

47th Annual Research and Education Forum

University of Puerto Rico Medical Sciences Campus

Shaping the Future of Health
through Research, Emerging Technologies,
and Education



March 17-19, 2027

Ethical Review Self-Assessment Guide (IRB/IACUC)





UPR
RCM

University of Puerto Rico Medical Sciences Campus



Introduction

Preparing an abstract for presentation at the University of Puerto Rico Medical Sciences Campus (UPR-MSC) Research and Education Forum involves more than presenting scientific or scholarly results. Authors are also responsible for ensuring that their projects complied with all applicable ethical and regulatory requirements before the project began.

Depending on the nature of the project, institutional review or approval may have been required before any activities involving human participants, identifiable private information, identifiable biospecimens, or laboratory animals were initiated.

This guide is intended to help authors identify situations in which institutional ethical review or another official institutional determination may have been required before a project began. It also provides practical guidance on reporting ethical approvals accurately when submitting an abstract to the Forum.

This document is provided for educational purposes only. It does not replace the policies of the institution where the work was conducted or any official determination issued by an Institutional Review Board (IRB), Human Research Protection Program (HRPP), Institutional Animal Care and Use Committee (IACUC), or other authorized institutional office.

Whenever uncertainty exists, authors should consult the appropriate institutional office before submitting an abstract.

Important

The category selected for submission to the Research and Education Forum **does not determine** whether institutional ethical review was required.

For example, **Biomedical Sciences, Clinical Sciences, Epidemiology, Social Sciences, Education, and Public Policy, Evidence-Based Practice Projects,**



Program may or may not require IRB or IACUC review or another official institutional determination, depending on:

- the project's objectives;
- the activities performed;
- whether human participants or identifiable private information were involved;
- whether laboratory animals were used;
- whether the activity was designed to contribute to generalizable knowledge; and
- the policies of the institution where the project was conducted.

When in doubt, consult your institution before submitting your abstract.

How to Use This Guide

Answer each question in the order presented.

If your project involved **human participants or identifiable private information**, follow the Human Research section.

If your project involved **live laboratory animals**, follow the Animal Research section.

If your project consisted of an **Educational Project, Community Project, Quality Improvement Project, Evidence-Based Practice Project, Program Evaluation, or Public Health Activity**, carefully review the Special Situations section before reaching a conclusion.

At the end of this guide, complete the Final Author Checklist before submitting your abstract.

Quick Reference

If your project involved...	You should have considered...
Living individuals	IRB review or another official institutional determination
Identifiable private information	IRB review or another official institutional determination
Identifiable biospecimens	IRB review or another official institutional determination
Live laboratory animals used in research, teaching, or testing	IACUC approval
Educational Projects	Whether your institution required IRB review or another institutional determination
Community Projects	Whether your institution required IRB review or another institutional determination
Program Evaluation	Whether your institution required IRB review or another institutional determination
Quality Improvement Projects	Whether your institution required IRB review or another institutional determination
Evidence-Based Practice Projects	Whether your institution required IRB review or another institutional determination
Public Health Activities	Whether institutional review or another institutional determination was required
Case Reports or Case Studies conducted at UPR-MSU	Generally, no IRB review is required under current UPR-MSU policy; however, authors remain responsible for protecting patient privacy, maintaining confidentiality, and complying with institutional policies and applicable laws.



If your project involved...	You should have considered...
Systematic Reviews, Scoping Reviews, and Meta-analyses based exclusively on published literature	IRB review is generally not required unless identifiable private information, restricted datasets, or other information subject to institutional oversight were used.

Fundamental Principles

Before completing this self-assessment, remember the following principles.

1. Not every scholarly activity requires IRB review.

Many educational activities, community outreach programs, quality improvement initiatives, evidence-based practice projects, and public health activities do not constitute human subject's research.

However, this determination must be made according to the policies of the institution where the work was conducted.

2. The title of a project does not determine whether ethical review was required.

A project entitled "Educational Project," "Community Project," "Quality Improvement Project," or "Program Evaluation" is not automatically exempt from institutional review.

Similarly, a project classified as research does not automatically require full IRB review.

Only the appropriate institutional authority can determine the level of review or whether another institutional determination applies.

3. Different types of projects require different forms of institutional oversight.

Projects involving human participants generally fall under IRB or HRPP oversight.

Projects involving live laboratory animals generally require IACUC review.

Some activities may also require review by other institutional compliance offices.

4. Ethical review, when required, should be obtained before the project begins.

Obtaining approval after data collection or after the project has been completed generally does not satisfy institutional requirements.

5. The Forum does not determine whether ethical review was required.

The Scientific Committee and the Organizing Committee evaluate abstracts submitted to the Forum but do not determine whether a project required IRB review, IACUC approval, or another institutional determination.

Authors are responsible for complying with the requirements of the institution where the work was conducted.

Before Continuing

Proceed to **Question 1** and answer each question carefully.

If, at any point, you are uncertain whether your project required institutional review or another official determination, contact the appropriate office at your institution



CHAPTER 1 - Determining Whether Your Project Required Institutional Ethical Review

This self-assessment is intended to help authors identify situations in which institutional ethical review or another official institutional determination may have been required before a project began.

Answer each question in sequence.

QUESTION 1

Did your project involve any of the following?

Human Participants

- ☐ Living individuals
- ☐ Interaction or intervention with living individuals
- ☐ Identifiable private information
- ☐ Identifiable biospecimens

OR

Laboratory Animals

- ☐ Live vertebrate laboratory animals

If you answered NO to every item above,

Proceed to **Question 5**.

Your project may not have required IRB or IACUC review.

However, continue reading the Special Situations section because some projects still require an official institutional determination.

If you answered YES to one or more items,

Continue to **Question 2.**

QUESTION 2

What activities were performed?

Human Research

Did your project include one or more of the following?

- ☐ Surveys
- ☐ Interviews
- ☐ Focus groups
- ☐ Questionnaires
- ☐ Educational assessments
- ☐ Classroom evaluations
- ☐ Program evaluations involving participants
- ☐ Community needs assessments
- ☐ Medical record review
- ☐ Electronic health record review
- ☐ Educational record review
- ☐ Collection or analysis of identifiable biological specimens
- ☐ Photographs of identifiable individuals



- ☐ Audio or video recordings
- ☐ Observation of identifiable individuals
- ☐ Collection or use of identifiable private information

If **YES**,

your institution **may have required** one of the following before your project began:

- IRB review;
- Exempt determination;
- Determination of Not Human Subjects Research; or
- another official institutional determination.

Continue to **Question 2A**.

Animal Research

Did your project involve one or more of the following?

- ☐ Research
- ☐ Teaching
- ☐ Research training
- ☐ Experimental procedures
- ☐ Animal surgery

- ☐ Behavioral studies
- ☐ Drug or chemical administration
- ☐ Collection of tissues or biological specimens
- ☐ Animal breeding
- ☐ Testing or evaluation
- ☐ Observation involving regulated animal activities

If **YES**,

your project most likely required IACUC approval before the work began.

Continue to **Question 3**.

QUESTION 2A

Educational, Community, and Public Health Activities

Many abstracts submitted to the Research and Education Forum fall into one of the following categories:

- ☐ Educational Project
- ☐ Community Project
- ☐ Health Education Project
- ☐ Public Health Activity
- ☐ Program Evaluation



- ☐ Quality Improvement Project
- ☐ Evidence-Based Practice Project
- ☐ Government Program
- ☐ Community Outreach Initiative

These categories **do not automatically determine** whether institutional ethical review was required.

Ask yourself the following questions.

Was your project conducted primarily to:

- ☐ improve classroom instruction?
- ☐ improve patient care within your institution?
- ☐ improve an existing program?
- ☐ evaluate educational outcomes?
- ☐ assess community needs?
- ☐ evaluate a public health intervention?
- ☐ implement evidence-based practice?

If **YES**,

continue.

Did your project also include one or more of the following?

- ☐ Collection of information from participants
- ☐ Collection of identifiable private information

- ☐ Surveys
- ☐ Interviews
- ☐ Focus groups
- ☐ Educational testing
- ☐ Comparison of educational or clinical interventions
- ☐ Systematic evaluation of outcomes
- ☐ Collection of participant feedback for research purposes
- ☐ Plans to contribute to generalizable knowledge through scientific dissemination

If **YES**,

your institution **may have required**:

- IRB review;
- an Exempt Determination;
- a Determination of Not Human Subjects Research; or
- another official institutional determination before the project began.

Only the appropriate institutional authority can make this determination.



QUESTION 3

Before your project began, did your institution issue an official determination?

Human Research

- ☐ IRB Approval
- ☐ Exempt Determination
- ☐ Determination of Not Human Subjects Research
- ☐ Another official institutional determination

Animal Research

- ☐ IACUC Approval
- ☐ Equivalent institutional approval
- ☐ Another institutional determination
- ☐ I do not know
- ☐ No institutional review or approval was requested

If you selected **"I do not know"** or **"No institutional review or approval was requested,"** consult the appropriate office at your institution before submitting your abstract.

The Research and Education Forum cannot determine whether your project required institutional review.

That responsibility belongs to the institution where the work was conducted.

Remember

The following statements are **NOT** always true.

- X** Educational Projects never require IRB review.
- X** Community Projects never require IRB review.
- X** Program Evaluations never require IRB review.
- X** Quality Improvement Projects never require IRB review.
- X** Evidence-Based Practice Projects never require IRB review.
- X** Public Health Activities never require IRB review.

Whether institutional review was required depends on:

- the objectives of the project;
- the activities performed;
- whether human participants or identifiable private information were involved;
- whether the activity was designed to contribute to generalizable knowledge;
and
- the policies of the institution where the project was conducted.



CHAPTER 2 - Special Project Categories

Not every scholarly activity involving people or animals constitutes research requiring Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) review.

The following guidance addresses situations that frequently generate questions among authors submitting abstracts to the Research and Education Forum.

Whenever uncertainty exists, consult the institution where the project was conducted before submitting your abstract.

Case Reports and Case Series

For projects conducted at the University of Puerto Rico Medical Sciences Campus (UPR-MS):

According to the current policies of the Human Research Subjects Protection Office (HRSPO), individual Case Reports and many Case Series generally do **not** constitute Human Subjects Research and therefore generally do not require IRB review.

However, authors remain responsible for:

- ☐ Protecting patient privacy.
- ☐ Maintaining confidentiality.
- ☐ Removing direct and indirect identifiers when appropriate.
- ☐ Obtaining patient authorization when required.
- ☐ Complying with institutional privacy policies.
- ☐ Complying with all applicable federal, state, and institutional requirements.

Authors affiliated with other institutions must follow the policies of the institution where the work was conducted.

Educational Projects

Educational projects are among the submissions to the Research and Education Forum.

Examples include:

- classroom innovations
- curriculum development
- simulation-based education
- educational interventions
- educational assessments
- teaching methods
- student evaluations
- faculty development activities

Educational projects **do not automatically require IRB review.**

However, an official institutional determination may have been required before the project began if the activity:

- involved human participants;
- collected identifiable private information;
- compared educational interventions;
- systematically evaluated educational outcomes;



- collected data for research purposes; or
- was designed to contribute to generalizable knowledge.

The title "**Educational Project**" alone does not determine whether IRB review was required.

Community Projects

Community outreach activities frequently involve interaction with individuals outside traditional clinical settings.

Examples include:

- health fairs
- health education programs
- community screenings
- community needs assessments
- health promotion activities
- outreach campaigns
- educational workshops

Community projects **do not automatically require IRB review.**

However, institutional review or another official institutional determination may have been required if the project:

- collected identifiable participant information;
- evaluated outcomes systematically;

- compared interventions;
- collected information for research purposes; or
- was intended to contribute to generalizable knowledge.

Public Health Activities

Public health practice and public health research are not always the same.

Examples include:

- disease surveillance
- outbreak investigations
- vaccination campaigns
- community health assessments
- health education initiatives

Some public health activities are conducted solely for operational purposes and may not constitute human subjects research.

Others may require institutional review depending on their objectives, methods, and applicable institutional policies.

Authors should follow the policies of the institution where the activity was conducted.

Quality Improvement Projects

Quality Improvement (QI) projects are intended primarily to improve healthcare processes or institutional performance.



Examples include:

- reducing medication errors;
- improving patient flow;
- reducing hospital-acquired infections;
- improving appointment scheduling;
- increasing compliance with clinical guidelines.

Many Quality Improvement projects do not require IRB review.

However, if the project was designed to produce generalizable knowledge or involved systematic investigation involving human participants or identifiable private information, institutional review or another official determination may have been required.

Evidence-Based Practice Projects

Evidence-Based Practice (EBP) projects typically involve implementing evidence to improve patient care.

Examples include:

- implementation of clinical practice guidelines;
- nursing practice improvements;
- medication safety initiatives;
- patient education interventions.

Many EBP projects are conducted solely for local practice improvement.

Nevertheless, some projects may require institutional review depending on their objectives, methodology, and institutional policies.

Program Evaluation

Program evaluation is frequently performed to assess the effectiveness of educational, clinical, or community programs.

Examples include evaluations of:

- residency programs;
- academic courses;
- continuing education activities;
- community interventions;
- government-funded initiatives.

Program evaluations **do not automatically require IRB review**.

Institutional review may have been required if the project involved human participants, identifiable private information, systematic investigation, or was intended to contribute to generalizable knowledge.

Systematic Reviews, Scoping Reviews, and Meta-analyses

Projects based exclusively on published literature or publicly available information generally do not require IRB review.

However, authors should consult their institution if the project involved:

- identifiable private information;
- restricted datasets;



- non-public records;
- protected health information; or
- data subject to institutional oversight.

Animal Research

Projects involving live vertebrate laboratory animals generally require IACUC approval before any regulated activities begin.

Examples include:

- animal experiments;
- surgical procedures;
- behavioral studies;
- breeding protocols;
- administration of drugs or chemicals;
- collection of tissues or biological specimens;
- teaching laboratories using regulated species.

Authors should report the applicable IACUC protocol information in accordance with the Forum's Abstract Submission Guidelines.

Remember

Publication or presentation at the Research and Education Forum **does not determine** whether institutional review was required.

Likewise, the category selected for submission does **not** determine whether IRB review or IACUC approval was necessary.

Only the institution where the work was conducted can determine whether a project required:

- IRB review;
- IACUC approval;
- an Exempt Determination;
- a Determination of Not Human Subjects Research; or
- another official institutional determination.



UPR

RCM

University of Puerto Rico Medical Sciences Campus

CHAPTER 3 - Frequently Asked Questions

The following questions address situations that frequently arise during abstract preparation for the University of Puerto Rico Medical Sciences Campus Research and Education Forum.

Does every project require IRB approval?

No.

Many scholarly activities do not require IRB review.

However, only the institution where the work was conducted can determine whether a project required:

- IRB review;
- an Exempt Determination;
- a Determination of Not Human Subjects Research; or
- another official institutional determination.

Does presenting my work at the Forum automatically make it "research"?

No.

Presenting or publishing the results of a project does not determine whether institutional ethical review was required.

The need for review depends on the nature of the activity, how the information was collected, whether human participants or laboratory animals were involved, and the policies of the institution where the work was conducted.

My project was an Educational Project.

Does that mean IRB review was unnecessary?

Not necessarily.

Many educational activities are conducted solely to improve teaching and learning and do not require IRB review.

However, if your project involved human participants, identifiable private information, systematic data collection, comparison of educational interventions, or was designed to contribute to generalizable knowledge, your institution may have required IRB review or another official institutional determination before the project began.

My project was a Community Project.

Does that automatically mean IRB review was unnecessary?

No.

Community projects may or may not require institutional review.

If your project involved identifiable participant information, surveys, interviews, outcome evaluation, or systematic investigation designed to contribute to generalizable knowledge, institutional review or another official determination may have been required.

My project was a Quality Improvement initiative.

Do all Quality Improvement projects require IRB review?

No.

Many Quality Improvement projects are performed solely to improve local clinical practice.

However, some Quality Improvement activities may require institutional review depending on their objectives, methodology, and institutional policies.



My project involved Evidence-Based Practice.

Do Evidence-Based Practice projects require IRB review?

Not always.

Many Evidence-Based Practice initiatives are implemented exclusively to improve patient care.

Institutional review requirements depend on the objectives of the project, the activities performed, and the policies of the institution where the work was conducted.

My project was a Program Evaluation.

Does it require IRB review?

Not necessarily.

Program evaluations are frequently conducted for operational purposes.

However, some program evaluations may require institutional review depending on their objectives and methods.

My project involved Public Health activities.

Do public health activities require IRB review?

Some do.

Public health practice and public health research are not always the same.

Authors should follow the policies of the institution where the work was conducted.

I used medical records.

Does that require IRB review?

Projects involving identifiable medical records frequently require institutional review or another official determination.

Consult your institution before submitting your abstract if you are uncertain.

I analyzed an existing dataset.

Do I need IRB review?

It depends.

The answer depends on whether the data were identifiable, coded, publicly available, or subject to institutional restrictions.

Institutional policies should always be followed.

My project involved laboratory animals.

Do I need IACUC approval?

Projects involving live vertebrate laboratory animals generally require IACUC approval before regulated activities begin.

Authors should report the applicable protocol information in accordance with the Forum's Abstract Submission Guidelines.



My project involved animal tissues obtained from another approved study.

Do I still need IACUC approval?

Institutional policies differ.

Consult the institution where the work was conducted before submitting your abstract.

My mentor told me IRB approval was unnecessary.

Is that sufficient?

No.

Only the appropriate institutional authority can determine whether a project required IRB review or another institutional determination.

FINAL AUTHOR CHECKLIST

Before submitting your abstract, confirm each of the following.

Institutional Review

- ☐ I determined whether my project required institutional ethical review before it began.
- ☐ When required, I obtained the appropriate institutional review, approval, or determination before beginning the project.
- ☐ I understand that the title of my project does not determine whether IRB review or IACUC approval was required.

Human Research

When applicable,

- ☐ My IRB Approval, Exempt Determination, Determination of Not Human Subjects Research, or other official institutional determination has been documented.
- ☐ The protocol or determination number reported in my abstract is accurate.
- ☐ The approval or determination date is reported accurately when required by my institution.

Animal Research

When applicable,

- ☐ My IACUC protocol was approved before the project began.
- ☐ The protocol number reported in my abstract is accurate.



UPR
RCM

University of Puerto Rico Medical Sciences Campus

☐ The approval information entered the submission system is identical to my institutional documentation.

Abstract Submission

☐ The required ethical statement appears in the body of my abstract.

☐ The information reported in my abstract matches the information entered the online submission system.

☐ All ethical information is consistent with my institution's official documentation.

Final Reminder

The Scientific Committee and Organizing Committee of the University of Puerto Rico Medical Sciences Campus Research and Education Forum do not determine whether a project required IRB review, IACUC approval, or another institutional ethical determination.

Authors are responsible for complying with the policies of the institution where the work was conducted.

Whenever uncertainty exists, consult the appropriate office at your institution before submitting your abstract, including, when applicable:

- Institutional Review Board (IRB)
- Human Research Protection Program (HRPP)
- Institutional Animal Care and Use Committee (IACUC)
- Privacy Office
- Office of Research Compliance
- Other authorized institutional office

Early consultation with the appropriate institutional office can prevent delays, uncertainty, and administrative rejection during the abstract submission process.

This guide is intended to help authors identify situations in which institutional ethical review may have been required before a project began. It is not intended to replace institutional policies or official determinations issued by authorized institutional offices.



UPR
RCM

University of Puerto Rico Medical Sciences Campus

