

**HUMAN RESEARCH PROTOCOL CONTINUING REVIEW
POINTS TO CONSIDER**

POINTS TO CONSIDER	Yes	No	???	N/A
1. Are the actual risks and benefits as anticipated?				
2. Have any subjects been seriously harmed?				
3. Has the IRB been informed of any unforeseen problems or accidents that may have occurred?				
4. Should the IRB request that the investigator(s) submit scheduled progress reports?				
5. Should the investigator(s) submit progress reports more often than annually?				
6. Since the last IRB review, have subjects been informed of any important new information that might affect their willingness to continue participating in the research?				
7. Have any new findings, knowledge, or adverse effects come to light that should be, but have not been, communicated to subjects?				
8. Does the progress of the project together with the results of other new research indicate that the IRB should either impose special precautions or relax special requirements it had previously imposed?				
9. Do the consent documents need to be revised?				
10. Has due care been used to reduce risks and increase the likelihood of benefit?				
11. Are the procedures agreed upon at the beginning of the research still being used?				
12. Does the protocol adequately provide for continuing assessment of the balance between risks and benefits?				
13. Should IRB approval be continued, or should approval be suspended or terminated?				
14. When should the IRB next review the project (taking into account what has been learned about the actual risk to subjects since the project first received IRB approval)?				