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.

**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**
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

**UCLA OHRPP**
reviews webIRB application.
- IRB approval or Certification of Exemption issued when review complete.

**OHRPP determination: Review not required. OK to publish/present.**

**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

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