**Institutional Data and Safety Monitoring Board (IDSMB) Request Form**

An IDSMB for clinical research projects is available through the Office of Clinical Research (OCR), Health Sciences and the Clinical & Translational Science Institute (CTSI).

To initiate a request, please complete the following application below and email to:

**Susan Sandusky at SLS127@pitt.edu**

Please attach the following: protocol, consent, IRB approval letter (if obtained), the relevant grant sections (aims, methods and human subject section).

|  |  |
| --- | --- |
| **Research Project Information** | |
| Request Date | <month/day/year> |
| Date IDSMB is needed | <month/day/year> |
| Project Type | **New or** **Ongoing** |
| Project Title |  |
| IRB Number(s) |  |
| Single Center | **Yes or No** |
| Multicenter Study | **Yes or No**. If yes, list potential sites outside of UPitt/UPMC |
| Funding Agency | <if NIH, include specific institute> |
| Proposed Level of Risk |  |
| Study Phase | <pilot, Phase I, II, III> |
| Proposed Length of Study |  |
| Expected Study Start Date | <month/day/year> |
| Short Description of Project or Abstract |  |
| Number of participants |  |
| Randomized | **Yes or No** |
| Blinded data | **Yes or No**. If yes, list who is blinded. |
| Level of public profile |  |
| Potential Risks |  |
| **Principal Investigator (PI) Information & Co-Investigators** | |
| PI Name |  |
| PI Address |  |
| PI Phone # |  |
| PI Pager # |  |
| PI Email |  |
| School (e.g. Medicine) |  |
| Department/Division |  |
| Department Chair |  |
| Name(s) of Co-Investigators |  |
| Name of Study Biostatistician |  |
| **PI’s Assistant Information** | |
| PI’s Assistant Name |  |
| PI’s Assistant Phone # |  |
| PI’s Assistant Email |  |
| **Coordinator Information** | |
| Research Coordinator Name(s) |  |
| Research Coordinator Phone # |  |
| Other phone # |  |
| Email |  |
| **Administrator Information** | |
| Dept. Administrator Name |  |
| Dept. Administrator Phone # |  |
| Dept. Administrator Email |  |
| **Fee Waiver Request** | |
| Fee Waiver Request  If waiver of fees is requested, please attach a letter of explanation addressed to ***Steven E. Reis, MD, Associate Vice Chancellor for Clinical Research.*** | **Yes** or **No** |