PCAC Phase I Evaluation
Interview Guide: PCAC Members

Format: 30-minute semi-structured (confidential) phone interview

I. PCAC Role

a. Please describe your understanding of the role the PCAC is intended to play within CAPriCORN.
   Probes:
   • Consult/advise/vote on/create:
     o Network policies and procedures
     o Ethics and regulatory issues
     o Research topic generation and prioritization
     o Proposal/protocol review
     o Patient recruitment
     o Communications with broader community
     o Dissemination
   • What about the PCAC’s role is not clear to you?
   • How can we work to clarify your understanding of the PCAC and its responsibilities?

b. To what extent has the PCAC fulfilled or are they fulfilling these functions during Phase I? Please explain.
   Probes:
   • What contributions have they made?
   • What has not yet been accomplished?
   • Which functions do you see as most important?
   • What should the priorities be during the remainder of Phase I?

c. What should the role of the PCAC be during Phase II?

   Phase I: Focused on the development and expansion of 29 individual CDRN and PPRN networks.
   Phase II: Focuses on enabling the participating networks (34 total; 27 from Phase I, 7 new) becoming fully capable of supporting both randomized and observation CER studies, rapid-cycle studies, and other types of health research using standardized data sets with strong patient privacy and security protections.

   Probes:
   • How similar to Phase I?
• How different from Phase I?

II. PCAC Composition

a. How would you describe the composition of the PCAC?
   Probes:
   • Size and distribution
   • Types of patient representatives
   • Types of clinician representatives

b. Do you think the PCAC is the appropriate size? Why or why not?
   Probes:
   • Should it be larger?
   • Should it be smaller?

c. Do you think the PCAC is the appropriate composition? Why or why not?
   Probes:
   • Should there be more or fewer patient representatives?
   • Should there be more or fewer clinicians?
   • Should there be different types of patients or clinicians?
   • Should the qualifications for PCAC membership be different?

III. PCAC Interactions

a. There are a number of additional external groups that exist within CAPriCORN (ERWG, CRC, cohort groups), what contributions can or should the PCAC make to the work of these groups? (Please see the brief descriptions of each listed on pg. 3)
   Probes:
   • What is the best approach to incorporating PCAC input into the work of these groups?
     o Regular participation by a designated PCAC member?
     o Periodic participation by one or more PCAC members?
     o Attendance by committee or workgroup leads at quarterly PCAC meetings?
     o Attendance by PCAC leadership at committee or workgroup meetings?

IV. Training Needs

a. What do you consider the most important training needs for the PCAC as we move into Phase II?
   Probes:
   a. Clinical Research
   b. CAPriCORN Disease Cohorts
   c. IRB training
   d. PCORnet

b. What knowledge and/or skills are you hoping to develop as a result of this training?
c. Do you have any suggestions for how best to approach presenting these topics to the PCAC?

V. **Wrap-Up**

a. Do you have any other thoughts or suggestions that would help to optimize PCAC contributions toward meeting the goals of CAPriCORN?

b. Do you have any other thoughts or suggestions regarding the process by which the PCAC is engaged in the work of CAPriCORN?

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**Working Group Descriptions:**

**Ethics and Regulatory (ERWG):** Comprised of members from the primary sites affiliated with CAPriCORN. Together these members have worked on developing procedures for the work of the central Institutional Review Board (called the Chicago Area IRB, CHAIRb) and policies for patient protection in line with HIPAA (Health Insurance Portability and Accountability Act).

**Clinical Research (CRWG):** Comprised of both experts in the five cohorts on which CAPriCORN’s work is focused along with representation of all of the institutions involved with CAPriCORN. The group has developed cohort characterization plans, surveys for collecting the appropriate information for the pending research, as well as begun the development of protocols for review by the CHAIRb. Subsets of CRWG members participate in cohort committees focused on Anemia, Asthma, Sickle Cell Disease (SCD), Weight Management, and Clostridium difficile (C. diff).

**Cohort Committees:** As part of the proposal development phase, six disease areas were selected as key conditions of focus for the network. These disease areas were chosen based upon the interest areas of local investigators and nationally prominent research expertise among the CAPriCORN member institutions. CAPriCORN disease cohorts are as follows: Anemia, Asthma, Sickle Cell Disease (SCD), Weight Management, and Clostridium difficile (C. diff). Comprised of researchers, clinicians, and patients these cohorts will be used to identify and answer clinically meaningful comparative research questions using the infrastructure being developed as part of Phase I.