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| SUPPLEMENT to IRB Submission Form/External IRB RequestResearch Under an IND or IDE Held by a Yale InvestigatorVersion dated 7/1/2021 |
| This section is required if the study is conducted under an IND or IDE that is held by a Yale School of Medicine Investigator or when exemption from IND is requested by the Investigator. A Yale University policy related to investigator-sponsored INDs and IDEs was published in May 2021. Please visit <https://medicine.yale.edu/ycci/researchservices/supportservices/general/indide/> for more information. |
| **IRES IRB#**  |
| **1.**[ ] N/A (complete #2) | **Name of individual who is the IND Sponsor:**  |
| Is this study the initial IND study or a study being submitted to an existing open IND? [ ]  Initial [ ]  Existing |
| **2.**[ ] N/A(complete #1) | **Name of individual who is the IDE Sponsor:** |
| Is this study the initial IDE study or a study being submitted to an existing open IDE? [ ]  Initial [ ]  Existing |
| **3.** | **Who is managing the submissions to FDA?** |
| [ ] YCCI IND/IDE Office[ ] External CRO, specify: [ ] Other, specify:  |
| **4.** | **Who is performing study monitoring for the study?** |
| [ ]  YCCI Monitoring Office[ ]  External Data Coordination Center, specify: [ ]  External CRO, specify: [ ]  Other, please describe:  |
| **5.** | **Who is performing project management activities for the study?** |
| [ ]  YCCI Project Management Office [ ]  External Coordination Center, specify: [ ]  Other, please describe:  |
| **6.**  | **What system will be used for electronic data capture?****Note: 21 CFR Part 11 compliant system is required for FDA regulated research.**[ ] OnCore[ ] RedCap[ ] Advarra EDC[ ] Other: |