WKSH 303 – Non-Exempt Reviewer Checklist

		Yes	No	N/A	Comments
1.	Purpose of the research				
2.	BACKGROUND AND ADDITIONAL PROCEDURES: Results of previous related research				
3.	RECRUITMENT PROCESS: Subject selection criteria				
4.	SUBJECT POPULATION: Subject inclusion/exclusion criteria				
5.	SUBJECT POPULATION: Is there a scientific and ethical justification for excluding classes of persons who might benefit from the research (e.g. non-English speakers or other vulnerable subjects)?				
6.	BACKGROUND AND ADDITIONAL PROCEDURES: Reasons for including vulnerable populations in research (for example, children; economically, educational, mentally or physically handicap, etc). Please add in the Comments box the protocol-specific safeguards used to protect the subjects' rights and welfare. Please see WKSH 305 for guidance on what needs to be documented.				
7.	PROCEDURES: Study design (discussion of the appropriateness of research methods, if needed.)				
8.	Does the study design consider the impact of all risks (physical, social, psychological, financial and confidentiality?)				
9.	PROCEDURES: Description of the procedures to be performed				
10.	Risks and benefits to subjects and risk: benefit analysis				
11.	RECRUITMENT PROCESS: Recruitment and informed consent/assent procedures				
12.	Documentation of informed consent and assent, if appropriate				
13.	Cost to subject for their participation in the research. If so, this information should also be included in the CONSENT document.				
14.	SUBJECT COMPENSATION AND COSTS: Compensation to subject for their participation, including payment schedule				
15.	Is the importance of the knowledge that may be expected to result from the research reasonable in relation to risk and benefits?				
16.	ATTACHMENTS: Advertisement(s) included?				
17.	ATTACHMENTS: Questionnaire(s) and/or Survey(s) included?				
18.	Is PHI to be recorded in this study?				
19.	Adequate written assurance that PHI will not be reused or disclosed to any other person or entity, except as required by law				

		Yes	No	N/A	Comments
20.	Request for waiver or alteration of informed consent process. Waiver or Alteration of Authorization by IRB requires determination that the waiver or alteration satisfies the following three criteria: (1) Research involves no more than minimal risk to participants; (2) the waiver or alteration will not adversely affect the rights and welfare of participants; and (3) the research could not practicably be carried out without the waiver or alteration (see WKSH 304 for guidance.				
21.	ATTACHMENTS: Investigational drug brochure/package insert for studies sponsored by drug manufacturer				
22.	CONSENT: Description of procedures and identification of any experimental procedures				
23.	CONSENT: Description of any benefits to the subject or to others which may reasonably be expected from the research				
24.	CONSENT: Description of any reasonable foreseeable risks or discomforts to the subject				
25.	CONSENT: Disclosure of appropriately alternative procedures or courses of treatment, if any, that might be advantageous to the subject				
26.	CONSENT: Statement describing the extent, if any, to which confidentiality of records identifying subjects will be maintained and that note the possibility that the sponsor, the FDA or appropriate federal, state or local officials may inspect the records				
27.	CONSENT: Is there a description of the protected health information (PHI) to be used or disclosed, identifying the information in a specific and meaningful manner?				
28.	CONSENT: Are the names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure clearly designated?				
29.	CONSENT: Is there a description of each purpose of the requested use or disclosure?				
30.	CONSENT: Is there an Authorization expiration date or expiration event for the duration that relates to the individual or to the purpose or use of disclosure? (Note: end of the research study or none are permissible for research, including for the creation and maintenance of a research database or repository.)				
31.	CONSENT: Is there a signature and date line for the individual or their legally authorized representative to sign and date?				
32.	CONSENT: Anticipated circumstances under which the subjects participation may be terminated by the investigator without regard to the subjects consent				
33.	CONSENT: Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.				

		Yes	No	N/A	Comments
34.	CONSENT: Explanation of whom to contact for information about the research study itself (Name and phone number of investigator obtaining consent)				
35.	CONSENT: For the subsection "Questions" the following sentence is included "You may contact the UH Human Studies Program at..... to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol. Please visit http://go.hawaii.edu/jRd for more information on your rights as a research participant."				
36.	CONSENT: Explanation of whom to contact in the event of a research-related emergency (name and phone number)				
37.	CONSENT: For research involving investigational drug or device, a statement indicating that the intervention is investigational and not approved by the FDA.				
38.	CONSENT: For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.				
39.	CONSENT: If appropriate, a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.				
40.	CONSENT: If appropriate, a statement that significant new finding developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.				
41.	ATTACHMENTS: For federally-funded studies, a grant application is attached to the IRB protocol application and was reviewed.				