ePRAF Attachment for Non-NIH Clinical Trials Proposal ID#

Check all that apply:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Initiator of Study:** | **Author of Protocol:** | **Type of Study:** | **Funding Source:** |  |
| Investigator | Investigator | Drug Study | Industry | Not funded |
| Sponsor | Sponsor | Device Study | Government | Internally supported by FIU Foundation, ORED, HWCOM, etc. |
| Cooperative Group | Cooperative Group | Chart Review | Cooperative Group |
| Other | Other | Observational | Foundation |
|  |  | Specimen Study | Other |
|  |  | Behavioral Study |  |  |
|  |  | Other |  |  |

1. Protocol Title:
2. Drug/Device Name (if applicable):
3. Drug/Device FDA-approved for indication (if applicable):
4. IND/IDE # (if applicable):
   1. Is IND held by the investigator?
   2. If yes, initial FDA IND date:
5. FDA Phase (if applicable):
6. Publish study to FIU website for information/recruitment purposes:
7. Clinical trials.gov ID (if applicable):
8. If cooperative group, name group and provide protocol number:
9. If drug or device study, investigational drug or device will be:

Provided by sponsor free of charge

Sponsor funds will be used to purchase drug or device

Other:

1. Study Sites:

|  |  |  |
| --- | --- | --- |
| FIU Campus: HCN, Stempel, etc. | Jackson North | Other |

1. Documents: Please attach all documents related to this study:

Protocol

Informed Consent Draft

Sponsor Contract Template

Sponsor Draft Budget

Other Pertinent Information (treatment manuals, IND/IDE letter, etc.)

Billing Grid

Please note that:

1. All clinical trials need to be registered at clinicaltrials.gov.
2. NIH policies and guidance on clinical trials require that all staff involved in the conduct, oversight, and management of NIH-funded clinical trials received Good Clinical Practice (GCP) training. Additional details on available GCP training to meet NIH requirements available at <http://research.fiu.edu/irb/training-requirements/>

If there are any questions related to this form, please contact Maureen Pelham, Director of Research Development, at 305-348-2494.