CQI evaluations may include surveys, focus groups, or interviews of stakeholders or parties. Some of these activities may require the oversight of an Institutional Review Board (IRB). All of these activities require considerations of several issues to ensure that participation is voluntary, risks are minimal, and that participants understand what they are agreeing to do. Children and parents are the most vulnerable. They may feel they have no choice but to participate; they may face risks to their privacy; and they may not understand what is being asked of them. Evaluators need to be sure to address these issues if they are involving parents and children in evaluation activities.

Considerations for Protecting Participants

Ensure that Participation is Voluntary
Participation in evaluation activities should be voluntary. Parents and children under court jurisdiction are required to do many things by the court, by their caseworker, etc. They are likely to assume that there will be negative consequences to them if they do not participate. Professional stakeholders will more easily understand that their participation is voluntary.

Suggestions
To avoid perceptions of coercion, clearly explain to parents and children that:
• their participation is voluntary,
• they may withdraw at any time,
• there will not be a negative impact on their case if they choose not to participate

Provide Information
If the project is not a research project then formal informed consent and signed forms are not required nor needed. However, participants should be given enough information in an understandable manner to make a decision about whether to participate. Their actual participation can demonstrate their agreement to do so.

Suggestions
Provide written information to parents and children.
• Brief project description & purpose
• Clarify that individual parents/children are not topic of interest and will not be identified
• Confidentiality
• Voluntariness
• Check reading level (Word has this option)

Maintain Confidentiality Information
A breach in confidentiality is likely the greatest risk to participants. A confidentiality lapse may expose that a person is involved with the child welfare system or may reveal a person’s thoughts about their judge or lawyer. It is critical to maintain the confidentiality of all data.

Suggestions for confidentiality
• Keep all data with names in locked files
• Promptly replace names with codes on forms and keep name/code list separately
• Avoid using names in data files
• Use focus groups with parents with extreme caution because confidentiality cannot be assured; do not use focus groups for children
**Avoid or Minimize Sensitive Issues**

Most topics of interest to CIP CQI efforts will focus on non-sensitive topics (e.g., interactions with attorneys, perceptions of court processes/judges) that are unlikely to be upsetting to parents or children. Information about maltreatment, TPR, and other such sensitive issues can usually be gathered from files. There may be some sensitive questions that can be best answered by participants (e.g., “When did you last see your brother?”). Sensitive questions should be only included if they are necessary and care should be taken when including them.

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**Protect Children**

Minor children cannot consent to participation. Although written consent is not required if the project does not require IRB oversight, you may want written consent from a parent, foster parent or someone else who can make decisions on behalf of the child. Regardless of consent from an adult, children should also assent (agree) to participate.

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**Is IRB oversight required?**

The answer to this is probably **not** for most CQI activities. The Child Welfare Agency may have an IRB. If anyone involved with your project is associated with a college or university you may see if you can involve their IRB.

You **DO** need IRB approval if:

- Your project is research “that is conducted or supported by a federal department or agency” CFR 45 § 46.101(a)(2).
  
  — Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. CFR 45 § 46.102(d)

- Whether you intend to publish your findings publicly is not relevant to whether your project is research.

You do **NOT** need IRB approval if:

- Your project is a program evaluation. Program evaluation is defined as, “a systematic method for collecting, analyzing and using information to answer questions about a project, policy or program, particularly about their effectiveness and efficiency.”
  
  — Information gained is used to improve a program or practice.

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**For More Information:**

- CFR 45 § 46 is the HHS Policy for the Protection of Human Research Subjects
  
  ---- http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

- Policy & Guidance - Quality Improvement Activities FAQs. This guidance is directed towards medical quality improvement activities, but the issues are similar to court quality improvement activities.
  

- Policy & Guidance-Intent to Publish.


- If you have additional questions, the CBCC Research and Evaluation Team can help determine if IRB is needed.