|  |  |
| --- | --- |
| SUPPLEMENT to IRB Submission Form/External IRB Request  Safety During Pandemic  Version dated 8/1/2021 | |
| The following questions refer to research staff and participant safety during pandemic. Yale established guidelines for safety on the campus and in research. Researchers must familiarize themselves with the guidelines:   * Travel: <https://covid19.yale.edu/travel-guidelines> * Health: <https://covid19.yale.edu/health-guidelines> * Work on campus: <https://your.yale.edu/work-yale/workplace-guidance>   This form is not required for secondary data analysis research. | |
| **IRES IRB#** | |
| **Attestation** | |
|  | **I will comply with all relevant (local, national, institutional, state, and Yale) travel, health, and safety guidelines during conduct of this research.** |
| **1.** | **Does your research include in-person interactions with participants or research staff?** |
| **YES**  **NO - If you answered NO, you do not have to complete the rest of this questionnaire** |
| **2.** | **Where is your research conducted?** |
|  | On Yale/YNHH System Campus   * Include specific locations of the buildings: Click or tap here to enter text.   Outside of Yale/YNHH (*if checked, complete the questions below*):   * State: Click or tap here to enter text. * Country: Click or tap here to enter text. * Description of the research locations: Click or tap here to enter text. |
| **3.** | **Categorize your study:** |
|  | **Therapeutic research (biomedical) conducted on Yale/YNHH campus - You do not have to complete the rest of this questionnaire**  **Therapeutic research (biomedical) conducted outside of Yale/YNHH campus**  **Research with in-person interactions between vaccinated Yale affiliates and individual research participant (not in group setting) that can be accomplished at six-foot physical distance and appropriate PPE (e.g. masking) - You do not have to complete the rest of this questionnaire**  **Research involving in-person interactions with groups of research participants gathered together explicitly for the purpose of research, e.g., focus groups**  **Research that may involve staff who are not vaccinated, such as local research assistants, subcontractors, enumerators, or others**  **None of the above applies** |
| **4** | **Describe how appropriate and effective social distancing and PPE use will be accomplished.** |
|  |
| **5** | **If your research involves staff who are not fully vaccinated or whose vaccination status is unknown, describe training and/or other protocols you will provide to ensure that non-Yale affiliates engaged in this research will not be exposed to infection risks greater than a vaccinated Yale researcher’s risk. You may attach training manuals and protocols, plans for providing PPE and correct instruction of its use, information about researchers’ local travel, etc.** |
| **N/A (only Yale staff will be involved, or I will confirm vaccination status of non-Yale affiliates)** |
| **6** | **Does your research involve any non-therapeutic research procedures (not conducted at the time of standard of care procedures) that could increase the symptoms of COVID infections or compromise the participant’s immune system? For example, vaping, sham surgery, etc.?** |
| **NO**  **YES:** List the specific procedures |
| **6A** | **If you answered YES to question 6, describe a plan to minimize the risk of participants’ exposure to COVID (PPE in use, cleaning protocols, etc.)** |
|  |
| **IN-PERSON INTERNATIONAL RESEARCH ONLY** | |
| **1.** | **Describe the length of stay in the countries where research activities will occur.** |
|  |  |
| **2.** | **Describe the research related work that will be conducted during the quarantine period if one is required after arriving in the country.** |
|  |  |
| **3.** | **Describe the current infection rates and COVID impacts in the country.** |
|  |  |
| **4.** | **Describe the current local laws and guidelines related to safety and allowable activities during COVID pandemic.** |
|  |  |