**3.5 Overall Structure of the Study Team**

*Attach as a PDF file. Provide a brief overview of the organizational structure of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers. Two samples follow, one for a trial managed by a contract research organization, and one for a trial managed by the PI.*

# SAMPLE 1: TRIAL MANAGED BY A CONTRACT RESEARCH ORGANIZATION

**3.5 Overall Structure of the Study Team**

## Administrative Sites

This study will managed by XYZ, a contract research organization.

## Data/Coordinating Sites

Statistical, data collection and management, site monitoring, and clinical trial operations support will be provided through a Statistical and Clinical Coordinating Center (grant number…). Clinical product support will be provided as needed through the NIAID Division of Allergy, Immunology, and Transplantation (DAIT) Clinical Products Center (CPC).

## Enrollment/Participating Sites

This study will take place at ten major SLE centers within the United States where the site principal investigators are known to be highly qualified and have populations suitable for this study: Sites that have already provided us with letters of intention to participate include X, Y and Z.

Final qualification of Sites will involve two steps: first there will be a review of licenses and curriculum vitae for all investigators and sub-investigators. Subsequently there will be on-site visits to assess equipment and infrastructure, enrollment rates in past trials, training certificates and licenses, staff comprehension of human subjects protections, and site standard operating procedures. The site and institution must not have active FDA sanctions. Regulatory binders must be orderly and complete. Since there will be an unblinded pharmacist, the credentials and experience of that individual experience as well as the adequacy of a locked and appropriately stocked pharmacy will be examined.

## Separate Laboratory

We will use XYZ, an experienced nation-wide central laboratory, for the processing of safety laboratories. Each site will be provided with appropriate licenses and certificates from the central laboratory.

# SAMPLE 2: MULTI-SITE TRIAL MANAGED BY THE PI

**3.5 Overall Structure of the Study Team**

## Administrative Sites

### The study will be overseen by Drs. Pumpkin and Spice, with study coordinators working with each PBRN who will assure standard conduct of the study across PBRNs. Our project team has been organized into a coordination/analysis group (see Data/Coordinating Sites below) and PBRN-specific groups (see Enrollment/Participating Sites below). We will hold yearly face-to-face meetings and weekly conference calls or these groups. These calls and meetings will develop joint protocols and rules manuals for all aspects of the project and assure that each PBRN is implementing the interventions and collecting data in an identical manner as well as addressing any issues that might arise after study initiation, including practice changes during the study (see Multiple-PI plan for further details).

## Data/Coordinating Sites

Data will be collected by practice facilitators, described below. Data management, statistical support, site monitoring, and clinical trial operations support will be provided through by the Oklahoma Clinical and Translational Science Institute (OCTSI).

## Enrollment/Participating Sites

This study will take place in two states, Oklahoma and South Carolina, where there is a diversity of patient populations including most located in rural settings. We will have the benefit of collaborating with two PBRNs, the Oklahoma Child Health Research Network (OCHRN) and the South Carolina Pediatric Practice Research Network (SCPPRN). The networks have established records of productivity and a history of working collaboratively on several relevant projects**.**

Each PBRN is overseen by a director, has faculty trained as academic detailers, and has access to trained, certified practice facilitators. Activities of OCHRN are administered through OCTSI. OCTSI employs more than 20 certified practice facilitators. These individuals are geographically distributed throughout the state and have strong relationships with clinical practices within their regions. The South Carolina PBRN directly employs a trained certified practice facilitator who has a strong ongoing relationship with member practices. OCTSI will provide project-specific training and coordinate the practice facilitators in all PBRNs. Practice facilitators will collect data, provide feedback to practices, and work to facilitate practice change.

The PIs, with support from the directors of the two PBRNs, will be responsible for recruiting practices from within their respective networks. Practice facilitators will provide the informed consent and enrollment of providers and nurses at each practice, as well as patients participating in the study.

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