

Parker University IRB Annual Update

Title of Protocol: _____

IRB Protocol # _____

Principal Investigator _____

Secondary Investigator(s) _____

Department _____

IRB Date of Approval _____

A. POINTS OF INFORMATION FOR ANNUAL UPDATE (use additional pages as necessary.)

1. When did the study actually begin? _____

2. What is the funding status of the study? Include source and length of funding.

3. What is the estimated completion date of the study?

4. How many subjects have completed the study? _____

5. How many subjects are currently in the study? _____

6. Did *any* subject withdraw from the study? _____ Yes _____ No If yes, state the number of withdrawals and the reason(s).

7. Were there any problems or complications in the study that affected the subject or others?
___ Yes ___ No **Attach a description of any problems or complications.**

8. Did any subject experience adverse reactions or injury during the study?
___ Yes ___ No **Attach a description of adverse reactions or injury and treatment.**

9. Were any changes initiated in the research protocol during the last twelve months that could potentially affect the subject? ___ Yes ___ No **A description of any changes provided (submit revised protocol).**

10. Additional Comments:

B. CURRENT ASSESSMENT OF THE RISKS VERSUS THE BENEFITS

Provide a current assessment of the risk/benefit ratio based upon study results.

C. ADDITIONAL MATERIALS REQUIRED

1. Copy of current informed consent form(s).
2. List of any publication(s) derived from the study.
3. Current Protocol (complete).

SIGNATURE OF PRINCIPAL INVESTIGATOR*

DATE

POSITION

DEPARTMENT

SIGNATURE OF FACULTY DEAN / STUDENT SUPERVISOR

DATE

POSITION

DEPARTMENT

Non-exempt proposals are approved for a maximum period of one year. It is the responsibility of the investigator to comply with an IRB annual update for all protocols.