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| Instructions |
| * Complete this template when adding or removing individuals to FDA studies conducted under an Investigational New Drug (IND) or an Investigational Device Exemption (IDE). * CLICK™ IRB   + Include the template with a Modification or a Modification and Continuing Review Submission.   + Select Modification scope:     - “Study team member information” to modify the Study Team Members SmartForm to add or remove individuals AND     - “Other parts of the study” to modify the Supporting Documents SmartForm to upload this template.   + Upload this completed template to the “Supporting Documents” SmartForm page. * See HRPP Manual Section 7 for more information regarding studies that involve investigational drugs or devices. |
| Complete Questions 1 – 4. |
| 1. Study title. |
| Addition of Team Members to the Study |
| 2. Are you requesting that individuals be ADDED to the study?  No  Yes  *If you answered yes, complete 2A., 2B., etc. for as many individuals as needed; use multiple forms as needed.* |
| 2A. Complete the following information to ADD an individual to the study. |
| Name of Individual. |
| Title: |
| Is this individual listed on the 1572 for this study (IND)?  No  Yes |
| Describe the individual’s role in the study, including the procedures they will be performing. |
| Describe the individual’s qualifications for their role, including relevant professional training or degree and experience with the procedures they will perform, and/or who will be responsible for training them with the procedures they will be performing. |
| 2B. Complete the following information to ADD an individual to the study. |
| Name of Individual. |
| Title: |
| Is this individual listed on the 1572 for this study (IND)?  No  Yes |
| Describe the individual’s role in the study, including the procedures they will be performing. |
| Describe the individual’s qualifications for their role, including relevant professional training or degree and experience with the procedures they will perform, and/or who will be responsible for training them with the procedures they will be performing. |
| 2C. Complete the following information to ADD an individual to the study. |
| Name of Individual. |
| Title. |
| Is this individual listed on the 1572 for this study (IND)?  No  Yes |
| Describe the individual’s role in the study, including the procedures they will be performing. |
| Describe the individual’s qualifications for their role, including relevant professional training or degree and experience with the procedures they will perform, and/or who will be responsible for training them with the procedures they will be performing. |
| 2D. Complete the following information to ADD an individual to the study. |
| Name of Individual. |
| Title. |
| Is this individual listed on the 1572 for this study (IND)?  No  Yes |
| Describe the individual’s role in the study, including the procedures they will be performing. |
| Describe the individual’s qualifications for their role, including relevant professional training or degree and experience with the procedures they will perform, and/or who will be responsible for training them with the procedures they will be performing. |
| Removal of Team Members from the Study |
| 3. Are you requesting that individuals be REMOVED from the study?  No  Yes  *If you answered yes, complete 3A, 3B, etc. for as many individuals as needed; use multiple forms as needed.* |
| 3A. Complete the following information to REMOVE an individual from the study. |
| Name of Individual. |
| Title. |
| What was the individual’s role in the study? |
| Describe whether another individual will be replacing this individual. |
| 3B. Complete the following information to REMOVE an individual from the study. |
| Name of Individual. |
| Title. |
| What was the individual’s role in the study? |
| Describe whether another individual will be replacing this individual. |
| 3C. Complete the following information to REMOVE an individual from the study. |
| Name of Individual. |
| Title. |
| What was the individual’s role in the study? |
| Describe whether another individual will be replacing this individual. |
| 3D. Complete the following information to REMOVE an individual from the study. |
| Name of Individual. |
| Title. |
| What was the individual’s role in the study? |
| Describe whether another individual will be replacing this individual. |
| Statement of Investigator (FDA Form 1572) |
| 4. Will the 1572 form be updated based on the personnel change?  No  Yes |
| The FDA definition of sub-investigator includes any individual member of the research team who assists the investigator and makes a direct and significant contribution to the data. The determination of whether an individual should be included as a sub-investigator should be based on whether the individual is performing significant duties related to the trial. In general, if an individual is directly involved in the performance of study-specific procedures that make a significant contribution to the data and/or the collection of data, that person should be listed on the 1572. Anyone who documents results or findings on a study-specific form always should be listed on the Form 1572.  There are two instances when it is necessary for an investigator to complete and sign a new 1572: when an investigator is participating in a new protocol that has been added to the IND and when a new investigator is added to the study (21 CFR 312.53(c)). If there are other changes to information contained on a signed and dated 1572 (e.g., an IRB address change, the addition of new subinvestigators, the addition of a clinical research lab), the investigator should document the changes in the clinical study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator. The sponsor can accumulate certain changes and submit this information to the IND in, for example, an information amendment or a protocol amendment. |