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**Note to File**

**Date:**

**RE: Delegation of Responsibility and Key Personnel**

Per local practice, only key personnel are listed on study-specific training and delegation logs. The Principal Investigator (PI) determines the key personnel for each study depending on the individual's level of responsibility.

"Key personnel" is defined as individuals who have a significant role in performing critical study functions and making direct contributions to the data. The institution maintains current CITI Human Subjects and CITI GCP training certifications for each of these individuals, however CVs and Licenses are maintained/provided only for those individuals acting as Investigators, either PI (s) or Sub-I (s).

• These individuals include, but are not limited to, those that are listed in the staff tab in OnCore (clinical trials management system) such as Principal Investigator(s), Sub-Investigator(s), Research Nurse( s ), Clinical Research Coordinator( s ), IRB Coordinator( s ), Pharmacokinetics Technician(s), Research Assistant(s), Investigational Pharmacist(s), Pharmacy Technician(s), and others as determined by the PI.

• A temporary substitute ( e.g., an individual that covers for key personnel that are out of office) is not considered key personnel and will not be added to study-specific logs. The PI and key personnel are responsible for providing protocol and role-specific training and oversight of those individuals.

• Clinical staff(e.g., nurses and fellows) who provide ancillary or intermittent care as part of their day to day responsibility/role but who do not make a direct and significant contribution to the clinical data are not considered key personnel and will not be added to study-specific logs. The PI and key personnel are responsible for providing protocol and role-specific training and oversight of those individuals.

Signed,

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