For Drugs, Devices, or Other Active Agents to be Used

1. List marketed drugs being used in the study that will be used for an FDA approved indication.

2. List marketed drugs in the study that are approved for other indications, an unapproved route of administration, dosage greater than FDA recommendations, etc.

3. List investigational drugs under FDA regulations

Generic name:
Trade name:

Study is: (**Check one**)
☐ Phase ☐ Phase II
☐ Phase III ☐ Phase VI
☐ N/A

Sponsor name: **Required:** IND#:

4. List chemicals, metabolites, or biological agents not controlled by FDA regulations that will be administered to subjects.

5. Describe the use of an investigational device. Give the name of the device and include a section in the protocol describing the device, its potential hazards, and safeguards against possible hazards. Why does the device sponsor consider the device to be either a significant or non-significant risk device?

Name of device: (**Check one**) ☐ Phase I ☐ Phase II ☐ Phase III

Device is (check one) ☐ Significant Risk Device
☐ Non-significant Risk Device

HCFA Reimbursement (Check one) Category A ☐
Category B ☐

Sponsor name: **Required:** IDE#: **or**
Protocol Development Program (PDP)#:

6. Will subjects be exposed to radiation from procedures that are part of the research study and not part of their routine clinical care? ☐ Yes ☐ No

(If "Yes," describe below and request approval from the Radiation Safety Committee-777-3180) Date Submitted: