

## What's research, what's quality improvement, and why does it matter?

**Research** (IRB def): A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**.

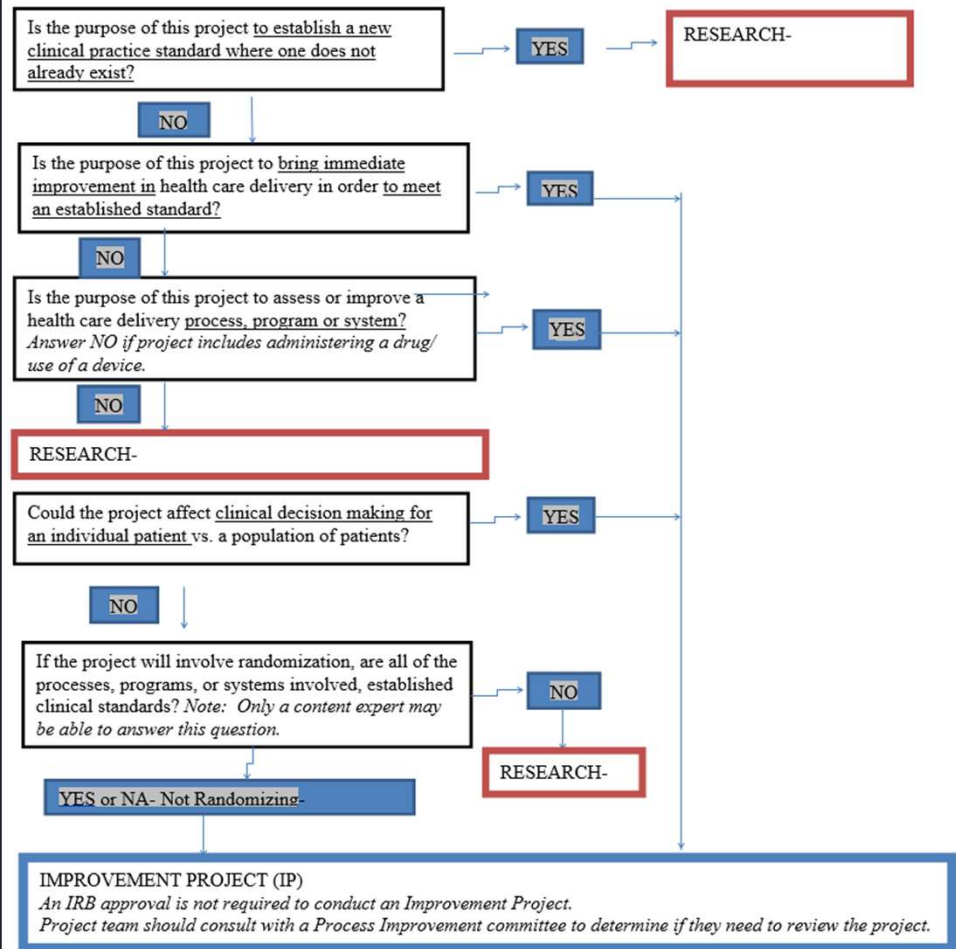
**Quality improvement:** No regulatory definition, but one is “systematic, data-guided activities designed to bring about immediate improvements in health delivery in particular settings.”

	<b>QI</b>	<b>Research</b>
<b>Purpose</b>	Improve care now or operations in the current setting	Develop or contribute generalizable knowledge
<b>Rationale</b>	Literature or consensus support for implementing change	Extending to new knowledge, beyond what is established
<b>Methods</b>	Adaptive and iterative design, tend to avoid randomization	May include randomization, fixed protocol
<b>Risk</b>	No risk to participants beyond usual care	May include risk
<b>Participants</b>	Participants already typically in setting	May include recruiting participants who aren't normally in setting

# UVA IRB QI Definition

1. Implementing an **accepted practice to improve the delivery or quality of care or services** ( including, but not limited to education, training and changing procedures related to care or services) if the purposes are limited to altering the utilization of an accepted practice and collecting data or biospecimens to evaluate the effects on the **utilization of the practice**.
1. Data collection and analysis, including the use of biospecimens, for an institution's own **internal operational monitoring and program improvement purposes**, if the data collection and analysis is limited to the use of data or biospecimens originally collected for any purpose other than the currently proposed activity, or is obtained through oral or written communications with individuals (e.g., surveys or interviews).

## Health Care Delivery Improvement Project vs. Research: IRB-HSR\*





## When is QI also research?

When you are trying to generalize the QI effort:

- Studying a completed QI effort to generalize it
- Applying a QI effort across different settings

When the intervention being implemented is untested, and you are interested in establishing how well it achieves its results



## Examples of QI vs. Research

**QI:** Developing and implementing a new late policy

- May not be generalizable outside the health system since there are many location-specific processes and nuances.

**Research:** Does implementing a late policy affect rates of preventive screenings?

- Focus is on the outcome of the policy, not the policy itself, which is generalizable to other settings.
- Even though late policies are not the same across locations, this could provide information on the impacts of policies.



## When should you involve the IRB?

When you are doing research (e.g. developing generalizable knowledge)

When you aren't sure if you're doing research

- IRB can determine if it is research or not

Note: You can still disseminate information about QI projects without IRB review, but you need to include language about it being a QI project and not make generalizable claims