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Clinical Trials Office

Title: **Processing an MDG Approval**

Once an MDG Committee approves a study, the MDG Committee Coordinator completes the following tasks:

1. Document Approval and any discussion related to approval in the MDG Minutes and have MDG leader sign Minutes and add to shared Drive MDG Folder for your Team.
2. Create protocol record in JeffTrial
   1. Register the protocol in JeffTrial (see [JeffTrial Protocol Registration](https://confluence.jefferson.edu/display/jefftrial/Protocol+Registration+Required+Fields)) and enter all required information including (but not limited to):
      * PI
      * Sponsor
      * MDG approval
      * Upload the approved protocol
      * Management group information
        + Select the team that represents the group doing the clinical research coordination
        + If the CTO Regulatory Operations team is supporting the study, add “PSU Reg”
        + Other options in Drop Down if appropriate
      * Key study personnel
        + See [JeffTrial Staff List Requirements](https://confluence.jefferson.edu/display/jefftrial/Main+%3E+Staff#:~:text=Staff%20List%20Requirements%3A)
        + If a non-CTO group is coordinating the study, e.g. Radiology, add the lead coordinator from that department as Study Site Contact.
3. Send MDG approval notification by e-mail
   1. **Must be sent within 2 business days of MDG Committee meeting**
   2. Use the approved MDG approval e-mail template on SKCC intranet

[*https://skccapp01pa.kcc.tju.edu/clinicaltrials/DocLibrary/clinical.php*](https://skccapp01pa.kcc.tju.edu/clinicaltrials/DocLibrary/clinical.php)

* + - * Include the following people on the email:
  + PI
  + Applicable MDG Leader
  + All Directors within the CTO
  + If the CTO’s Regulatory Operations team is supporting the study, copy the appropriate Regulatory Manager, and (if known) the applicable Regulatory Coordinator
  + If another group is coordinating the study, e.g. Radiology or Dermatology, copy the lead coordinator from that department

1. If a Calendar build is needed, send a separate email to JCRI with a copy of the final protocol.
2. If a budget is needed, send an email to JCRI Contracts and Budgets with the contract, budget and final protocol when available.
3. Complete the Study Program form and Submits for CRLC Review – via email to [Tracey.newhall@jefferson.edu](mailto:Tracey.newhall@jefferson.edu) - form can be found in the CRO Shared File: Clinical Trials Office\Project Management\SKCC Program Assignments.
4. Complete the MDG Priority Form and obtain MDG Lead’s Signature within 4 weeks from MDG approval, but prior to PRMC submission.

[*https://skccapp01pa.kcc.tju.edu/clinicaltrials/DocLibrary/clinical.php*](https://skccapp01pa.kcc.tju.edu/clinicaltrials/DocLibrary/clinical.php)

1. Prepare and collect all documents for Protocol Feasibility Committee submission.