ECHN Institutional Review Committee

Clinical Quality Improvement/Assurance Checklist

Investigators are encouraged to use the “QI Checklist” to help determine whether the proposed activity is considered a Quality Improvement project or whether IRC review is required.

1. **Purpose**  
   - Is the project intended to improve the process/delivery of care while decreasing inefficiencies at an ECHN facility?

2. **Funding**  
   - Is the project internally funded or externally supported by agencies for direct benefit to existing patients?

3. **Project Staff**  
   - Is the proposed project conducted by the clinicians and staff who provide care or are responsible for the performance quality at an ECHN facility?

4. **Project Design**  
   - a. The individuals, (patients, employees) are not randomized to different intervention groups.
   - b. The project goal is to implement existing/known knowledge to improve or enhance health/clinical care.
   - c. The project does not have a fixed goal, methodology, population and time period; rather, based on data collection that is immediately evaluated and assessed, practices or behaviors are modified quickly.
   - d. The project does not delay feedback of the data from monitoring to the implementation of the change.

5. **Recruitment**  
   - Will the project involve a sample of the population (staff or patients) ordinarily seen at an ECHN facility?

6. **Consent**  
   - Will the planned activity only require consent that is normally sought in clinical practice and could the activity be considered part of the usual care?

7. **Benefits**  
   - Is it true that most of the current patients at an ECHN facility where the planned activity will take place could potentially benefit from the project?

8. **Risk**  
   - A) Is the risk to the participants no greater than what is involved in the care they are already receiving?  
   - OR  
   - B) Can the burden of participating in the activity be considered acceptable or ordinarily expected when reforms are being introduced to the way care is provided?

If the answer to **ALL** of these questions is **YES** then the activity is a QI/QA project and does not involve human subject research. **IRC review is not required.**

If the answer to any of these questions is **NO**, or if further clarification is needed, please consult with the IRC at (860) 646-1222, ext. 2234. **IRC review may be required.**