Clinical Research Checklist

Investigators are encouraged to use the “Research Checklist” to help determine whether the proposed activity is considered research.

1. **Purpose**
   - YES □
   - NO □
   Is the project intended to develop or test the efficacy of a new intervention that has not been studied before, or test hypotheses about issues that are beyond the knowledge of current science?

2. **Funding**
   - YES □
   - NO □
   Is the project funded by an entity (such as a sponsor) that makes clear its mission to conduct research or has a commercial interest in the results of the activity?

3. **Project Staff**
   - YES □
   - NO □
   Is the proposed project to be conducted by staff who do not have an ongoing commitment to improvement of the local care situation involved in the planned activity?

4. **Project Design**
   - YES □
   - NO □
   Is the project designed around a fixed protocol not allowing for frequent changes?

5. **Recruitment**
   - YES □
   - NO □
   Is there a formal process planned for recruitment?

6. **Consent**
   - YES □
   - NO □
   Will the activity require voluntary informed consent for interventions that are not part of standard clinical care?

7. **Benefits**
   - YES □
   - NO □
   While the participants may or may not benefit from the project, does the true benefit come from the knowledge gained from the analysis of the planned activity?

8. **Risk**
   - YES □
   - NO □
   A) Is the risk to the participants (regardless of its determination) separate from what is involved in the care they are receiving? OR
   B) Is the burden or commitment additional to what would be expected in their care?

If the answer to ANY of these questions is YES then the activity is most likely research and IRC review may be required. Please consult with the IRC at (860) 646-1222, ext. 2234 if further clarification is needed.