

Cover Page for Updated Drug or Device Brochures
MUSC IRB for Human Research

This form should be used to submit updated/revise Investigator Brochures to the IRB.

Principal Investigator:

Department:

Contact Person:

Phone/Fax #:

HR #:

Protocol #:

Study Title:

Date of Brochure:

Does the attached brochure include any new information on the frequency, severity or types of adverse effects which should be incorporated into the approved protocol or consent form. If *Yes*, a Request for Amendment Approval Form should accompany this form.

Yes No

Form Attached

Signature of
Principal Investigator: _____

Date:

Date Received by IRB: (stamp)

Signature of Designated IRB Official:
