Clinical Trials Methodology Workshop
Pre-course Check List

The Following are required:

1. This fall you will receive feedback on your application from your Protocol Development Group (PDG) faculty. **Address any queries or issues raised and revise your protocol as needed**. You are encouraged to communicate with the PDG leader by phone or email to review the critique and get advice; the better prepared you are before the workshop starts, the greater progress you will make.

2. Write a one sentence Title for your protocol that incorporates the type of study you plan to do, e.g. "Single center open label Phase 2 Study of… "

3. Write a draft of Background and Significance. This should be only 1-3 paragraphs, no more than 1 page.

   This section should include:
   - Discussion of important literature and data that are relevant to the trial and that provide background for the trial
   - Applicable clinical, epidemiological, or public health background or context of the clinical trial
   - Importance of the clinical trial and any relevant treatment issues or controversies

4. Write a rough draft of your Primary and Secondary Objectives and the Endpoints or Outcome Measures you plan to use to address each objective. (These will be extensively revised in your PDG group.)

   An objective is the purpose for performing the study in terms of the scientific question to be answered. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose (e.g., accuracy, diagnostic utility, safety, effectiveness) and/or specific purpose (e.g., superiority, effect on disease outcome, disease severity, or health behavior).

   A study endpoint or outcome measure is a specific measurement or observation to assess the effect of the study intervention. Give succinct, but precise definitions of the study endpoints used to address each of the study's primary and secondary objectives (e.g., specific laboratory tests that define safety or efficacy, clinical assessments of disease status, assessments of psychological characteristics, patient reported outcomes, behaviors or health outcomes).

5. Collect bibliography relevant to your protocol; bring key references with you.

6. Obtain copy of Patient Informed Consent Form/HIPAA template from home institution.

7. Determine the volume of potential study subjects available at your institution per year. If you do not think there are enough for your project, identify investigators/institutions who share your interest and will collaborate with you. If you do not have a realistic plan for accrual, you may need to re-think your proposal.

8. Complete the Collaborative Institutional Training Initiative (CITI) online course (https://www.citiprogram.org/), or equivalent training in human subject research regulations.

Please submit a certificate of completion of the CITI course or other proof of meeting this requirement by November 15, 2022. Send to dor@rsna.org

It is strongly recommended that you address the following before attending the Workshop:

1. Review the list of recommended pre-course materials and refresh your command of basic biostatistics using one of the suggested textbooks or the statistics series from AJR or Radiology, which are attached to this email.

   Additional references are listed which maybe pertinent to your project, for example if you are proposing a study of diagnostic accuracy, screening, or biomarkers.

2. Attend an IRB meeting at your home institution.

3. Review availability of institutional resources relevant to the proposed project, such as:

   a. statistical expertise;

   b. clinical database infrastructure;

   c. collaborating clinicians interested in the problem and/or willing to assist with patient accrual;

   d. pathologist or other specialties involved in defining the reference standard information, if relevant;

   e. image processing experts, if relevant;

   f. informatics support, if relevant;

   g. research assistant, or research nurse, if needed;

   h. basic scientists studying aspects of the problem.