**INSTRUCTIONS**

The purpose of the Protocol Intake Form is to document trials under consideration by the PI and/or the CTO and to maintain a comprehensive inventory of trials under CTO purview. The CTO Regulatory team should complete Part I of this form at the time of study receipt/notification, and route to the responsible Research Manager to complete Part II and sign-off.

*Regulatory Team*, please route Protocol Intake Form to Research Manager, prior to feasibility review, for confirmation of CTO utilization.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PART I - PROTOCOL INFORMATION** | | | | | | | | | | | |
| **Principal Investigator (PI)** | | |  | | |  | |  | | | |
| **Disease Team** | |  | | | | **Research Manager** | |  | | | |
| **Disease Site(s)** | |  | | | | **Study information received *(date)*** | |  | |  | |
| **Winship Participating Sites *(check all that apply)*** | | WCI (Clifton) | | | Midtown | St. Joseph’s Hospital | | GradyJohns CreekOther *(list)* | | | |
| **Multi-site trial with Winship PI serving as overall study PI** | | Yes | | | *If yes, please describe:* |  | | No  Unknown | | | |
| **Will this trial utilize CTO staff?**  ***(check all that apply)*** | | Clinical | | | Regulatory | If PI is asking for selective CTO support, specify: | |  | |  | |
| **Emory-held IND trial?** | | Yes | | | No | Unknown | |  | |  | |
| **Sponsor Name** | |  | | | | **Protocol Number** | | | |  | |
| **Protocol Title** | |  | | | | | | | | | |
| **Funding Source** |  | | | **Study Source** | | | Choose an item. | | **PI Interest** | | Choose an item. |

|  |  |  |  |
| --- | --- | --- | --- |
| **PART II – RESEARCH MANAGER REVIEW** | | | |
| For all interventional treatment trials, with confirmed PI interest in utilizing CTO resources (e.g., regulatory, clinical), initiate feasibility review and route to the Regulatory Team for initiation of study start-up activities. | | | |
| For interventional non-treatment or non-interventional studies, with confirmed PI interest in utilizing the CTO’s resources (e.g., regulatory, clinical), please determine Cancer Center Support Grant (CCSG) applicability and if CTO resources are available to support the trial, with assistance from the Assistant Director, Clinical Research Staff, when needed.   * CCSG applicability: If CTO resources will be utilized for the study and the trial is CCSG-relevant, initiate feasibility review and route to the Regulatory Team for initiation of study start-up activities. If CTO resources will not be utilized for the study or the trial is not CCSG-relevant, notify the Assistant Director, CR Staff, who will confirm the decision and inform the PI and Regulatory Team. The Regulatory Team will archive the trial. | | | |
| **Determination of CCSG-applicability and CTO Resource Utilization** | | | |
| **Study Type** | Choose an item. | **Clinical Research Category (DT4)** | Choose an item. |
| **Is this trial CCSG-applicable?**  *(Note: If trial is DT4 applicable, select yes)* | **Yes  No** | **Should CTO resources be utilized?**  *(If trial is not CCSG-applicable, but CTO resources should be utilized please describe why in comment box below)* | **Yes  No** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **SIGNATURES** | | | | | | |
| **Research Manager Sign-off** |  |  | | |  | |
|  | ***Signature*** | | |  | ***Date*** |  |
| **Assistant Director, CR staff**  ***(if trial was not approved)*** |  |  | | |  |  |
|  | ***Signature*** | |  | | ***Date*** |  |
| **Comments** |  |  | | |  |  |