WIC Protocol Format Checklist

October 2013

This checklist describes the elements that must be included in protocol submitted to WIC. Protocols that do not address the elements below will be returned to the study team for revision. Please note the following:

*WIC will accept protocols that use a different format ONLY if they address the elements below.

*A project summary may be substituted for a formal protocol for studies that will not be enrolling subjects at any WIC site (e.g., chart reviews, specimen analysis). A project summary may be brief and should describe what study activities will be conducted at each site and who will be involved in conducting those activities at each site. The project summary must provide sufficient detail for the involved IRBs to determine whether deferral of IRB oversight to a single IRB is appropriate.

☐ Study Objectives

State the broad research goal and specific aims of the project in a clear, concise manner using lay language.

☐ Study Significance

Explain what the proposed research is intended to accomplish and the importance of the results.

☐ Research Design and Procedures

Describe the research design and the procedures to be used to accomplish the specific aims of the project.

☐ Study Procedures

Describe what research activities will take place at each site. Be sure to specify any differences in study procedures across study sites. If ALL study procedures will be identical across study sites, state this.

☐ Study Coordination

Identify the lead site of the study. The protocol also must include a plan for communication among the involved sites and should address the following:

*Who is responsible for ensuring each site knows what they should be doing according to the approved protocol?

*Who is responsible for communicating protocol changes/amendments to all sites?

*Who is responsible at each for reporting noncompliance, unanticipated problems, and adverse events to the lead site?

☐ Subject Population

Describe the subject population to be enrolled for this study, including any vulnerable populations (e.g., children, prisoners, non-English speakers). Describe the exclusion and inclusion criteria for subjects to be enrolled for this study.

☐ Identification and Recruitment of Subjects

Describe how subjects will be identified and recruited at each site. Be sure to specify any differences in how subjects will be identified and recruited across study sites. Specific issues that should be addressed include:

*Will medical records be accessed to identify potential subjects?
*How will potential subjects be approached about study participation and who will approach them?
*What methods will be used to recruit subjects at each site?

☐ Data Collection

Describe how data will be collected and protected at each site.

☐ Sample/Specimen Collection

Describe how samples will be collected at each site. Include how they will be stored, protected, and shared, as applicable. If samples will be banked for future use, describe this.

☐ Timeline

The protocol should include a timeline in chart or graph format that reflects the project activities and anticipated time frame of completion.

☐ Study Monitoring

If your study involves interaction with living individuals, describe your institution's standard and, if applicable, study specific plans for monitoring at each site involved in the research.