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

An IDSMB for clinical research projects is available through the University of Pittsburgh 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 Entire 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 # |  |
| Email |  |
| **Administrator Information** | |
| Dept. Administrator Name |  |
| Dept. Administrator Phone # |  |
| Dept. Administrator Email |  |
| Where is account held? | Pitt or UPMC? |
| 32-digit Account # for payment (invoiced and charged after each meeting) | <*this may be TBD until after the grant is awarded*> |
| 32-digit Departmental Account # (will only be used if the project account # is not active) | <*this is required before a Cost Estimate can be given*> |
| **Fee Waiver Request** | |
| Fee Waiver Request  If waiver of fees is requested, please attach a letter of explanation addressed to ***Steven E. Reis, MD, Director, Clinical and Translational Science Institute & Distinguished Service Professor of Medicine, School of Medicine*** | **Yes** or **No** |