Protocol Elements Checklist

(From the Einstein IRB)

Use this checklist as a guide to ensure that a protocol to be submitted for IRB review is scientifically sound and adequately designed, and that you have included all the required elements. This outline includes statistical recommendations that have been provided by the Division of Biostatistics. Some of these may not be applicable to a feasibility study or a pilot study in which the analyses are mainly descriptive. It is highly recommended that you consult with a statistician prior to submission of a protocol for review.

1) Background/Significance

a) Include an evaluative review of the state of current knowledge in the area of the research and indicate how the study builds on or extends this body of information.
b) The review should clearly place the research in context to form the basis for its rationale.
c) Present the results of any pilot studies.

2) Study Design

a) Describe the study design, e.g. clinical trial (phase I, II, III); observational cohort study; case-control study.
   - State study objectives, and if applicable, specific hypotheses
   - Clearly state target population and recruitment methods
   - State inclusion/exclusion criteria clearly
   - State primary and secondary outcome(s)

   ➢ For Randomized clinical trials
   - Indicate whether a parallel or crossover study, and the number of treatment groups
   - Describe randomization and blinding procedures
   - Describe what safety outcomes will be monitored
   - Include a data safety monitoring plan

   ➢ For Observational studies
   - Describe predictors of interest along with potential confounders and effect modifiers
   - Describe matching criteria, if applicable
   - Describe duration of follow-up, and timing of data collection

b) Describe the planned interventions and their timing.
c) Define the outcome measures pertaining to each aim.

3) Study Population

a) Describe the study population: number, age range; health status or other characteristics pertinent to the study

- Describe how the sample size and power of the study were determined, including the statistical approach and any assumptions on which the calculations are based.
- Take into account anticipated drop-out or loss-to-follow up rate.
- Pilot and exploratory studies do not need formal sample size calculations but a data analysis plan should still be included (see above)

b) State inclusion/exclusion criteria.
c) Provide appropriate justification for the exclusion of any population group (e.g. Minors, Women, Ethnic groups, Non-English Speaking people, etc.)

[N.B. federal regulations require inclusion of women, minors and minority group members in research unless adequate justification is provided**.** Acceptable justifications for exclusion of minors are listed below in Appendix 1**]**.

d) State whether subjects who do not have the capacity to consent will be enrolled.
   - Provide justification for inclusion of such subjects.
   - Describe how surrogate consent will be obtained.
e) Identify the sources of research material.
   - State whether materials will be obtained from individually identifiable living human subjects.
   - Indicate the type of material (*e.g.* blood samples, tissue specimens, records, data, etc.)
   - Indicate whether the material will be obtained as part of routine clinical care or for the specific purpose of research.

4) Participant Recruitment

a) Describe the plan for participant recruitment.
b) Describe sources and method(s) for recruitment of both subjects and controls.
c) Describe the method(s) for ensuring voluntariness of participation.
d) Describe the plan for Patient Privacy protection.

5) Informed Consent

a) Provide an Informed Consent Form containing all of the necessary elements (see below).
b) Describe the informed consent process.
   - Who will obtain consent?
   - Where will consent be obtained?
c) Provide clear justification if a waiver or alteration of the informed consent process is requested.
d) If minors are included, describe the plan for parental approval and child assent.

e) Describe any costs or remuneration:
   - State any reimbursement or remuneration, including the pro-rating scale if multiple visits are required.
   - Clearly identify tests and procedures as for Research Purposes or Standard Clinical Care.
   - Include a listing of any costs (tests/procedures/supplies which are the responsibility of the subject).

f) For studies with complicated schedules, provide a 1-page table or flow diagram.
g) Stat the plan for obtaining HIPAA authorization (or waiver as appropriate).

6) Risk/Benefit

a) Identify all anticipated risks (*e.g.* medical, social, psychological, and/or legal).
b) Describe how anticipated risks will be minimized.
c) Document how potential benefits to participants or others justify potential risks.
d) Describe the plan for data storage and for maintenance of subjects' confidentiality.
e) If subjects will be video or audio-taped, address the following: What will be taped, how the tapes will be used, when the tapes will be destroyed, and whether taped subjects will be compensated.

7) Data Analysis

a) Clearly state statistical methods to be used to evaluate study objectives
b) Describe methods for interim analyses or early stopping, if applicable
c) Describe how possible confounding and/or effect modification will be addressed
d) Describe how loss to follow up will be addressed

8) Data quality control and database management.

a) Describe methods for data entry and data management.
b) Describe the mechanism for checking and editing the data.
c) Describe computer data security and subject confidentiality. This is particularly important for multicenter studies.

References: Include a bibliography of all references in the protocol

Appendix 1: Criteria for Exclusion of Minors from Research protocols

1. the research topic to be studied is irrelevant to children;
2. there are laws or regulations barring the inclusion of children in the research. For example, the regulations for protection of human subjects allow consenting adults to accept a higher level of risk than is permitted for children;
3. the knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. NIH

program staff can be contacted for guidance on this issue if the information is not readily available;

4. a separate, age-specific study in children is warranted and preferable (consult NIH Policy for specific example of such studies).
5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.
6. Study designs aimed at collecting additional data on pre-enrolled adult study participants (e.g., longitudinal follow-up studies that did not include data on children).
7. Other special cases justified by the investigator and found acceptable to the review group and the Institute Director.