

Mapping/defining existing quality criteria/standards for sites

Working Group 2



Category Development

Category Heading	Description & Queries
Staff Experience	Does the staff have the appropriate experience in studies & years? Are they adept at conducting trials or willing to learn?
Requirements (Training)	Is there adequate training? Access and review of relevant guidance documents
Documentation (Quality Management)	Presence of an internal Quality Assurance procedure Are evaluation processes established?
Infrastructure	Is the environment child-friendly? Required equipment and services for study Staff adept at working with children and families
Cycle Times (IRB, Contracts, Budget)	Use of standard templates (agreements, indemnities, etc.) Personnel for budget negotiations with sponsors
Patient Engagement	Conduct of patient orientation Provision of general information to participants Relevant participant material availability



Next Steps?

What we propose:

Two main articles relevant for future work:

- “A Trial Assessment of Infrastructure Matrix Tool to Improve the Quality of Research Conduct in the Community”
- “A Framework for Assessing Clinical Trial Site Readiness”

Categories – could we work with sub categorization and bring in more questions?

Next step for this?

