Clinical Trial Review for Emory Medical Laboratory Services

1. Does your study require “routine” or “standard of care” labs?
   (Review attached for a list of labs considered “routine” or “standard of care”)
   ☐ YES
   If Yes, STOP – Routine Labs do not require prior EML review/approval – Do Not Submit Checklist!
   Important: If labs required by the protocol are on the attached form,
   *Indicate EML Labs as Exempt on the CRKP form in eIRB application*
   ☐ NO
   If No, CONTINUE – Your clinical trial requires review and approval by EML – Submit Checklist!
   Complete the information below. Submit both forms directly to:
   Rebecca Willis (totianne.willis@emoryhealthcare.org) & Michelle Hicks (michelle.hicks@emoryhealthcare.org)

2. Does your study require special processing and/or lab methods?
   ☐ N/A
   ☐ YES
   If Yes, Continue – Your clinical trial requires review and approval by EML – Submit Checklist!
   Complete the information below. Submit both forms directly to both:
   Rebecca Willis (totianne.willis@emoryhealthcare.org) & Michelle Hicks (michelle.hicks@emoryhealthcare.org)

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**DATE:** Select date from drop-down.

**PROTOCOL TITLE:** Click here to enter text.

**IRB #:** Click here to enter text.

**Anticipated Start Date:** Select date from drop-down.  **Anticipated End Date:** Select date from drop-down.

1. Samples will be drawn by: ☐ LAB  ☐ Study Nurse  ☐ Other, please specify  Click here to enter text.

2. Check all labs to be requested to be drawn for clinical trial on the attached Research Lab Request Form.
   - Add: Please list all Labs that will be drawn by EML and shipped to your Clinical Trial’s Central Laboratory (Indicate additional tubes if any that will be drawn by EML (e.g. Draw x1 Red Top, x2 Purple Tops, etc.)

3. Is the sponsor requiring special or particular lab methods to be used? ☐ Yes  ☐ No
   a. If so, please elaborate and submit Checklist to EML for review/approval:

4. Is special processing required? ☐ Yes  ☐ No
   a. If so, please elaborate and submit Checklist to EML for review/approval:

If questions, please contact Rebecca Willis @ (404) 712-7373 or Michelle Hicks @ (404) 712-2587