CRIHB 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, tribe-community involvement.
   - **D. Consent process**: capacity to consent, feasibility, compensation/coercion, waivers.
2. **Obtain additional information**: resolve contradictions, need information not present.
3. **Minimize potential harms**: biological, medical, psychological, social, and cultural harms to individual, family, and tribe-community.
4. **Maximize potential benefits**: to individual, family, community, society [knowledge].
5. **Ensure justice:** Is intended population appropriate? Does it receive maximum benefits?
6. **Ensure the consent process fully informs & freely consents potential participants**.

Summary *Fill out after completing Checklist; the 'IRB-critical' check is the far right column.*

General:	Yes	N/A	No
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:			
10. Should the IRB waive all or some elements of, informed consent?	(__)	(__)	(__)
11. Should the IRB waive requirements to document informed consent?	(__)	(__)	(__)
12. Are procedures adequate to negotiate and administer full consent?	(__)	(__)	(__)
13. Are all necessary elements of informed consent included?	(__)	(__)	(__)

Additional IRB Decisions:	Yes	No
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? (Check if 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 greater than minimal risk; the 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. Consider the IHS policy on specimens.

D. Sensitive information affecting insurability, compensation, litigation, being jailed. (__)
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 <u>exempt</u> from IRB review? *[45 CFR 46.101(b)]* (<u>Check if Present</u>)

*Research is exemptible when <u>all</u> research methods are **<u>only</u>** 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 <u>existing</u> data, documents, records, or specimens properly obtained. (__)

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

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

The research must also comply with <u>all</u> 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 Agency; (__)
<u>and</u> that
2) it concerns only issues under usual administrative control (48 Fed Reg 9268-9), *e.g.*, regulations, eligibility, services, or delivery systems; (__)
<u>and</u> 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]: <u>observe</u> public behavior (including participatory observation), or do <u>interviews</u> or <u>surveys</u> or <u>educational tests</u>: (__)

The research must also comply with <u>one</u> of the following:
<u>either</u> that
1) the participants cannot be identified, directly or statistically; (__)
<u>or</u> that
2) the responses/observations could not harm participants if made public; (__)
<u>or</u> that
[.101(b)(3)] 3) federal statute(s) completely protect all participants' confidentiality; (__)
<u>or</u> that
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. (__)
The research must also comply with <u>one</u> of the following:
<u>either</u> that
1) the food has no additives; (__)
<u>or</u> 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 IRB to consider it Exempt (that is, for the IRB not to review it), the research must <u>also</u> meet <u>all 4 criteria</u>, below:

F.	It is <u>in fact less than minimal risk</u> to individuals, families, and communities;	(__)	(__)	(__)
	<u>and</u> that			
G.	if potentially exempt because participants cannot be identified, the research indeed protects anonymity *[see § 4.A.]*;	(__)	(__)	(__)
	<u>and</u> that			
H.	if volunteers give information about others, inadvertent disclosure presents no more than minimal risk to those others;	(__)	(__)	(__)
	<u>and</u> that			
I.	if done in a care facility, info sheet has a strong disclaimer *[§13T]*	(__)	(__)	(__)

.....

3. Does the research qualify for <u>expedited review</u>, not by the full IRB? *[46.110]*(<u>Check if Present</u>)

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

The IRB review:

<u>either</u> is of

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

<u>or</u> it is of

B. minor changes in previously approved research within the approved period; (__)

<u>or</u> 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 (__)

<u>or</u> it is of

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

- existing data, documents, records, specimens originally for nonresearch purposes (__)
  <u>If from fed gov records or specimens, Privacy Act may apply; see § 8.C.</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-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.

.....

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, has it a Certificate of Confidentiality?	(__)	(__)	(__)
E. Do the procedures protect against the risks sufficiently?	(__)	(__)	(__)

.....

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 it present the **prospect of direct benefit** to child? *If yes, IRB may approve & one parent may permit. 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, IRB may approve & 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 CRIHB IRB for review. If A, B, & C are "no," it is not approvable.*	(__)	(__)	(__)

.....

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)]*	(__)	(__)	(__)

.....

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 FWA/MPA, effective date, conditions? (__) (__) (__)
and
B. Is the approval still valid, *i.e.*, effective date < 1 year old? (__) (__) (__)

.....

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-community 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-community; and (__) (__) (__)
3) have the tribe-community review all publications? (__) (__) (__)

B. Will the tribe-community review the questionnaire(s) if indicated? (__) (__) (__)

C. Will the researchers comply with the Privacy Act?
It applies to non-federal-government research wanting confidential identifiable data from government records [e.g., medical] without consent of the person. Fed agency:
a) determines that the use or disclosure does not violate law or policy;
b) determines that the research 1) could not be accomplished without giving records with individual identifiers; & 2) warrants the risk to privacy;
c) requires 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) obtains a written statement by researchers that they will abide by a-c) above.

1) If HIPAA applies, have the researchers complied with the Health Insurance Portability and Accountability Act? (__) (__) (__)

.....

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

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, some IRBs may assesses risks, benefits, and science methods only in >MR research.

Yes N/A No
[.111(a)(2)] B. 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 **quantitative** research, e.g.,: Yes N/A No
(a) validated measures, (__) (__) (__)
(b) adequate sample size, (__) (__) (__)
(c) pretest, (__) (__) (__)
(d) controls, (__) (__) (__)
(e) other [_____] (__) (__) (__)

		Yes	N/A	No
2)	For qualitative 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. Are potential harms minimized to individuals, families, and communities? *[E.G., provide follow-up counseling to families and individuals. See § 8.A. to minimize tribe-community harms.]* (__) (__) (__)

If not, what should be changed? _____

_____

[.111(a)(2)] D. Are potential benefits maximized to individuals, families, and communities? *[E.G., newsletters to participants with the status of the research and meaning to individuals, families, and tribe-community of the results. See § 8.A. to maximize tribe-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? _____

_____

10. Should the IRB waive the requirement to obtain informed consent, or some required elements of informed consent? *[46.116(c) or (d)]* (Check if 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 federal gov records or specimens, and if the IRB waives consent, the federal 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?*** (__) (__)

.....

11. Should IRB waive requirements to document informed consent? *[46.117(c)]*(Check if 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, Yes No
should the project still require the research
either to
1) document fully informed consent, (__) (__)
or to
[.117(c)] 2) offer each volunteer a written fact sheet? (__) (__)

.....

12. Are procedures adequate to negotiate and administer full consent? Yes N/A No

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'? (__) (__) (__)

C. Does the project adequately describe the *all processes of consent*: Yes N/A No
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

		Yes	N/A	No
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. (__) (__) (__)

.....

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 *[Applies 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; state, e.g., "possible benefits," "benefits may ...." State if no benefits to individual. Giving "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" *[Applies most often in clinical trials of drugs or procedures.]*	(__)	(__)	(__)
@ *[(a)(1)]*	I. Which procedures-treatments are experimental--say "experimental" *[Applies only to experimental research, not observational.]*	(__)	(__)	(__)
@ *[(a)(4)]*	J. The alternatives to the research's diagnostic method or treatment *[Applies to mainly diagnostic or treatment research. A boilerplate "the alternative is not to take part" is seldom sufficient; what are real alternatives (e.g., routine care). What is standard care?]*	(__)	(__)	(__)
[(b)(4)]	K. Procedure for the orderly termination of a volunteer's participation *[K, K1, and K2 apply primarily to clinical trials, sometimes to*	(__)	(__)	(__)

compensation. Will early termination decrease compensation?]

		Yes	N/A	No
[(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 study relevant to their continued participation or treatment *[Applies 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 applies only to greater-than-minimal-risk research. An IRB may want to include in some not-greater-than- minimal-risk-research either M, M1, M2, or M3.]*	(__)	(__)	(__)
@	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 is 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." This usually is 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 explanation, 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 IHS, or the Department of Health and Human Services, endorse this research." *[This is 10th grade readability.]*	(__)	(__)	(__)
@ *[(a)(8)]*	T. Non-coercion disclaimer. E.G. [strong disclaimer, for care-providing institutions], "It is voluntary to take part. You may refuse to take part with no penalty or loss of care or services by [tribe] or others. You may quit at any time, with no penalty or loss of care or services you are qualified for." *[This is 8th grade readability. Change 'tribe' to appropriate term, e.g., 'IHS,' 'us,' 'the clinic,' or similar.]*	(__)	(__)	(__)

.....

14. Additional IRB decisions: *[46.103(b)(4)(ii), 46.111(a)(6)]*

		Yes	No
[.103(b)(4)]	A. Should IRB seek compliance reports from sources other than the PI?	(__)	(__)

If "Yes," reason(s): (_____)

		Yes	No
	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.)*	(__)	(__)

Note: This Checklist can be used/modified by CRIHB IRBs without notice.

Susan Dahl
IRB Chairperson
California Rural Indian Health Board, Inc.
4400 Auburn Blvd., 2nd Floor
Sacramento, CA 95841
(916) 929-9761 susan.dahl@ihs.gov