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Boston Medical Center
HEALTH SYSTEM

To IRB or Not to IRB: That is the Question

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Learning Objectives

- Differentiate the underlying intent of research and quality improvement projects
- Critically appraise whether a project should or should not be submitted to the IRB

We fulfill our ethical obligations to patients by submitting human subjects research activities to the IRB

For research that involves human subjects, regulations require that an ethics committee (IRB) must review and approve prior to starting.

- Ensures that research is conducted according to ethical principles outlined in the Belmont Report (including respect for persons, beneficence, and justice)

What happens if we don't submit to the IRB when we should have?

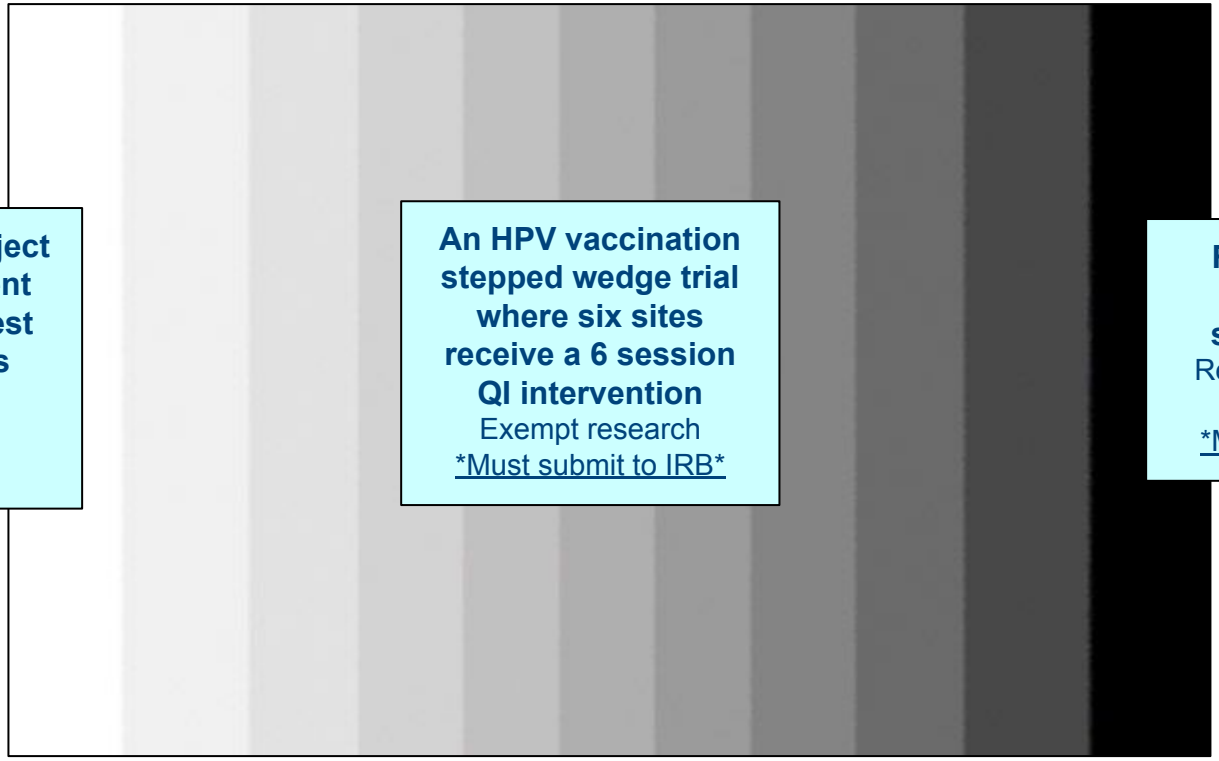
- Possible **harm to the patient**/subject.
- **Breach of ethical obligations** to the patient/subject.
- **Formal evaluation by OHRP and/or FDA**.
  - Determination letters/Warning letters and resulting corrective actions, enforcement actions (including debarment).
  - OHRP holds institution responsible for conduct of its agents; FDA holds sponsor, investigator and IRB responsible.
- **State licensing board findings/actions**.
- **Erosion of public trust in the research enterprise**.

What happens if we submit to the IRB when it was not needed (i.e. for QI work)?

- There's no harm, but you may create unnecessary delays to realizing improvement

There are a broad spectrum of of activities that take place under the auspices of both research and quality improvement

Quality Improvement **Research**



GIM diabetes project to improve patient receipt of A1C test every 6 months
QI
Do not need to submit to IRB

An HPV vaccination stepped wedge trial where six sites receive a 6 session QI intervention
Exempt research
Must submit to IRB

RCT on effect of tocilizumab vs standard of care
Research - full review required
Must submit to IRB

Lack of clarity about what these terms mean, and blending of methodologies creates a lot of confusion about whether or not you need to submit to the IRB.

The key difference between research and quality improvement is the underlying intent or goal of the work

	Research	Quality/Process Improvement
Involvement of human participants?	Both involve direct or indirect engagement of living individuals, in our context, patients and healthcare providers.	
Intent	To discover new, generalizable knowledge. To test a novel hypothesis.	To bring established knowledge into daily practice. To improve delivery of care.
Intervention Tested	May involve **treatments or practices that are not currently considered standard of care**. May involve, blinding, randomization or withholding standard of care.	Operational processes to deliver the care may be new, but **underlying intervention tested are consensus-based and/or evidence-based, and codified in practice guidelines** (e.g. point of care A1c testing; HPV vaccination initiated at age 9)
Data collection	Systematic; **oriented toward proving effectiveness or superiority of the intervention under study**	Systematic; **oriented toward studying the effect of process change** and comparing to established standards/benchmarks

Both research and quality improvement are systematic and involve the gathering and analysis of data about patients. **The key questions to ask yourself are:**

- **Why are you doing this project?** and **What is the expected outcome?**

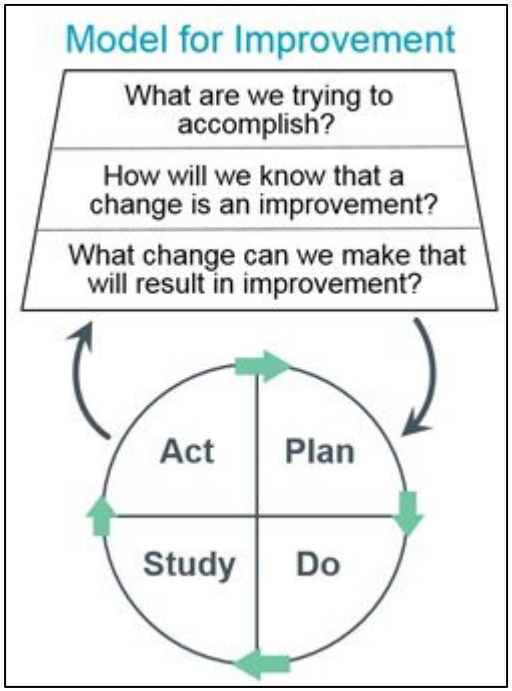
This will point toward intent, and help you assess whether IRB submission is warranted.

The central feature of quality improvement is taking what we know works (evidence) and achieving desired changes in clinical practice

- Quality improvement is the **framework used to systematically improve care**. Quality improvement seeks to **standardize processes and structure to reduce variation**, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations (CMS.gov)

- **Commonly used frameworks**
  - Institute for Health Model for Improvement
  - Lean
  - Six Sigma

- QI as a methodology is meant to be 'practical' means of realizing improvement
  - Involves hypothesis testing tied to predictions around interventions that will lead to improvement (PDSA)
  - Necessitates measuring what is necessary to realize improvement (no controls)
  - And **improving what needs to be improved based on established best practice**



Randomization, intent to withhold interventions from certain groups, and the evaluation of interventions that are not standard of care are all features of research activities

Examples

The following table gives examples of QI/QA projects in different categories, including changes that would make the project not qualify as QI/QA:

Basic QI/QA Project	QI/QA that is **not** research	QI/QA that **is** research
Add a medical record alert for patients ≥60 not vaccinated for pneumococcus	Track provider utilization of alerts and vaccination rates	Randomize alert to go to provider or medical assistant
Deliver a training program to radiologists on minimizing radiation dose	Assess radiologist satisfaction with training and comprehension	Compare radiation doses for patients of radiologists who got trained in-person vs. electronically
Implement a more user-friendly standard checklist for fall-risk screening	Track checklist usage and assessment outcomes	Randomize floors to repeat assessment every 24 vs. every 48 hours

But as you can see, **activity exists on a spectrum,** and may blend aspects of both QI and research

But what if my project has features of both QI *AND* Research?

The IRB is required to review activities that meet the definition of Human Subjects Research.

Some projects may be both QI and research if they are intended to improve processes at the local level AND meet the definition of Human Subjects Research

- Ex. A QI project in which an a patient informational handout is created for participants in clinic to raise awareness about a given condition.

Depending on the specific intent of the investigator, this project could be a QI and Research project.

When Do I Need to Submit to the IRB?

Does my project involve **Research**? (45 CFR 46.102 (l))

YES, then

Does my project involve **Human Subjects**? (45 CFR 46.102 (e))

YES, then

You should submit to the IRB!

When Do I Need to Submit to the IRB?

Does my project involve **Research**? (45 CFR 46.102 (l))

Per OHRP regs:

"a *systematic investigation*, including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge*."

If the study activities do not meet this definition, IRB review is not explicitly necessary*

Is it Research?

A ***Systematic investigation*** is the use of a predetermined method to gain information by collecting and analyzing data.

Generalizable knowledge is conclusions that can be applied to circumstances outside of the specific instances of the investigation.

*Intent to publish alone does not necessitate IRB review

Is my Study Design Research?

Features that *may suggest a QI/QA project is research designed to contribute to generalizable knowledge include:

1) Randomization
2) Deception
3) Unproven intervention
4) Altering or withholding standard treatment

*Having one or more of these features does not automatically cause the project to be Research; **intent and context matter**

Intent and Context

A significant feature of QI/QA activities is that any intervention that is undertaken has already been proven to be beneficial in other settings.

This differs from other research, like clinical trials, which are designed to test drugs, devices, procedures, or process changes that <u>are *not* known to be</u> <u>better</u> than standard care; therefore, it is possible to randomly assign individuals or deceive participants about the true nature of the new intervention or change to standard care.

Ask yourself:

1. Is there genuine uncertainty in the expert medical community over whether an intervention will be beneficial (i.e. clinical equipoise?)
   - ❑ Yes → likely research
   - ❑ No → likely QI
2. Is the intent to create generalizable knowledge (intervention as new standard of care)?
   - ❑ Yes → likely research
   - ❑ No → likely QI

When Do I Need to Submit to the IRB?

Does my project involve **Research**? (45 CFR 46.102 (l))

NO, then

Only submit to the IRB if you need a formal determination that this is not research *Required for some QI-only journals (PLUS)

When Do I Need to Submit to the IRB?

Does my project involve **Research**? (45 CFR 46.102 (l))

YES, then

Does my project involve **Human Subjects**? (45 CFR 46.102 (e)

Are they Human Subjects?

A Human Subject is a ***living*** **individual**:

(i) About whom a researcher obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) About whom a researcher obtains, uses, studies, analyzes, or generates identifiable private information about the individual or identifiable biospecimens; or

(iii) Who is or becomes a subject (either a healthy human or a patient) in research, either as a recipient of the test article or as a control, or upon whose specimens, either identified or not identified, an investigational device is used.

Are they Human Subjects?

A Human Subject is a ***living*** **individual**:

(i) About whom a researcher obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

If you are interacting directly with and getting data/specimens about the participant

(ii) About whom a researcher obtains, uses, studies, analyzes, or generates identifiable private information about the individual or identifiable biospecimens; or

If you are obtaining Identifiable data or specimens regardless of source about the subject

(iii) Who is or becomes a subject (either a healthy human or a patient) in research, either as a recipient of the test article or as a control, or upon whose specimens, either identified or not identified, an investigational device is used.

If you are using an investigational device on a subject or their data/specimens

When Do I Need to Submit to the IRB?

Does my project involve **Research**? (45 CFR 46.102 (l))

YES, then

Does my project involve **Human Subjects**? (OHRP 45 CFR 46.102 (e)

NO, then

You should submit to the IRB as “Not Human Subjects Research”

When Do I Need to Submit to the IRB?

Does my project involve **Research**? (45 CFR 46.102 (l))

YES, then

Does my project involve **Human Subjects**? (45 CFR 46.102 (e)

YES, then

You should submit to the IRB as “Human Subjects Research”

Now What? – Possible Types of Review

NHSR: The QI project is NOT research

- Submit to the IRB only if you need a formal determination from the IRB that it is not research. *Requirement for certain QI journals
- Your publication cannot refer to the project as “research”

NHSR: The QI project IS research, but no Human Subjects are involved.

Exempt: The QI project IS research involving Human Subjects, and meets one of the exempt criteria under the regulations.

Non-exempt (Expedited or full board): The QI project is research involving human subjects but does not meet Exempt or NHSR criteria.

Exempt Determination – Revised Common Rule 2018

1. **Research involving normal educational practices**
   - Does not impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.
2. **Research involving survey/interview procedures:**
   - Includes educational tests and or observation of public behavior (when researcher does not participate in activities**)**
   - Can be either anonymous or identifiable
3. **Research involving benign behavioral interventions**:
   - Includes collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording
   - Needs participant abbreviated consent.
4. **Secondary research uses of identifiable private information or biospecimens;**
   -if either publicly available, non-readily identifiable, are solely for healthcare operations, or if data was originally conducted on behalf of the federal government for non-research purposes.
5. **Research on Public Benefit**:
   - Designed to study, evaluate, improve, or otherwise examine public benefit/service programs, including procedures for obtaining benefits or services,
6. **Taste and food quality evaluation and consumer acceptance studies**

Equivalent protections

For projects that are not externally funded and not FDA regulated, our institution has agreed to review the following activities to the same standard:

- (9) **Chart review** data that have been or will be **collected solely for non-research purposes.** *Does not apply to prospective data typically
- (10) Research involving the study of materials (data, documents, records, or specimens) that **have been collected for research purposes** when the consent for the research does not preclude such additional research. Used for secondary use when study team has access to identifiers/mastercode **otherwise likely Exempt 4.**
- ***(11) Research involving Quality Improvement/Quality Assurance.***
- (12) Research with children involving survey procedures, interview procedures, or observation of public behavior where the investigators or research staff ***participate in the activities being observed. (*If no participation, likely Exempt 2)***
- (13) Other Minimal risk research that does not fit in category 9-12.

Exempt Category 11 'Research involving QI'

Projects ***without external funding***, eligible for equivalent protections under the Common Rule can qualify for this if:

- All patients who get an intervention are expected to benefit. ***Are not testing effectiveness or comparative effectiveness**
- All measurements that are collected are to determine the effect of the process change.
- All patients involved in the intervention receive standard care at a minimum.
- The intervention meets evidence-based or consensus-based quality standards.
- Confidentiality protections are appropriate to the sensitivity of the data collected.
- Obtaining consent from the patients is not practicable because the change or intervention will be carried out in a clinical setting where there is no meaningful way for patients to opt out of receiving the intervention.

Exempt Category 11 Important notes

Consent from the patients who experience the intervention is not required – typically because it is being done in a setting in which they can't reasonably opt-out

***if they can reasonably opt out, this suggests a research only design.

If any **subjects**, including healthcare professionals, participate in surveys, interviews, focus groups, or training, they must provide abbreviated consent (a shorter consent process that does not require a signature unless PHI is collected)

- RE: To be considered "Subjects" data must be "about whom"

Your obligations around HIPAA in QI

- All Protected Health Information (PHI) involved in a QI/QA project must be transmitted, stored, analyzed, or otherwise exist only on HIPAA-compliant electronic systems that meet the security standards for protection of PHI established by Boston Medical Center or the Boston University Dental Clinic.
    - Project team members must receive requisite compliance trainings
    - If you are a project lead, it is your responsibility to oversee the appropriate use and safeguarding of PHI.
- When in doubt, ask an IRB analyst or email medirb@bu.edu

QI or Research or Both?

QI: Goal is to develop a new information sheet for patients that experience a given condition in a department to increase awareness of a condition

Research: Goal is to create the informational handout with the intent to see the effect on patient awareness and understanding about their condition evaluated via interviews.

QI for Research: Goal is to create a new information sheet for patients that experience a given condition in a department, begin implementing it, and compare its effectiveness to an information sheet that is already currently in use by the department.

Alternatively, QI for Research: Goal is to create a new information sheet for patients that experience a given condition in a department and write up a paper about how a model like this if implemented at other institutions may be beneficial. If the intent is for other sites to be able to replicate and use the model, it then becomes generalizable and thus meets the definition of research.

Scenario One: An ortho resident wants to submit their work to a peer reviewed journal

An orthopedics resident starts **a project to help make sure elderly female patients with LC1 osteoporotic pelvic ring fractures are receiving recombinant parathyroid therapy** (an **established, evidence-based treatment** for women meeting criteria). The **resident wants to submit a manuscript** describing the QI project to the Journal of the American Academy of Orthopedic Surgeons. The journal says authors must " Include approval for human studies by IRB or animal utilization study committee." **Should the resident submit to the IRB?**

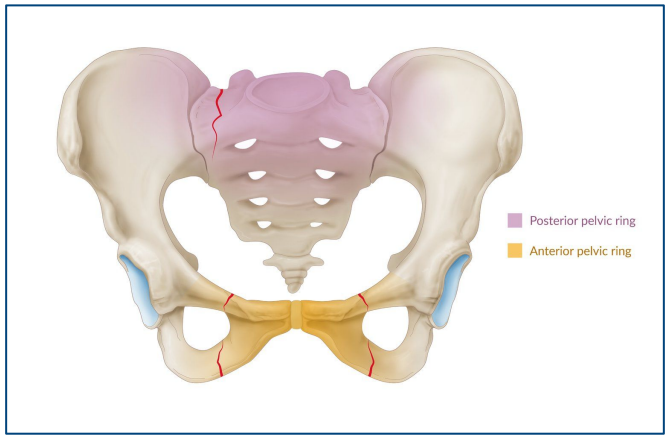


Image source: Pelvic fracture - Knowledge @ AMBOSS [Internet]. [cited 2022 Mar 21]. Available from: https://www.amboss.com/us/knowledge/Pelvic_fracture

Scenario One: An ortho resident wants to submit their work to a peer reviewed journal

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Should the resident submit to the IRB?

Yes

No

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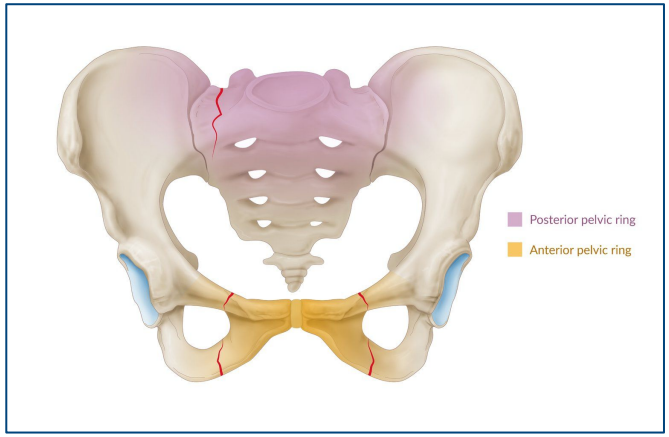
Answer:

- **Intent to publish alone does not necessitate IRB review**. If the project does not meet the definition of *research* and will only described in the manuscript as a QI project, **you do not need to submit to the IRB.**
- **<u>What can you do?</u>**
  a. **See if the journal would accept self-certification using a planned statement** like “This project was undertaken as a Quality Improvement Initiative at Boston Medical Center, and as such was not formally supervised by the Institutional Review Board per their policies”
  b. **See if the journal would accept a determination of NHSR** (abbreviated application)
  c. **Rarer circumstances**: Submit under exempt 9 (essentially, submitting as research involving chart review)



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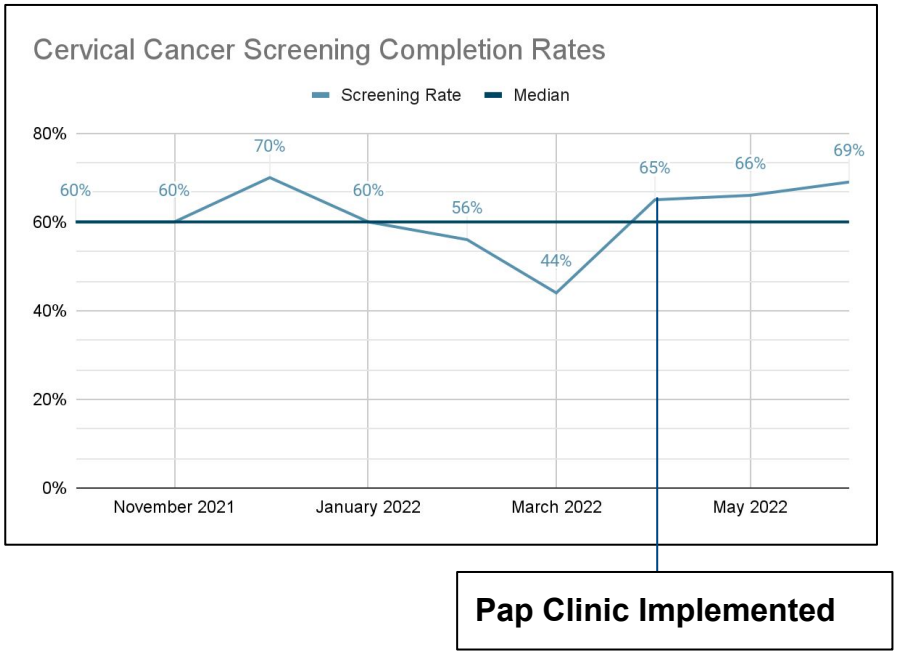
Scenario Two: A GIM team collects patient reported metrics by telephone to evaluate reasons for no shows

General Internal Medicine suite 6C seeks to **improve cervical cancer screening rates**. As a part of the project, the team intends to **call patients and ask three survey questions** to understand reasons the patient missed their most recent appointment to complete a pap smear. The data will be saved securely on the GIM department drive. **Should the GIM team submit to the IRB?**



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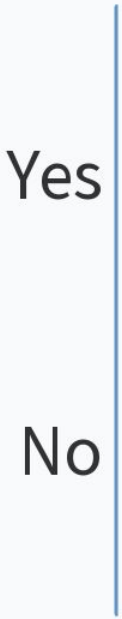

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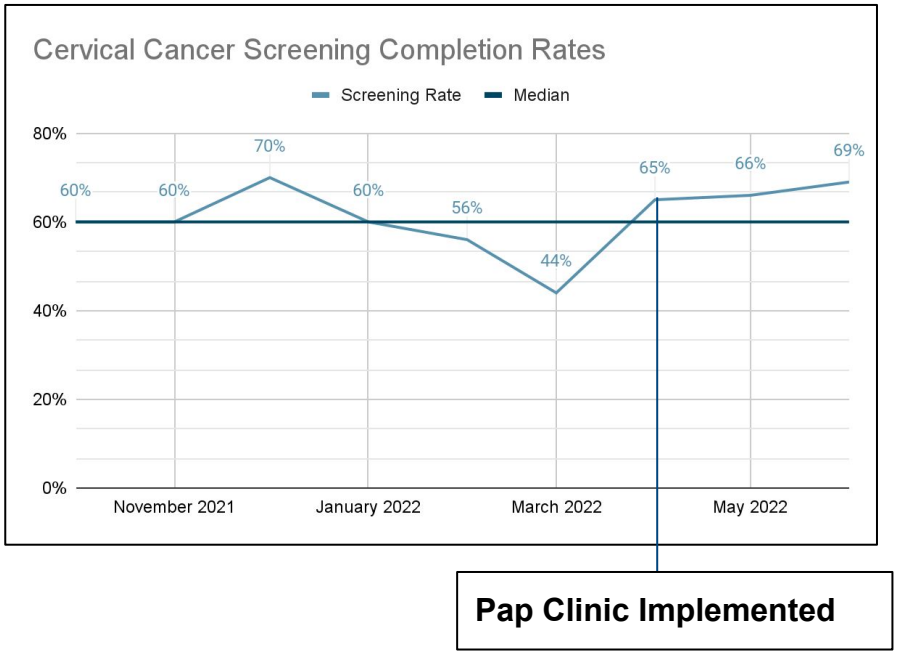
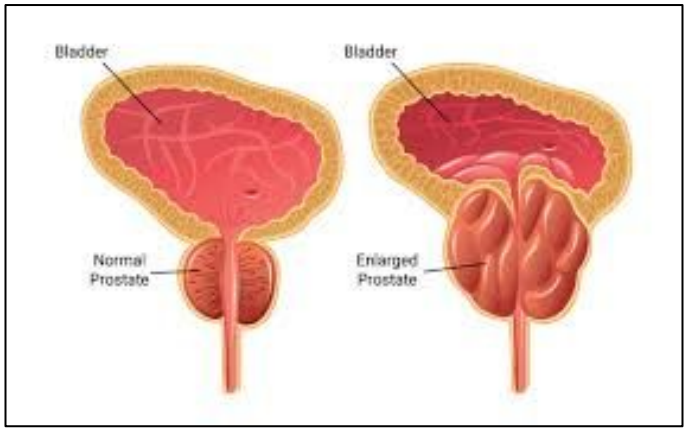
Answer:

- **If the <u>intent</u> of the project is to gather information to inform local quality improvement efforts** and not to generate new knowledge, then **you do not need to submit to the IRB**.
- Observe the differences in primary outcomes in research vs QI framing:
  - **Quality Improvement Primary Outcome**: Cervical Cancer Completion Rates (operational improvement)
  - **Research Primary Outcome**: Patient reported reasons for no show (descriptive study of barriers to care)
- Prime scenario for Exempt Category 11 if it meets the definition of research



Scenario Three: A multidisciplinary team from Anesthesia, Surgery, and Urology working to reduce post-operative urinary retention

A group from Anesthesia, Surgery, and Urology decide to form a team and work together to **reduce incidence of postoperative urinary retention (POUR)**. They discuss contributing factors like slow time to ambulation and systemic opioid use. They also discuss how **patients with untreated or undertreated benign prostatic hyperplasia are also at increased risk for developing POUR**. Tamulsolin (Flomax) is a medication with a **known indication for the treatment of an enlarged prostate**. They want to evaluate whether an increase in pre-operative treatment could reduce POUR incidence. **Should the team submit to the IRB?**



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Should the multidisciplinary team submit to the IRB?

Yes

No

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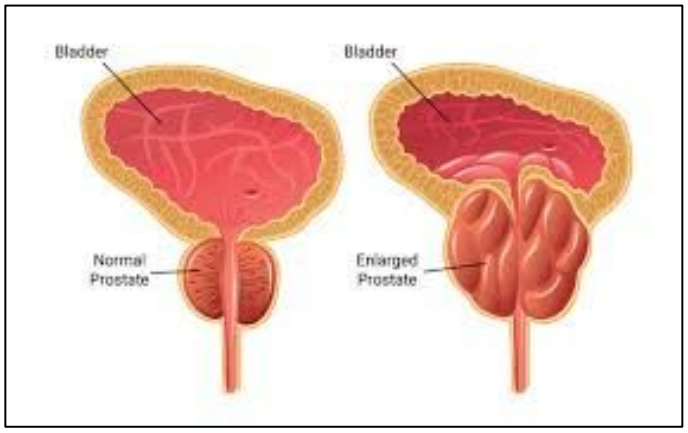
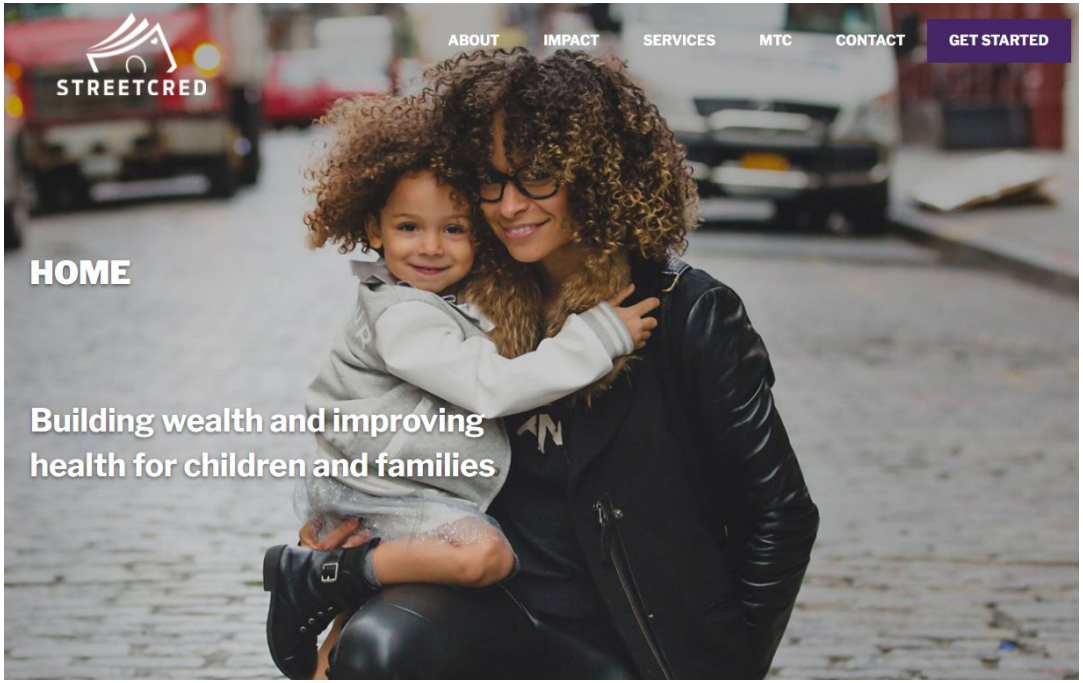


Answer:

- This project could go either way - as always, **it depends on intent and framing.**
  - **Research intent**: To evaluate a new indication for preoperative use of tamsulosin (Flomax) compared to standard of care
    - May include features like randomization + treatment/control groups
    - Must submit to IRB!
  - **Quality improvement intent**: To standardize prostate symptom screening such that patients with moderate to severe symptoms are referred appropriately to Urology in advance of their surgery.
    - Do not need to submit to IRB

Scenario Four: The StreetCred Program wants to survey families that have used their services

StreetCred is a Pediatric program that **helps families file their taxes in the waiting room when they bring their child for a pediatric visit**, and enables them to receive the full tax refund to which they are entitled. They intend to monitor routinely collected metrics like patient show rates to their Pediatric visits. They also intend to survey patients with the overall goal to evaluate the impact the program has on participants' perception of financial stability. **Should the StreetCred team submit to the IRB?**



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Should the StreetCred team submit to the IRB?

Yes

No

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Scenario Four: The StreetCred Program wants to survey families that have used their services

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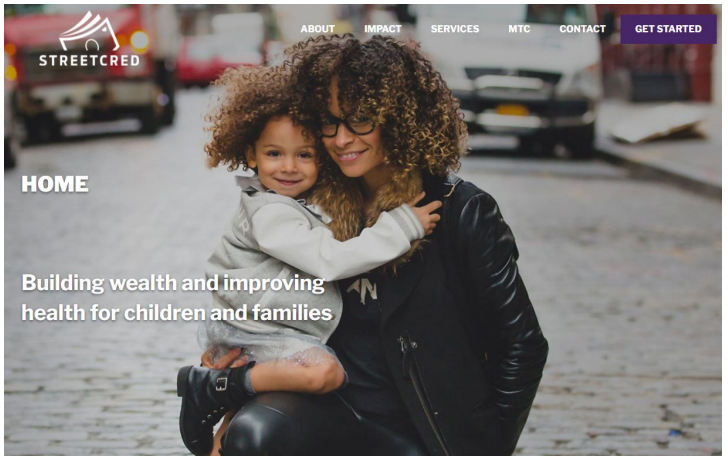
Answer:

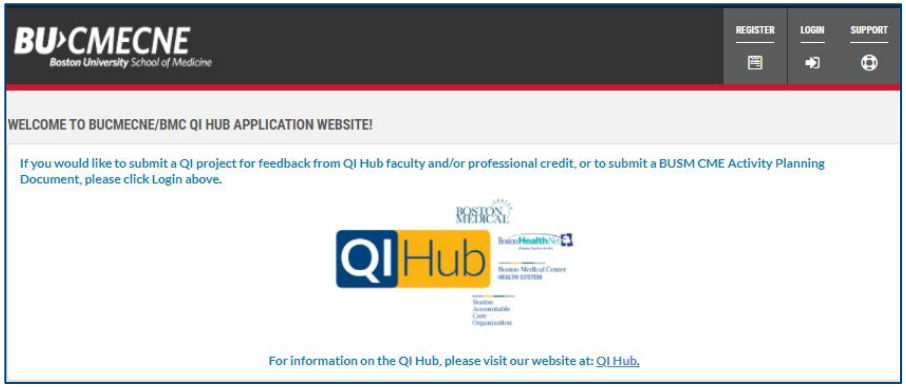
- Because this project has features of both research and QI, **it should be submitted to the IRB.**
- If you have a project with features of QI and research, the IRB can help you parse which aspects must be formally supervised by the IRB, and which non-research activities do not require IRB supervision (i.e. QI).
  - **Research intent:** Describe characteristics of patients that benefit from StreetCred, and patient reported experience using the program
  - **Quality improvement intent**: Monitoring show rates to identify opportunities to improve operational processes



Research must be submitted to the IRB through the INSPIR system; quality work is not required to be submitted*

Submit research work to INSPIR II for IRB determination

https://www.bumc.bu.edu/irb/inspir-ii/



https://cme.bu.edu/qihub

Submit QI work to QI Hub for feedback on QI methods, securing professional credits

IRB Checklist:
https://www.bumc.bu.edu/irb/submission-requirements/when-to-submit/quality-improvement/

*Unless, as discussed earlier, it contains research elements

Questions?