

Connxus – Quality Improvement/Research Form

Please complete this form to determine if your activity is Quality Improvement or Research

Name of the Principal Investigator/Project Lead

Provide a brief description of the project and goals.

Project Title

Funding (if not funded, enter N/A)

1. The activity is not intended to develop or contribute to generalizable knowledge.	TRUE	FALSE
2. The project is intended to directly affect institutional or programmatic practice.	TRUE	FALSE
3. The activity is intended to improve the process/delivery of care within a specific healthcare setting or improve a specific institutional or educational program/practice.	TRUE	FALSE
4. The project does not involve testing an experimental drug, device (including medical software or assays), or biologic.	TRUE	FALSE
5. The project has not received funding (e.g., federal, industry) to be conducted as a human research study.	TRUE	FALSE
6. Project does NOT involve randomization.	TRUE	FALSE
7. This is not a multi-site project where all sites implement the same procedures (i.e., a rigid protocol).	TRUE	FALSE
8. There is sufficient existing evidence (i.e., published information) to support implementing this practice, or the change is being mandated by institutional policy.	TRUE	FALSE
9. The activity could be considered part of usual care or practice. Consent beyond what is already obtained in clinical practice is not necessary.	TRUE	FALSE

How to use this form

If all the above responses are “True” then: The activity described appears to constitute quality improvement (QI). IRB review is likely not required because your project does not appear to constitute human subject research as defined under 45 CFR 46.102(d). If the project results are disseminated, they should be characterized as QI findings. If the activity changes in any way that might affect the intent or design, please complete this self-certification again to ensure that IRB review is still not required.

If any of the above responses is “False” then: The activity described appears to constitute Research.