Flowchart to Determine if UCLA IRB Approval Required For Quality Improvement (QI) Projects

### Establish QI Intent
Activities intended ONLY to improve clinical care. Including but not limited to improving quality of performance, the patient experience, & cost of care.

- **Not sure**
- **QI intent only**
- **Research intent exists**

#### QI Activities Underway & Intent Changes:
Research may now be proposed
- New data will be collected beyond what is needed for QI purposes;
- New project design; and/or
- Clinical care sites beyond UC/UCLA

#### Submit webIRB application
- To obtain UCLA OHRPP/IRB determination whether project involves human subjects and requires UCLA IRB review and approval or Certification of Exemption from IRB Review
- **Yes human subjects**
- **No human subjects**

- **Is research and involves human subjects**
- **NHSR – Not human subjects research**

### Contact UCLA OHRPP for further assistance and formal determination of whether IRB review is required. ***

For reference: Review Quality Improvement or Research Worksheet to further assess whether project should be considered “research”. Indicators of research intent are:

- Randomization to enhance confidence in differences that might be obscured by nonrandom selection
- Testing issues that are beyond current science and experience, such as new treatments
- Involvement of researchers who have no ongoing commitment to improvement of the local care situation
- Protocol has fixed goal, methodology, population, and time period
- Feedback from implementing changes is delayed or altered
- Funding from outside organization with a commercial interest in the results

### UCLA OHRPP Contacts
- (310) 825-7122
girb@research.ucla.edu
- SGIRB Administrator
  Gloria Varghese
gvarghese@research.ucla.edu
- NGIRB Administrator
  Paul Lillig
  plillig@research.ucla.edu

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