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| **SECTION 1.0: Instructions** | | | | |
| **1. All submissions to be reviewed by Schulman Associates IRB must be accompanied by this signed cover page in order to be processed. The University of Michigan IRB will review the specific forms, sign the Institution Cover Page, and return a scanned copy to the submitting party.** | | | | |
| |  | | --- | | **2. University of Michigan IRB Submission Requirements: Provide the following information to the University of Michigan IRB.** | | * Completed Cover Page uploaded into section 44 of the eResearch application | | * University of Michigan PEERRS up to date | | * University of Michigan ancillary committee reviews | |  | | **3. Schulman Associates IRB Submission instructions:** Upon receiving approval from the University of Michigan IRB to submit to Schulman IRB, submit signed cover page and all required submission documents via Schulman [Secure eSubmission](https://portal.sairb.com/Submission/). Institutional submissions that require Full Board Review should be submitted by 3:00 pm EST one week prior to the desired meeting date. | | **NOTE:** Please visit [SAIRB Institutions Page](http://www.sairb.com/institutions/) for submission requirements for [New Study](http://www.sairb.com/institutions/submit-a-study/) Submissions, [Added Site](http://www.sairb.com/institutions/submit-site/) Submissions, [Federally Funded/FWA](http://www.sairb.com/Investigators/SubmitSite/Pages/fwasite.aspx) and [Transfer of IRB Oversight](http://www.sairb.com/institutions/transfer-irb-oversight-for-sites/) studies. | | | | | |
| **SECTION 2.0: Contact Information** | | | | |
| **1. Institutional Information:** | | | | |
| Institution Name: |  | Protocol #: | |  |
| Principal Investigator: |  | Sponsor Name: | |  |
| **2. Cover Page Completed by (Site Main Point of Contact for Follow-Up Questions):** | | | | |
| Name: |  | Title: |  | |
| Phone: |  | Email: |  | |
| **3. Institutional Contact (AMC) \**For Schulman Associates IRB Internal Use Only*:** | | | | |
| Name: | University of Michigan IRBMED | Contact Role(s): | CC (AMC Site Access 1.0 and CC on Correspondence) | |
| Phone: | N/A | Email: | IRBMEDcentralIRB@umich.edu | |
| **SECTION 3.0: Informed Consent Template Language** | | | | |
| **Will a waiver of Informed Consent be requested?**  Yes**>>>** Fill out the [Request for Waiver or Alteration of Informed Consent Form](http://www.sairb.com/IRBForms/Request_for_Alteration_or_Waiver_of_Informed_Consent_Form.docx)  No**>>>Please note:** The University of Michigan currently has pre-negotiated informed consent language on file with Schulman Associates IRB. | | | | |
| **Please indicate below how the Informed Consent will be submitted:** | | | | |
| Please incorporate the University of Michigan pre-negotiated language into submitted Informed Consent. | | | | |
| The Informed Consent with the University of Michigan pre-negotiated language inserted is being submitted. | | | | |
| NOTE: UM Study team**: Provide Schulman with a copy of section 25-1 of the acknowledged eResearch application. This will be used to ensure appropriate PHI examples are included in consent(s).** | | | | |
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| |  | | --- | | **SECTION 4.0: Institutional Deferral** | | |  |  |  |  | | --- | --- | --- | --- | | **This is to confirm that the University of Michigan hereby authorizes Schulman Associates Institutional Review Board to be the reviewing IRB on the above listed protocol. This institution *wants to be* copied on correspondence between Schulman Associates IRB and the University of Michigan employees as well as granted access to approval documents.** | | | | |  | | | | |  | Signature:  or Authorized Designee:  Judith Birk, JD, Director, IRBMED  Corey Zolondek, PhD, CIP, Assistant Director, IRBMED  Michael Geisser, PhD, Co-Chair, IRBMED  Alan Sugar, MD, Co-Chair, IRBMED  Angela Faber, Ceding Applications Coordinator, IRBMED  Farideh Almani, Authorizations Agreements Coordinator, IRBMED |  | Signature Date (mm/dd/yyyy) | | |
| **SECTION 5.0: Questions** |
| **Please forward any University of Michigan questions to** [**IRBMEDcentralIRB@umich.edu**](mailto:IRBMEDcentralIRB@umich.edu)**. For any Schulman Associates IRB questions, contact Maria Stivers, Manager, Institutional Services at** [**Mstivers@sairb.com**](mailto:Mstivers@sairb.com) **or 513-794-5743.** |