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 necessary 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?
   N/A will medical care for adverse effects be given?
   Who? Where?

2. □ Yes □ No □ N/A is compensation for adverse effects available?
   □ 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 __________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________