Determining EBP, PI or QI, or Research

Instructions: Answer each column on the left by checking which box (☐) most closely reflects the intent of the work to be accomplished. Review responses as a team. Recognize that all three methods are systematic evaluative methods that include living individuals as part of the evaluation. Discuss and select as a team the method most closely matching the intent. Proceed with relevant notifications and approvals.

	EBP	PI/QI	Research
Which definition fits?	☐ EBP is the practice is the process of shared decision-making between practitioner, patient, and others significant to them based on research evidence, the patient's experiences and preferences, clinical expertise or know-how, and other available robust sources of information (STTI, 2008). ☐ Healthcare delivery based on the integration of the best research evidence available combined with clinical expertise, in accordance with the preferences of the patient and family (Sackett et al., 1996; Sacket, Straus, Richardson, Rosenberg, & Hayes, 2000).	☐ QI is the organizational strategy that formally involves the analysis of process and outcomes data and the application of systematic efforts to improve performance (AHRQ, 2011a). ☐ The degree to which healthcare services for individuals and populations increases the likelihood of desired health outcomes and are consistent with current professional knowledge (IOM, 2004, para. 3).	☐ Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (USDHHS, n.d.-b). ☐ Systematic investigation designed to contribute to generalizable knowledge (USDHHS, n.d.-b).
Intent			
	EBP	**PI/QI**	**Research**
Who benefits?	☐ Future patients and families ☐ Future clinicians ☐ Organization	☐ Current patients and families ☐ Current clinicians ☐ Organization	☐ Clinicians ☐ Scientific community ☐ Subjects (on occasion)
What is the purpose?	☐ Improve quality and safety within the local clinical setting by applying evidence in healthcare decisions.	☐ Improve quality or safety of processes or patient experience within the local clinical setting. ☐ Evaluate changes in efficiency or flow.	☐ Contribute to and/or generate new knowledge that can be generalized.

What is the scope of interest?	☐ Specific unit or patient population within an organization	☐ Specific unit or patient population within an organization	☐ Generalize to populations beyond organization
Methodology			
	EBP	**PI/QI**	**Research**
Which process, or outcome measurements are used?	☐ Measures for key indicators using tools with face validity and may be without established validity or reliability. ☐ Measures include knowledge, attitude, behavior/practices, outcomes, and balancing measures (Blick & Graham, 2010; Institute for Healthcare Improvement [IHI], 2017).	☐ Measures are simple, easy to use, and administer. ☐ Measures are for key indicators only.	☐ Measures are complex. ☐ Increased time is required to fill out the measure. ☐ Measures require a detailed administration plan. ☐ Estimates of reliability, validity, specificity, and/or sensitivity are required.
Which design fits?	☐ An EBP Process Model	☐ Examples include: ☐ Six sigma ☐ Plan Do Study Act (PDSA) ☐ LEAN ☐ Continuous Quality Improvement (CQI)	☐ Randomized Control Trial ☐ Quantitative ☐ Qualitative
What is the timing?	☐ Planned ☐ Variable timeline based on available clinical practice guidelines or other synthesis reports	☐ Rapid cycle (for example, PDSA)	☐ Planned and longer
Are there extraneous variables?	☐ Acknowledged, but not measured	☐ Acknowledged, but not measured	[ ] Controlled and/or measured ☐ Tight protocol control
What is the sample?	☐ Convenience sample	☐ Convenience sample	☐ Varied sampling based on study question; may include an established process to improve generalizability of results

What is the sample size?	☐ Small, but large enough to observe changes ☐ Feasible for data collection	☐ Small, but large enough to observe changes ☐ Feasible for data collection	☐ Size based on estimates of adequate power or saturation
Which data collection is used?	☐ Minimal time, resources, cost	☐ Minimal time, resources, cost	☐ Complex, tightly controlled plan for resources constructed
Which data analysis is used?	☐ Descriptive statistics, run chart, or statistical process control charts for trended data; may use inferential statistics	☐ Descriptive statistics, run chart, or statistical process control charts for trended data	☐ Complex with inferential statistics to promote generalizability of results
Are there relevant regulating bodies?	☐ Organization	☐ Organization ☐ Influenced by: ☐ The Joint Commission ☐ Centers for Medicare & Medicaid Services	☐ Organization, Office of Human Research Protections, FDA, state and local laws
Are there additional burdens or risks?	☐ Patient and/or population is expected to benefit directly from observations. ☐ Risk of participation is the same as receiving usual clinical care. ☐ If risk or burden is higher than with usual care, consider research and/or Not Human Subjects' Research (HSR) Determination review by IRB.	☐ Patient and/or population is expected to benefit directly from improved flow or process. ☐ Risk of participation is the same as receiving usual clinical care. ☐ If risk or burden is higher than with usual care, consider research and/or Not HSR Determination review by IRB.	☐ Participant is aware of risks. ☐ Informed consent is required. ☐ IRB approval is required. ☐ Subject may or may not benefit from participation in study.
Is IRB approval required?	☐ Generally not required when evaluation is limited to PI/QI unless per organizational policy or if plan is to publish as an abstract or paper in a	☐ Generally not required unless per organizational policy or if plan is to publish as an abstract or paper in a peer-reviewed journal; recommend	☐ Required

	peer-reviewed journal. Recommend a HSR Determination review by IRB if there are questions or organization policy/requirements.	checking policy and/or with an organizational leader.	
Is dissemination possible?	☐ Expected to disseminate within the organization; publication is increasingly becoming an expectation. Recommend a HSR Determination review by IRB if plan to publish as an abstract or paper in a peer-reviewed journal; publication may be expected for public accountability and transparency based on CMS regulations. ☐ Does not indicate generalizability of findings or research (see disseminating PI/QI data). ☐ Adopt SQUIRE 2.0 criteria (Standards for QI Reporting Excellence [SQUIRE], 2015.)	☐ Expected to disseminate within the organization; may be expected for public accountability and transparency based on CMS regulations; may be published. ☐ "The intent to publish is an insufficient criterion for determining whether a PI/QI activity involves research. Planning to publish an account of a PI/QI project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of nonresearch activities for a variety of reasons, if they believe others may be interested in learning about those activities." (USDHHS, n.d.-b, para 6)	☐ Expected
From Cullen, Hanrahan, Farrington, DeBerg, Tucker et al., 2018, pp 97-100. The table is based on the following primary citations: AHRQ, 2011a; Bick & Graham, 2010; IHI, 2017; IOM, 2004; OHRP, 2009; Sackett et al., 1996; OHRP, 2009; Sackett et al., 1996; Sackett et al., 2000; Sigma Theta Tau International 2005-2007 Research and Advisory Committee, 2008; SQUIRE, 2015; USDHHS, n.d.-b.			