**Graceland University IRB Committee**

**Quality Improvement Determination Form**

Quality Improvement (QI)is the process involving evaluating using scientific methodology to bring immediate performance improvements in health care delivery. Performance can be measured in terms of clinical outcomes, patient satisfaction, error rates, productivity and other metrics. All health care institutions including hospitals and ambulatory clinics utilize QI projects to improve patient outcomes. Results are used ***locally*** to improve care by improving the process being monitored. This process does not require IRB approval.

However, if you are considering the publication or presentation of the results of this QI effort outside of Graceland University, then you must complete this form and submit to the IRB to verify that you will be conducting a QI effort and that it currently does not meet the definition of human research.

1. Does this project involve any of the following (check all that apply):

|  |  |
| --- | --- |
| [ ]  Investigational Drug or Device[ ]  Randomizing patients  | [ ]  A fixed clinical protocol that may not be altered by caregivers and staff[ ]  Outside Graceland University site |
| [ ]  Objectives other than producing an improvement in safety or care.*If any of the above is checked, then this project cannot be approved by the IRB as a QI project, and must be submitted and approved by the IRB as a Research Protocol before it can move forward.*[ ]  None of the above |
|  |

1. Which of the following best describes the process that is being evaluated?

[ ]  The process is currently the standard of care

[ ]  The process is being introduced at this time as the standard of care

[ ]  The process is not currently the standard of care, and is prospectively being evaluated compared to the current standard of care. *This project cannot be approved by the IRB as a QI project, and must be submitted and approved by the IRB as a Research Protocol before it can move forward.*

1. Please describe the QI Project

Describe:

1. Please describe the location and\or patient population being evaluated by the QI project:

Describe:

1. Please describe the role the individual leading this Project has as it relates to conducting Quality Projects (ie: in charge of quality for department\division, asked to conduct this quality project by institution’s Quality Department, etc.).

Describe:
2. Please list the outcome measures being collected as part of the QI effort

Please List:

1. Please describe

a) the process by which the quality data will be collected and analyzed,

b) how the process being evaluated will be revised based on that analysis, and

c) how often will this same collection\analysis process sequence be repeated?

Describe:

1. At what point will this QI project be terminated (ie: at what point will your outcome measures indicate that the “quality” of the process is sufficient)?

Describe:

1. Please list any data being collected that is not part of the QI effort?

Please List:

1. Is this project being funded?

[ ]  No

[ ]  Yes Please Indicate funding source:

1. At this time, do you have any intention to publish or present the information gathered outside of Graceland University?

[ ]  No

[ ]  Yes

Updated 4/5/17