



NSABP FOUNDATION, INC.

RESEARCH COLLABORATORS DEFINITIONS

SITE RELATED TERMS

Central Monitored Site - a Treating Site that has original source documentation and investigator and IRB regulatory documents available for the on-site monitoring visits, and/or a pharmacy. The monitoring visit may be related to that Central Monitored Site's own industry funded and other non-federally funded research studies and/or such activities of a Remote Site(s).

Central Pharmacy Site – a pharmacy location that receives investigational product for dispensing to Remote Sites.

Legal Entity – the entity authorized to enter into contracts on behalf of a Research Collaborator.

Payee Institution – the institution that checks are made payable to from NSABP.

Research Collaborator– an institution that has been accepted by NSABP to participate in NSABP industry funded and other non-federally funded research studies and is the institution, or its Legal Entity, that enters into the contractual agreements with NSABP. The Research Collaborator must be both a Treating Site and a Central Monitored Site.

Research Collaborator Network – a network of sites comprised of a Research Collaborator and its Research Sites.

Remote Site – a Treating Site that is monitored at a Central Monitored Site. A Remote Site must (i) have the capability to forward original source documents to the Central Monitored Site for monitoring, and (ii) receive drug from its Central Monitored Site's pharmacy.

Research Site – a Treating Site or Central Pharmacy Site that is cooperating with a Research Collaborator and through that cooperation participates in NSABP industry funded and other non-federally funded research studies. A Research Site may be a legal affiliate/subsidiary of the Research Collaborator or it may be a separate legal entity.

Treating Site – a location where a study subject is seen, consented, treated, and/or data are collected and completed for an NSABP industry funded and other non-federally funded research study.



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PERSONNEL RELATED TERMS

Check Addressee – the person designated by the Research Collaborator to receive checks issued by NSABP Foundation related to the industry funded and other non-federally funded research studies. This is not the Payee Institution. The Check Addressee will default to the Collaborating Scientific Investigator unless otherwise designated.

Collaborating Scientific Investigator ("CSI") – the Investigator designated by the Research Collaborator to be the primary scientific contact related to the Research Collaborator's relationship with NSABP.

Contract Contact ("CC") – the person designated by the Research Collaborator who is authorized to interact with NSABP Foundation regarding contracts.

Fiscal Contact ("FC") – the person designated by the Research Collaborator as the primary contact for payment related communications.

Investigator - a licensed health care professional who is a qualified clinical investigator, and who is employed or otherwise engaged by a Research Collaborator or one of its Research Sites to conduct NSABP industry funded or other non-federally funded research studies.

Program Coordinator ("PC") – the member of the Research Staff designated by the Research Collaborator, who is the primary contact for administration of NSABP programs at the Research Collaborator.

Research Staff – individuals identified by the Research Collaborator, CSI, or a Study PI, and approved by NSABP, to be listed on the NSABP Research Collaborator roster. Research Staff may be designated by a Study PI to be on the study-specific delegation of duties log as having significant roles in the conduct of an NSABP industry funded and other non-federally funded research study.

Study Principal Investigator ("Study PI") – the principal investigator designated by the Research Collaborator, who is named on an NSABP industry funded and other non-federally funded research study IRB approval letter for the Research Collaborator. Each Study PI must have oversight of the study for the Research Sites listed on the Form FDA 1572 associated with such IRB approval letter.