Data Safety Monitoring Service Request Form

Instructions:
To submit documents required for assistance with creation of a Data Safety Monitoring Board/Plan, please complete this questionnaire and upload all supporting documents to:
MYRESEARCHNAVIGATOR@LISTSERV.CC.EMORY.EDU

***Upload the following Documents**:*

- ✓ *Protocol*
- ✓ *DSMP**
- ✓ *DSMB**

*(*if applicable. Not required)*

Your service determination will be completed within 7-14 business days and a studio consultation will be scheduled if applicable.

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1. Date: (MM/DD/YYYY)

2. Contact Information: Name:

Title (MD, PhD, RN, PA-C etc.):

3. Email Address:

Phone Number:

4. Preferred Contact:

☐ Phone
☐ Email
☐ No Preference

4. **Best Time to Discuss Request**
☐ Morning (8am - 11am)
☐ Afternoon (12pm-3pm)
☐ Evening (After 4pm)
☐ No Preference

5. School (School of Medicine, Rollins School of Public Health, etc.):

6. Department (Emergency Medicine, Neurology, Medical Oncology, etc.):

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7. Support Requested (Check all that apply)

☐ Data Safety Monitoring Board (DSMB) Registry of participating members
☐ Data Safety Monitoring Plan (DSMP) Charter Template
☐ NIH Guided DSMB Charter Template
☐ Information regarding available resources
☐ Biostatistics, Epidemiology, Research, and Design (BERD)
☐ Office of Compliance (OC)
☐ Full Studio Consultation (Clinical Trials Audit and Compliance (CTAC), Regulatory Knowledge and Support (RKS), and Clinical Research Navigator (CRN)
☐ Other (please specify):

8. Protocol Title:

9. Is this a Clinical Trial?

☐ Yes
☐ No, Skip to Question #12

10. If #9 is Yes, indicate the type of clinical trial below:

☐ Interventional
☐ Observational, Skip to Question #12

11. Indicate Phase of the Clinical Trial:

☐ Phase I: Testing of an experimental drug or treatment in a small group of people for the first time. The clinical trial evaluates the treatment's safety, efficacy, safe dosage, and identify side effects.
☐ Phase II: The experimental drug or treatment is given to a large group of participants to determine effectiveness, and further evaluate its safety.
☐ Phase III: The experimental drug or treatment is given to a large group to confirm its effectiveness, monitor side effects, data collection to evaluate experimental drug or treatment safe usage, and/or compare commonly used treatments.
☐ Phase IV: Treatment currently approved by the FDA for use. Data collection to indicate the drug's risks, benefits, and best use.

12. Who holds the Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

☐ Emory Investigator/Sponsor Investigator
☐ University of Georgia (UGA) Investigator/Sponsor Investigator
☐ Morehouse School of Medicine (MSM) Investigator/Sponsor Investigator
☐ Georgia Institute of Technology (Georgia Tech) Investigator/Sponsor Investigator
☐ Sponsor
☐ Other (please specify):

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13. Indicate all locations where study will be conducted: (Check * all that apply)

☐ The Emory Clinic (Building A, B, or C)
☐ Winship Cancer Institute (WCI)
☐ Emory University Hospital-Main Campus (EUH)
☐ Emory University Hospital-Midtown (EUHM)
☐ Emory University Decatur Hospital
☐ Emory Johns Creek Hospital (EJCH)
☐ Emory Orthopaedic & Spine Hospital (EUOSH)
☐ Emory Wesley Woods Hospital (EWWH)
☐ Emory Children's Center (ECC), Scottish Rite PRC, or CHOA PRC
☐ Atlanta VA Medical Center
☐ Grady Healthcare
☐ Morehouse School of Medicine (MSM)
☐ University of Georgia (UGA)
☐ Georgia Institute of Technology (Georgia Tech)
☐ Other (Specify Location for MSM and UGA Studies)"

14. Has protocol been submitted to the IRB?

☐ Yes
☐ No

Date (submitted or anticipated):

15. Is this a multi-site study in which you are the lead Principal Investigator?

☐ Yes
☐ No, Skip to Question #17

16. If #15 is Yes, list the names of other participating sites: