When Should a QI/QA Project Be Presented to the IRB?

First, determine if the project meets the definition of research.

The definition of RESEARCH per federal regulations:

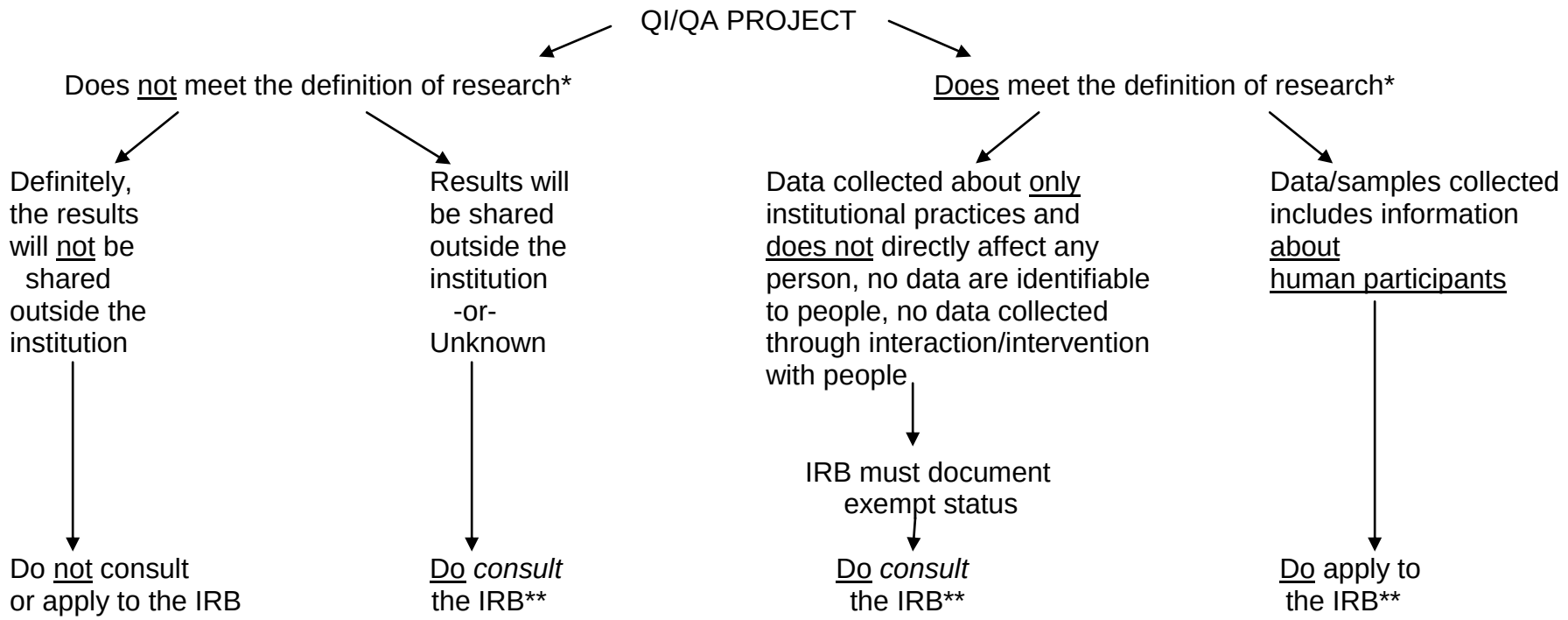
- DHHS definition* - Any systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge [i.e., the knowledge gained from a study that may be applied beyond the actual study population or specific organization in which the project was conducted] *(*For complete definition see Dept. of Health and Human Services regulations 21CFR46)*

  or
- FDA definition* - Any experiment that involves an FDA-regulated test article and one or more human subjects and is already subject to FDA requirements or will be part of an application for a research or marketing permit *(*For complete definition see Food & Drug Admin. regulations 21CFR50)*

If the project does not meet the definition of research	**If the project meets the definition of research**
Determine if and how the information will be shared: For instance, (1) the results will be shared outside the institution, *or* (2) it is unknown whether the results will be shared outside the institution, *or* (3) the results will definitely not be shared outside the institution. ▪ If the project results will be shared outside the institution, consult with the IRB*. An application may be, but probably will not be required. ▪ If it is unknown whether the results will be shared outside the institution, consult with the IRB*. An application may be, but probably will not be required. ▪ If the project results definitely won't be shared outside the institution, do not consult or apply to the IRB.	Determine if the research is about humans: For instance, (1) the results will include information about human participants, *or* (2) the results will be only information about institutional practices (does not directly affect any person, no data are identifiable to any person, no data are collected through interaction/intervention with any person). ▪ If the project includes human participants (or their information/samples), then apply to the IRB*. ▪ If the study results will be only information about institutional practices and will not directly affect any person and data will not be identifiable to any person and data will not be collected through interaction/intervention with any person, the IRB must document that the research is exempt from IRB oversight, consult the IRB*.

See the decision tree with additional details on the next page.
Also see the OHRP Quality Improvement Activities FAQs at http://www.hhs.gov/ohrp/qualityfaq.html#q2

DECISION TREE: When Should a QI/QA Project Be Presented to the IRB?



***Definition of Research per the federal regulations –**

DHHS definition* - Any systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge [i.e., the knowledge gained from a study that may be applied beyond the actual study population or specific organization in which the project was conducted] *(*For complete definition see Dept. of Health and Human Services regulations 21CFR46)* **or**

FDA definition* - Any experiment that involves an FDA-regulated test article and one or more human subjects and is already subject to FDA requirements or will be part of an application for a research or marketing permit *(*For complete definition see Food & Drug Admin. regulations 21CFR50)*

Take the following into consideration:

	Research	QI/QA
Purpose	Test a formal hypothesis	Assess a process, program or system
Starting Point	A prospectively designed, formal, written research hypothesis	An established set of standards
Benefits	Knowledge sought may not benefit subjects involved in study	Knowledge sought directly benefits process/program/system
Risks/Burdens	May put subjects at risk	No risk, with exception of possible loss of privacy/confidentiality
Data Collection	Systematic data collection	Systematic data collection
End Point	Answer research question	Improve the program/process/system
Testing/Analysis	Determine validity of hypothesis	Compare the program/process/system to established set of standards
Intended Result	Share findings with individuals associated with the investigation and individuals not associated with the investigation	Share findings with only those individuals associated with the process/program/system.

** For contact information for the IRB see the CONTACT US link on the web at www.pennstatehershey.org/web/irb