The Certificate does not mean that the Department of Health and Human Services or IHS endorse this research." *This is 10th grade readability*.

@ *[(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 quit at any time, without penalty or loss of care or services for which you are qualified." *[This is sample wording; if IHS is not involved, omit 'by IHS or others']*

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14. Additional IRB decisions: *[46.103(b)(4)(ii), 46.111(a)(6)]* No Yes

[.103(b)(4)] A. Should IRB seek compliance reports from sources other than the PI? __ ___

If "Yes," reason(s): _____

B. Should the IRB:

[.103(b)(4)] 1) get reports from or review the research sooner than annually, or __ ___

[.111(a)(6)] 2) monitor the research or consent procedures? __ ___

If "Yes," reason(s): _____

C. Is the research > minimal risk? *(This is necessary for 'Annual' Reviews.)* __ ___