**Study Title:
IRB #**

**Principal Investigator: Sponsor:***If investigator-initiated study, please use the* [*IIT Management Checklist*](http://ctac.emory.edu/clinical_trial_resources/IIT%20Management%20Checklist%205%2012%2016.doc)*. Investigators holding an IND or IDE (Sponsor-Investigators) are advised to use the* [*SI Trial Initiation Checklist*](http://compliance.emory.edu/documents/SI_INDIDE_TIC.docx)*.*

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| **Task** | **Date completed and initials** | **Comments** |
| **Study materials (e.g., scientific protocol and consent)**[ ]  Obtain or develop the [lay summary](http://irb.emory.edu/documents/Biomedical%20Lay%20Summary%20Guidance.doc), [scientific protocol](http://www.irb.emory.edu/documents/Protocol%20Guidelines-Biomedical.docx) and [informed consent form with HIPAA authorization](http://www.irb.emory.edu/documents/Emory_BioMed_ICFHIPAA_Template.doc) [ ]  Obtain documentation on the study intervention if applicable (e.g., investigator’s brochure or package insert for drugs, device manual for devices, information on a [dietary supplement](http://www.irb.emory.edu/documents/dietarysupplements-medicalfoods-research.docx))[ ]  Identify study personnel |  |  |
| **Required submissions as applicable**[ ]  [Office of Sponsored Programs](http://www.osp.emory.edu/) via EPEX for grants and contracts or [Grady Office of Grant Administration](https://gradyhealth.org/office-of-grants-administration/) for [Grady studies](https://gradyhealth.org/office-of-research-administration/)[ ]  [Clinical and Translational Review Committee](https://winshipcancer.emory.edu/research/clinical-trials-office/clinical-translational-review-committee.html) for cancer-related studies[ ]  [Institutional Review Board](http://www.irb.emory.edu/) (IRB) via [eIRB](https://eresearch.emory.edu/Emory/), [Form A (WIRB Eligibility Checklist)](http://www.irb.emory.edu/documents/Emory%20WIRB%20Form%20A.doc) for WIRB studies to WIRB listserv or contact IRB for other external IRBs[ ]  [Office for Clinical Research](http://www.ocr.emory.edu/) (OCR)for studies with billable items and services[ ]  [Office of Quality checklists](http://irb.emory.edu/forms/clinical.html) (including nursing checklist)[ ]  [Conflict of Interest](http://www.coi.emory.edu/) (COI) via [eCOI](https://www.ecoi.emory.edu/)[ ]  [Radiation safety](http://www.ehso.emory.edu/programs/radiation/) and/or [Biosafety](http://www.ehso.emory.edu/programs/research-biosafety/index.html), if applicable [ ]  [Investigational Drug Service](http://ocr.emory.edu/ids/index.html), if applicable |  |  |
| **Grady and Veterans Affairs (VA), after IRB approval**[ ]  [Grady Research Oversight Committee](https://gradyhealth.org/static/office-of-research-administration/) (ROC)[ ]  [VA Research and Development Committee](http://www.atlanta.va.gov/services/research/Investigators.asp)[ ]  [Emory Saint Joseph’s Hospital (ESJH) ROC approval](http://irb.emory.edu/documents/ESJH-clinical-research-procedures.docx) |  |  |
| **Study personnel**[ ]  IRB approval for all personnel[ ]  [eCOI](https://www.ecoi.emory.edu/) completion for applicable personnel[ ]  Documented study-specific training for all personnel[ ]  Delegation of authority log for all personnel[ ]  Sponsor forms for all personnel (e.g., financial disclosures) |  |  |
| **FDA documentation, if applicable**[ ]  [1572](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf) for drug studies[ ]  Investigator agreement for device studies |  |  |
| **Websites, if applicable**[ ]  Trial listed on [clinicaltrials.gov](http://ocr.emory.edu/ct.gov/index.html) [ ]  Other for recruitment/advertising, as approved by the IRB |  |  |