# Investigator Initiated Research Frequently Asked Questions

## Q: What are the areas of focus for the research external funding applications?

**A:** High level information can be found in the Resource Section of our website, under the "Therapeutic Areas" document. If you have further questions, please contact the Medical Operation team at the contact information above.

# Q: Are there deadlines for submissions?

**A:** Yes, the deadlines are posted on the website. Completed concept proposals and/or full applications should be submitted by midnight of the deadline.

## Q: How do I receive an application?

A: You can receive an application either through your local Medical Affair contact or through our mailbox (<u>external\_funding@baxter.com</u>). We advise that you first review our "Therapeutic Areas" document to ensure the proposal is aligned with our areas of focus.

# Q: How is the internal review process completed?

**A:** A dossier is completed for each study. All the study information is sent to a committee of reviewers, which is composed of Subject Matter Experts, Statisticians, and other pertinent individuals.

# Q: How will I know of the funding decision?

**A:** The Program Manager will provide a formal, written notification, which will specify if your submission is awarded or declined for funding. In some cases, we may reach out to you for clarification before reaching a funding decision.

# Q: What happens if I receive an award notification?

**A:** The Program Manager will send an award kit with further information and will guide you through the contracting process. The External Funding Program Manager will also be available throughout the study duration for questions, receiving deliverables, and processing payments.

## Q: Do you support product requests?

A:Yes

# Q: What are the expectations of an awarded IIR?

**A:** Our standard is that Baxter may have access to the de-identified data, own the intellectual property, and that the investigator will seek to publish.

## Q: Do you accept applications from countries outside of the USA?

**A:** Yes, as a global company with global interests, we accept applications from all countries. There are instances where we may have region-specific needs.

# Q: My application applies to several areas. How do I know which area to submit to or do I have to submit to all?

**A:** You only need to submit the application once. We recommend you submit your application to the therapeutic area you believe it most aligns to. We will redirect internally if we find it aligns better with another area.

# Q: Are there any limitations to be considered when I complete my application?

A: Yes, we do have a limit of only being able to provide a maximum of 20% overhead cost. In addition, we cannot provide funding for the purchase of capital investments, which includes: devices, equipment, laptops, databases, software, etc. These items are required to be leased from another party, or temporarily loaned by Baxter, with the expectation that the items are returned at the completion of the study. While we may cover the expenses of the lease/loan, we do need to ensure a proper agreement is in place.

## Q: Does Baxter fund preclinical studies?

**A:** Yes. If studies involve the use of animals, Investigators will be required to provide information to Baxter to comply with Baxter's Justification for External Preclinical Study (JEPS) review and an IACUC approval letter, which requires additional review that can take up to 2 weeks.

## Q: Do you require studies to be registered on public websites?

**A:** Awarded clinical studies will need to be registered on http://www.clinicaltrials.gov/ or a local registry once an agreement is fully executed. Proof of study registration is required for the study. If the awarded study is preclinical, then registration is not required.

# Q: Do you require detailed budget information at time of submission?

**A:** Yes, your study budget should be aligned to fair market value and expenses should be appropriately itemized. Direct and indirect costs that should be taken into consideration, and include: subject related costs, study related personnel costs, data management expenses, publications costs, IRB review fees, etc.