WAIANAE COAST COMPREHENSIVE HEALTH CENTER
IRB SCIENTIFIC REVIEW CHECKLIST

Proposal Title: _____

The check for the "IRB-critical" answer will be in the far right column.

Context	**Yes**	**N/A**	**No**
1. Are anonymity, security, confidentiality, and privacy maintained?			
2. If research with children and > minimal risk, does it meet regulations?			
2a. Does the research present the prospect of direct benefit to child?			
2b. Will it give vitally important knowledge about child's disorder?			
2c. Does it present opportunity to understand, alleviate, or prevent a serious problem affecting children?			
3. Does the research meet requirements and recommendations for trials?			
4. Will the research comply with WCCHC Research Policies?			
Risks, Benefits, and Justice			
5. Does scientific merit outweigh risk? For individuals, communities, and families, are risks minimized, and justice ensured?			
Informed Consent	**No**	**N/A**	**Yes**
6. Should the IRB waive all or some elements of informed consent?			
7. Should the IRB waive requirements to document informed consent?			
	Yes	**N/A**	**No**
8. Are procedures adequate to negotiate and administer full consent?			
9. Are all necessary elements of informed consent included?			
Additional IRB Decisions		**No**	**Yes**
10. Should the IRB seek reports of compliance from other than the PI?			
11. Should the IRB review the research sooner than annually, or monitor the process?			
12. Is the research more than minimal risk?			

Overall Strengths:

Overall Weaknesses:

Required Revisions (if Approve with Revisions)**:**

Recommendation: ☐ **Approve** ☐ **Approve with Revisions** ☐ **Reject**

Reviewer's Name _____ Date: _____

WAIANAE COAST COMPREHENSIVE HEALTH CENTER
RESEARCH COMMITTEE REVIEW SHEET

Proposal Title: _____

Score Key: 1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Weak

Community Based Merit of Proposed Research	
Collaborative Arrangements: To what extent has a collaborative arrangement been developed?	
Fit With Goals of WCCHC: How important is the proposed research to advancing knowledge and understanding issues set as priorities by the WCCHC?	
Identified Benefits to the Community: How appropriate are the identified benefits to the community?	
Community Involvement: To what extent has WCCHC staff and/or community members been involved in the proposed project?	
Cost to WCCHC: To what extent does the proposal appropriate sufficient funds for the implementation of the project?	
Ethical Issues/HIPAA: How well are ethical, HIPAA, data use issues addressed?	
Data Ownership: To what extent does the proposal indicate WCCHC ownership of data?	
Presentation of Findings: What is the plan to present findings of this project to the Waianae Coast Comprehensive Health Center Research Committee?	
Intellectual Merit of Proposed Research	
Originality: To what extent does the proposed activity suggest and explore creative and original concepts?	
Rationale: How well conceived and planned is the proposed activity?	
Study Design: How appropriate is the proposed methodology/procedures to achieving the stated research aims?	
Feasibility: To what extent is there clear evidence of commitment and possibility of completion of the project?	
TOTAL POINTS	
Total Points divided by 12	

Overall Strengths:

Overall Weaknesses:

Recommendation: ☐ Approve ☐ Approve with Revisions ☐ Reject ☐ Defer pending further documentation or revisions

Reviewer's Name _____ Date: _____

WAIANAE COAST COMPREHENSIVE HEALTH CENTER
IRB SCIENTIFIC REVIEW CHECKLIST SUMMARY

Proposal Title: _____

The check for the "IRB-critical" answer will be in the far right column.

Context	Yes	N/A	No
1. Does the research involve special concerns? [(a) Vulnerable participants with special protections are sought: children, fetuses, prisoners, people with mental impairment; b) Research presents more than "minimal risks"; c) Genetic research; d) Sensitive information that could affect insurability, compensation, litigation; e) Screening for, or diagnosis of, diseases with significant potential for loss of insurance or other services, or stigmatization; f) Radiation; g) Possible coercion on potential participant or on researcher to entice consent; h) Deception.]			
2. Should the research be exempt from IRB review? [(a) Use only existing data, documents, records, or specimens properly obtained; b) Research or demonstration service/care programs; c) Observe public behavior, interviews, surveys, educational tests that do NOT: i)Involve vulnerable participants; ii)Identify, directly or statistically, participants; iii)Harm participants if made public; iv)Breach confidentiality; OR v) all participants are elected, appointed, or candidates for public office; d)Research normal educational practices in educational settings; e) Food research to evaluate quality, taste, or consumer acceptance not involving vulnerable participants and the food has no additives or certified safe by the USDA, FDA, or EPA.]			
3. Does the research qualify for expedited review? [(a) Emergency use of an IND therapy for non-research care to a patient; b) Minor changes in previously approved research within the approved period; c) Continuing or annual review and the research meets one of the following –i) received expedited review initially andhas had no adverse events, ii) was found by full IRB to be not > minimal risk and has had no adverse events, iii) finished enrollment, & completed all interventions, & has only long-term F/U, iv) has not yet enrolled any person, and has found no new risks for the research, or v) is doing only data analysis; d) New research that is not more than minimal risk.]			
4. Are anonymity, security, confidentiality, and privacy maintained? [(a) Are all data in fact anonymous? 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?]			
5. If research with children and > minimal risk, does it meet regulations?			
5a. Does the research present the prospect of direct benefit to child?			
5b. Will it give vitally important knowledge about child's disorder?			
5c. Does it present opportunity to understand, alleviate, or prevent a serious problem affecting children?			
6. Does the research meet requirements and recommendations for trials? [WCCHC policy allows only Phase III and Phase IV trials]			
7. Will the research comply with WCCHC Research Policies?			
Risks, Benefits, and Justice			
8. If > minimal risks, does scientific merit outweigh risk? For individuals, communities, and families, are risks minimized, benefits maximized, and justice ensured?			
Informed Consent			
9. Should the IRB waive all or some elements of informed consent? [An IRB may grant a **"Waiver of Authorization"** only if the following criteria have been met (usually done in retrospective record reviews): a) The use or disclosure of PHI involves no more than minimal risks to the participants, b) The waiver will not adversely affect the rights and welfare of the participants, c) The research could not practicably be conducted without the waiver, d) When appropriate, the participants will be provided with additional pertinent information after participation, e) The research could not be practicably conducted without access to and use of			

the PHI, f) The research is of sufficient importance so as to outweigh the intrusion of the privacy of the individual whose information is subject to the disclosure, g) There is an adequate plan to protect the identifiers from improper use and disclosure, and h) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers.45CFR 164.512. **"Data Use Agreements"** may be applied for limited data sets (LDS). A covered entity may disclose a LDS for the purpose of research, public health, or health care operations. LDS still regarded as PHI and subject to HIPAA requirements. 16 PHI identifiers need to be removed from data set, only the following indirect identifiers may be retained: a) Zip code, b) Dates of service, c) Dates of birth and death, d) Geographic subdivision (state, county, city, precinct), but not street address. A limited data use agreement must be in place between the covered entity (WCCHC) and the recipient of the LDS.45CFR 164.514]			
10. Should the IRB waive requirements to document informed consent?			
11. Are procedures adequate to negotiate and administer full consent?			
12. Are all necessary elements of informed consent included?			
Additional IRB Decisions		**No**	**Yes**
13a. Should the IRB seek reports of compliance from other than the PI?			
13b. Should the IRB review the research sooner than annually, or monitor the process?			
13c. Is the research more than minimal risk?			

Overall Strengths:

Overall Weaknesses:

Required Revisions (if Approve with Revisions)**:**

Recommendation:

☐ **Approve** ☐ **Approve with Revisions** ☐ **Reject**

Reviewer's Name _____ Date: _____