University of Puerto Rico
MEDICAL SCIENCES CAMPUS
San Juan, Puerto Rico
INSTITUTIONAL REVIEW BOARD

INFORMED CONSENT EVALUATION CHECKLIST

Principal Investigator _____ IRB# _____

Title _____
_____
_____

☐ YES ☐ NO ***1. Are all necesarry elements of informed consent included?***

A. ☐ Yes ☐ No ☐ N/A A clear statement that the study is research

B. ☐ Yes ☐ No ☐ N/A All the research purposes (*i.e.*, protocols objectives) clearly stated

C. ☐ Yes ☐ No ☐ N/A How, why, and how many prospective volunteers are selected

D. ☐ Yes ☐ No ☐ N/A Expected duration of the volunteer's involvement

E. ☐ Yes ☐ No ☐ N/A Procedure(s) or treatment(s) to be done

F. ☐ Yes ☐ No ☐ N/A Reasonably expected benefits to volunteer and others

G. ☐ Yes ☐ No ☐ N/A Reasonably foreseeable discomfort and risks

H. ☐ Yes ☐ No ☐ N/A Especially for experiments, a treatment(s) or procedure(s) may involve risks that are currently unforeseeable

I. ☐ Yes ☐ No ☐ N/A Which procedure(s) or treatment(s) are experimental

J. ☐ Yes ☐ No ☐ N/A The alternatives to the research's diagnostic method or treatment

K. ☐ Yes ☐ No ☐ N/A Procedure for the orderly termination of a volunteer's participation

1) ☐ Yes ☐ No ☐ N/A Consequences of a volunteer's withdrawal from the research

2) ☐ Yes ☐ No ☐ N/A When may the researcher terminate a volunteer's participation without the volunteer's consent

L. ☐ Yes ☐ No ☐ N/A Plans to inform volunteers of significant research findings during or after the study relevant to their continued participation or treatment

M. ☐ Yes ☐ No ☐ N/A If more than minimal risk: "In case of injury or severe adverse effect . . ."

1. ☐ Yes ☐ No ☐ N/A will medical care for adverse effects be given? Who? Where?
2. ☐ Yes ☐ No ☐ N/A is compensation for adverse effects available? How?
3. ☐ Yes ☐ No ☐ N/A whom should a volunteer contact with injury or adverse effect?

N. ☐ Yes ☐ No ☐ N/A Who will answer questions about the research itself?

O. ☐ Yes ☐ No ☐ N/A How confidentiality or anonymity are maintained?

P. ☐ Yes ☐ No ☐ N/A Who in IRB will answer other concerns, complaints, or grievances?

Q. ☐ Yes ☐ No ☐ N/A Financial factors (extra costs of, or compensation for participation)

R. ☐ Yes ☐ No ☐ N/A Other elements a reasonable person would want to know
_____

S. ☐ Yes ☐ No ☐ N/A Non-coercion disclaimer

☐ YES ☐ NO ***2. Are the procedures adequate to administer informed consent?***

A. ☐ Yes ☐ No ☐ N/A Give an information copy of the consent form to all volunteers

B. ☐ Yes ☐ No ☐ N/A For children (21 years old or less) a form and process of parental permission

1) ☐ Yes ☐ No ☐ N/A For minors old enough (more than 2 years old) a process of their assent

3. Additional IRB decisions:

A. ☐ YES ☐ NO Should IRB require reports from this project sooner than annually? If YES, reason(s): _____
_____
_____
_____

B. ☐ YES ☐ NO Should IRB validate compliance reports from sources other than the PI? If YES, reason(s): _____
_____
_____
_____

Other Corrections to be made _____
_____
_____
_____
_____
_____