

**IMPORTANT**

**Five critical processes must occur before you recruit for a new study**

- 1. Is this a Device Study?**
  - If you have a study that involves a device it **must** be reviewed by Karon Dunavon and approved for use before the Clinical Trial Agreement and Budget Proforma are sent to Legal and Finance.
  - Send Karon Dunavon a copy of the information from the sponsor about the device.
  
- 2. Budget Preparation**
  - Identify those items in your study that are standard of care and those that are paid by the research study.
  - Fill out the Schedule of Contract Charges Sheet
  - Complete the Financial Proforma for Grants. Denise Scoffic or Bonnie Sandbrink can help with this.
  - Make sure there is a budget proposal from the sponsor which clearly identifies the costs covered by the sponsor.
  - Once this is finished move on to step 3.
  
- 3. Financial & Legal Approval**
  - Fill out the Office of Research Administration Tracking Form
  - Complete the Budget Proforma and Schedule of Contract Charges.
  - By e-mail send to Penny Yarber the completed Office of Research Tracking Form, Budget Proforma, Clinical Trial Agreement and the Schedule of Contract charges.
  - Get approval from Finance and Legal
  - You must have approval from the Finance and Legal Departments before the agreement will be signed by Dr. Hintze.
  
- 4. Request new G/L Account and Contract Account (as needed)**
  - **Contract Account:** fill out the Request to Add a Contract Account and submit with a copy of your Schedule of Contract Charges to Bonnie Aye in Finance.
  - **G/L Account:** Complete the New Account/Accounting Unit Request form and submit to Gail Sztukowski in Finance



## 5. Submit to the IRB

- Once it has been approved by the Finance and Legal Departments it is ready to be submitted for IRB review.
- Information about IRBNet.org can be found at <http://irbnetresources.org>. Click on Resources tab toward top left of the page. A pop up will appear where you enter the username (sjmmc) and the password (training02).
- For assistance in entering materials on IRBNet.org, a short training video is available at the Institutional Review Board website or call Penny Yarber at 314-251-6841.
- An invoice will be sent to you for the initial IRB fee and payment needs to be paid before the IRB will issue an approval letter.
- The IRB must have reviewed and approved the protocol; you must have the IRB approval letter, the IRB stamped approved consent(s) and the Clinical Trial Agreement signed by Dr. Hintze before recruitment begins and your site is initiated.

## Recruitment can then be initiated!

**Questions or concerns with this process should be addressed to:**

Donald York, Ph.D. or Penny Yarber, CIM  
Office of Research Administration  
251-6841

### Contact Numbers:

1. Bonnie Aye (Contract prices & contract accounts)	364-3944	Bonnie.Aye@Mercy.Net
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3. Karon Dunavan (New Devices)	251-4769	Karon.Dunavan@Mercy.Net
3. Denise Scoffic (Budget Proforma)	364-3553	Denise.Scoffic@Mercy.Net
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5. Gail Sztukowski (G/L Accts)	364-2577	Gail.Sztukowski@Mercy.Net
6. Penny Yarber (IRB)	251-6841	Penny.Yarber@Mercy.Net