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| SUPPLEMENT to IRB Submission Form/External IRB Request  Research Under an IND or IDE Held by a Yale Investigator  Version 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: |