Cover Page for Updated Drug or Device Brochures
MUSC IRB for Human Research
This form should be used to submit updated/revised 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:

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