Investigators

Demographic Questions, Version 1.1
Single IRB

PIN: _____
Date: _____
Interviewer: _____

INVESTIGATORS		
No.	**Question**	**Answer**
1.	What is your specialty? *Check all that apply*	❑ Allergy and asthma ❑ Cardiology ❑ Dermatology ❑ Endocrinology ❑ Gastroenterology ❑ General internal medicine ❑ General surgery ❑ Hematology ❑ Immunology ❑ Infectious disease ❑ Nephrology ❑ Neurology ❑ Obstetrics/gynecology ❑ Oncology ❑ Ophthalmology ❑ Orthopedics ❑ Otorhinolaryngology ❑ Pediatrician ❑ Primary care provider ❑ Psychiatry ❑ Pulmonary ❑ Rheumatology ❑ Urology ❑ Other (please specify): _____
2.	Which best describes the type of organization with which you are currently affiliated? ***[Read aloud responses]*** *Select only one*	❑ Academic institution or academic health system with research and education opportunities ❑ Pharmaceutical or medical device industry ❑ Community-based hospital with no affiliated academic institution ❑ Dedicated research site with no affiliated clinical practice responsibility ❑ Other (please specify): _____
3.	How many years have you served as a PI, sub-PI, or Co-I of multi-site, FDA-regulated clinical research?	[_____]

INVESTIGATORS		
No.	**Question**	**Answer**
4.	How many multi-site, FDA-regulated studies do you *currently* serve as the PI, sub-PI, or Co-I?	[_____]
5.	Including current studies, which types of multi-site, FDA-regulated studies have you conducted as the PI, sub-PI, or Co-I? ***[Read aloud stem responses; if yes, then follow up with bullet responses]*** *Select all that apply*	❑ Interventional trials for registrational purposes (typically Phase III) (then ask, check all that apply) ❑ Drug ❑ Biologic ❑ Medical devices ❑ Dose-ranging trials (typically Phase IIa/b) (then ask, check all that apply) ❑ Drug ❑ Biologic ❑ Medical devices ❑ Safety trials (typically Phase I) (then ask, check all that apply) ❑ Drug ❑ Biologic ❑ Medical devices ❑ Other (please specify): _____
6.	Have you used a single IRB before for *any* of your clinical studies?	❑ Yes ❑ No→ **Skip to Q9** ❑ Do not recall→ **Skip to Q9**
7.	Were any of those studies FDA-regulated?	a. Yes b. No c. Do not recall
8.	Were you involved in the selection of the relying IRB?	a. Yes b. No c. Do not recall
9.	Can we re-contact you if we need to follow up on any of the information you provide during the interview?	a. Yes b. No
10.	Can we re-contact you to provide you with a summary of the study's findings?	a. Yes b. No

Thank you. That concludes all my demographic questions. [Confirm interview scheduling]