|  |  |  |  |
| --- | --- | --- | --- |
| **MODIFICATION REQUEST FORM-MetroHealth is IRB of Record** | | | |
| **INSTRUCTIONS:**   * Use the attached form to request IRB approval of proposed changes. * Revisions need to be **tracked from the currently approved protocol/consent(s)/supporting documents**. * **Submit this modification request form** as a **word document and upload in eIRB** * Upload documents affected by the modification (i.e., consent, protocol, recruitment material, questionnaires, surveys etc..). Documents must be TRACKED, with updated version date. * In eIRB, under Summarize the modification, state, “see Modification Request form”. * Do not submit this modification request form if you are ONLY updating study personnel (not including PI). | | | |
| Study#:       Submission ID#       PI Name:       Version **Date:**  **Do you confirm that the PI approves the changes being submitted?** **Yes** | | | |
| Minor Changes/Minimal Risk  **OR** | | | |
| Significant Changes/Greater than minimal risk (full board review required): Examples include:   * Changes to Inclusion/Exclusion Criteria * Additional new risk(s) * Changes to Study Design/study plan and/or statistical plan * Change to study PI | | | |
|  | | | |
| 1. | Yes | No | **Are you changing the PI on this study? NEW PI NAME:       Email:**  **NOTE:**  It is MHS policy that principal investigators must be MHS staff (not specific to any one group of MHS employees) OR be an individual who has otherwise been formally granted privileges to practice at MHS. Students, residents, and fellows who work within the auspices of MHS can function in the capacity of the PI; however, these individuals are also required to obtain and secure the appointment of a MHS Responsible Investigator.  ***If YES****, include the following documents with this modification if METROHEALTH IRB is the IRB of Record:*   * *Modification request form (this form).* * *Confirm Current CITI/CREC training of new PI. If NIH funded, GCP training is required.* * *Revised IRB Protocol with New PI information* * *Revised Consent documents with New PI contact information* * *If applicable, you may need to complete and submit the “*[*Change in PI Letter*](https://irb.metrohealth.org/eIRB/sd/Doc/0/A88AS8FAQ08USUKH0K1A4LIG00/Change%20in%20PI%20Letter%20v.%2003-25-24.docx)*” (only if METROHEALTH IRB is the IRB of Record and you are NOT reconsenting subjects).*   **Will the former PI remain on the study?**   Yes  No  ***If YES****, in what position: (indicate)*  Sub-Investigator  Study Coordinator  Other (role)  **Explain the reason for the PI change:**  **Do you confirm that the NEW PI has adequate resources (including space, equipment, and personnel) for conducting the study?**  Yes    **Do you confirm that the NEW PI has adequate financial resources (funding) to conduct this study?**   Yes  ***If YES,*** *provide details of current funding source(s):* |
| 2. | Yes | No | **Has the funding/sponsor for the study changed?**  ***If YES****, list new sponsor/funding source:*  *List funding source(s) being removed:* |
| 3. | Yes | No | **Are you revising the IRB Protocol, Investigator Brochure(s) (IB) OR any surveys/questionnaires, or other supporting documents?**  ***If YES****, submit a copy of the revised IRB protocol, Revised IB, survey/questionnaires, or supporting documents (e.g., Manual of operations).* ***Turn track changes ON****, revise the date, and make all applicable revisions.*   1. *Attach the sponsor’s protocol/IB summary of changes, if applicable.* 2. *\*\*\*Include detailed* ***bulleted list and rationale*** *for the revisions.*   ***If there is a sponsor’s protocol and/or IB summary of changes, you must still list the key revisions.***  L*ist and provide sponsor, DSMB, and/or regulatory agency letters, if applicable*  **ADD BULLETED LIST and RATIONALE:** |
| 4. | Yes | No | **Are you revising the consent form(s)**?  ***If YES****, submit a copy of the revised IRB consent form.* ***Turn track changes ON****, revise the date and make all applicable revisions.*   1. *Attach the sponsor’s tracked and/or clean revised model consent, if applicable.* 2. *\*\*\*Include detailed* ***bulleted list and rationale*** *for the revisions.*   ***If there is a sponsor’s protocol summary of changes, you must still list the key revisions.***  **ADD BULLETED LIST and RATIONALE:** |
| 5. | Yes | No | **Are subjects** **currently enrolled in the study?**  *See additional information on* [*Reconsenting Requirements*](https://irb.metrohealth.org/eIRB/sd/Doc/0/FVBMURFJEK8USUKH0K1A4LIG00/Reconsenting%20Requirements.docx)  ***NOTE:*** *Please answer the questions below regarding RECONSENT:*   1. ***Current study status****:       (i.e., open to enrollment, remaining study activities limited to data analysis, study remains open only for long-term follow up)* 2. ***If RECONSENTING****,* ***include how you will notify subjects of the changes(s) and what is the timing for this notification:*** *(Note: Based on nature of additional risks for example, should subjects be informed of this new information immediately; if not, why not?):* 3. ***If NOT RECONSENTING, provide justification as to why not:*** |
| 6. | Yes | No | **Are you revising the METROHEALTH** **enrollment # OR if the METROHEALTH IRB is serving as the IRB of record for a multisite study, revising the overall enrollment #? *NOTE: If applicable, update the IRB protocol and ALL applicable consent(s)/assent(s).***  ***If YES****, please complete the questions listed below.*   1. Current # of subjects enrolled: 2. METROHEALTH IRB approved enrollment number: 3. METROHEALTH revised enrollment number: 4. What is the reason for increasing or decreasing enrollment at METROHEALTH or Relying sites? 5. Is the METROHEALTH site revising the statistical analysis/consideration of the protocol?   **Yes**  **No**  **If YES**, please explain: |
| 7. | Yes | No | **Are you adding an IND or IDE to a METROHEALTH investigator-initiated trial?**  ***If YES****, include documentation from the FDA.* |
| 8. | Yes | No | **Are you submitting recruitment material that is intended for the prospective subjects that is either new or a modification to already approved material)?**  ***If YES****,* ***Turn track changes ON****, revise the date and make all applicable revisions and submit a copy of the revised recruitment material OR submit the NEW (not previously approved) Recruitment material.*  **LIST ITEMS:**  *For revised recruitment material, outline the requested revisions below.* |
| 9. | Yes | No | **Are you requesting to alter the consenting process: either In-person Electronic Consenting OR Electronic Consenting (e-Consenting)? For additional guidance see: [HERE](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html)** ***NOTE:*** *Please complete the questions listed below and add the* [“Consenting Process](https://irb.metrohealth.org/eIRB/sd/Doc/0/8D1V9780RS8UUUKH0K1A4LIG00/CONSENTING%20PROCESS.docx)*” template to your approved IRB protocol—* ***Turn track changes ON****, revise the date and make all applicable revisions.*   1. *Include a detailed* ***rationale*** *for this request:*      1. *If applicable, did the study team receive Sponsor approval for e-consent?* **Yes**  **No**  **N/A**  * ***If YES****, please submit a copy of the approval documentation (i.e., email correspondence).* |
| 10. | Yes | No | **Are you revising the Data Security Plan (DSP)? [i.e., how data is collected, transferred, or stored].**  ***Turn track changes ON****, revise the date and make all applicable revisions.*  ***If YES****, include detailed* ***bulleted list and rationale:*** |
| 11. | Yes | No | **Does this modification include submission of a translated consent document or any other translated supporting documents?**  ***If YES,*** *please complete the questions listed below.*   1. Are any additional revisions required to the *ENGLISH* version of the document? **Yes**  **No**  * ***If YES,*** *those revisions must be approved by the IRB BEFORE you can submit a modification to add a translated version.*  1. Is the translated document presented in a way to accurately match it to the corresponding IRB approved *ENGLISH* counterpart? **Yes**  **No**     * ***Suggestion****: The footer of the translated document could include the version date of the corresponding IRB approved ENGLISH counterpart and date of translation.* 2. Is a Certificate of Translation included? **Yes**  **No** 3. Will a study team member perform the translation? **Yes**  **No** |
| 12. | Yes | No | **Does this modification revise a MetroHealth investigator initiated single site study to a multisite study where MetroHealth IRB will serve as the single IRB of record (sIRB)?**  **(i.e., METROHEALTH IRB will be serving as the reviewing IRB for non- METROHEALTH sites)? Please contact the IRB staff for assistance.**  ***If YES****, the protocol must be written/revised to address overall enrollment #’s, data safety and monitoring, and statistical analysis. A multisite protocol must be created or existing protocol modified to be adhered to by all Relying sites.* |
| 13. | Yes | No | **Does this modification** **affect institutions already approved to rely on the METROHEALTH IRB as the sIRB of record**?  ***If YES,*** *which Relying site(s) are affected by this modification?*    *Add site specific information here. (e.g., PI change at Site A only)* |