EXAMPLE ONLY: fictional project, people, and clinic, shown to illustrate a completed QI request.

Idaho State University

Office for Research | Human Subjects Committee (HSC)

Project Determination Request

Quality Improvement or Research

Last updated November 4, 2026

About this form

Purpose. Use this form to request an HSC determination of whether your project is quality improvement (QI) or human subjects research. Projects that are not human subjects research receive a **Not Human Subjects Research (NHSR)** determination letter from the HSC.

Relationship to Cayuse. Human subjects research is submitted as a protocol in Cayuse. Other projects do not need a Cayuse protocol; this form is their pathway. If your project is research, you will be directed to Cayuse. If you already know your project is research, you may submit directly in Cayuse.

Do not start your project until you receive your letter or HSC approval. Definitions are on the last page.

Submit the completed form to **humsubj@isu.edu**. Questions: Research Compliance Coordinator, **208-282-2179**.

1. Project Information

Project title *Use "project" rather than "study" for QI.*	Improving Statin Prescribing for Patients with Diabetes at Sagebrush Valley Rural Health Clinic: A Pharmacist-Led Quality Improvement Project
Project site(s)	Sagebrush Valley Rural Health Clinic (fictional), Idaho
Site contact *Name and title of the person at the site who agreed to the project.*	Jamie Fields, Clinic Manager
Site agreement *Has the project site agreed to host this project?*	☑ Yes ☐ In progress ☐ Not applicable (ISU program, course, or office)
Anticipated start and end dates	January 2027 to June 2027
Funding source	☑ None ☐ ISU internal ☐ External (name):

	Investigator	Faculty advisor (for student projects)
Name	Taylor Morgan, PharmD candidate	Casey Lee, PharmD, BCACP
Role	☐ Faculty ☐ Staff ☑ Student	Faculty advisor
Department or program	L.S. Skaggs College of Pharmacy, PharmD program	Department of Pharmacy Practice
Email	student.example@isu.edu	advisor.example@isu.edu
Phone	(208) 555-0142	(208) 555-0187

EXAMPLE

2. Project Description

Purpose

Up to 300 words: the problem, what you hope to improve or learn, and who will benefit.

The clinic's quality report shows that only 58% of patients with diabetes aged 40 to 75 have an active statin prescription. National guidelines already recommend statin therapy for nearly all patients in this group, and our clinic's goal is 80%.

This project will add a pharmacist review step to the clinic's existing chronic care workflow. Our aim is to raise the clinic's statin prescribing rate for eligible patients with diabetes from 58% to at least 75% within six months.

Patients with diabetes at the clinic will benefit from guideline-recommended care that lowers their risk of heart attack and stroke. Clinic providers and staff will benefit from a simple, team-based process they can continue after the project ends.

Procedures

Up to 300 words: what you will do, who is involved, what information you will collect or access, how, and where.

Each month, the clinic's two pharmacists will run an existing electronic health record (EHR) report of patients aged 40 to 75 with diabetes who have no active statin. Before each scheduled visit, a pharmacist will review the chart for documented reasons not to prescribe (for example, prior intolerance or patient preference) and, when appropriate, send the provider a standard recommendation in the EHR. Prescribing decisions stay with the provider and patient as part of routine care.

We will use Plan-Do-Study-Act (PDSA) cycles. Each month we will track (1) the percentage of eligible patients with an active statin, (2) the percentage of pharmacist recommendations accepted, and (3) reasons recommendations were not accepted. All measures come from routine EHR data and pharmacist documentation. There are no surveys, interviews, or patient contact beyond usual care.

The student will help run reports and summarize monthly results under the advisor's supervision. Results will be shared with clinic staff and leadership each month to refine the workflow.

Evidence base

Up to 300 words: is the practice already supported by evidence? Summarize it and cite key sources briefly.

Yes. Statin therapy for adults aged 40 to 75 with diabetes is a well-established recommendation in the American Diabetes Association Standards of Care in Diabetes and the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol. Pharmacist recommendations to prescribers are also an established way to close gaps in guideline-recommended medication therapy in primary care.

This project does not test a new intervention. It puts an existing, evidence-based practice into our clinic's workflow and measures whether our local performance improves.

EXAMPLE

3. Project Type

Quality improvement (QI) or program evaluation uses existing evidence to improve or assess a specific program, clinic, course, or service, for use in that setting. In contrast, **research** is designed to produce knowledge meant to apply beyond the people and setting studied.

A. How would you describe your project?	☑ Quality improvement ☐ Program evaluation ☐ Evidence-based practice implementation ☐ Research ☐ Not sure
B. The results are intended for use primarily within the specific program, clinic, or setting where the project takes place. *Sharing what you learned at a conference or in a publication is fine.*	☑ Agree ☐ Disagree ☐ Not sure

The HSC's determination is based on the whole form, not on these answers alone.

4. Design Questions

Part A. A "Yes" to any question usually means the project is research. **Parts B and C.** Answer as they apply. Choose "Not sure" rather than guessing.

#	Question	Answer
Part A. Research indicators		
1	Is the project intended to be research, or required to be research (for example, a thesis, dissertation, or research study)? A required culminating project, such as a DNP project, is not automatically research.	☐ Yes ☑ No ☐ Not sure
2	Is the project funded or supported as research?	☐ Yes ☑ No ☐ Not sure
3	Will you test a new, modified, or untested intervention that is not yet supported by sufficient evidence, or evaluate whether an intervention works in a way meant to apply beyond your setting?	☐ Yes ☑ No ☐ Not sure
4	Will you assign or randomize people or groups (such as classes or clinics) to different conditions to compare them, even if both approaches are evidence-based?	☐ Yes ☑ No ☐ Not sure
5	Will participants take on time, procedures, or risks beyond usual care, coursework, services, or work mainly so that the results can apply beyond your setting?	☐ Yes ☑ No ☐ Not sure
Part B. Consult the HSC if "Yes"		
6	Will the project involve a drug, biologic, device, or supplement used in a new, off-label, or investigational way?	☐ Yes ☑ No ☐ Not sure
7	Will the project enroll children, prisoners, or adults who cannot consent for themselves as participants?	☐ Yes ☑ No ☐ Not sure
Part C. Existing data only (may qualify as research not involving human subjects if the data were de-identified before you receive them)		
8	Will the project use only existing data that someone else has already collected and de-identified, with no way for anyone on your team to identify individuals and no contact with participants?	☐ Yes ☑ No ☐ Not sure

EXAMPLE

5. Data and Privacy

What kind of information will you collect or access?	☐ Surveys or questionnaires ☐ Interviews or focus groups ☐ Observation ☐ Tests or assessments ☑ Existing records or data ☐ Other:
From what source? *For example: clinic health records, course grades or learning management system data, program records, or participants themselves.*	Monthly reports from the clinic's EHR and pharmacists' routine documentation of their recommendations. All data are generated as part of usual patient care.
Form of the information	☑ Identifiable ☐ Coded (key exists) ☐ De-identified ☐ Anonymous ☐ Not applicable
How will it be stored and protected?	Patient-level lists stay within the clinic's EHR and secure network and are viewed only by clinic staff involved in care. Monthly summaries contain only counts and percentages; no patient identifiers leave the clinic. The student completes the clinic's HIPAA training and confidentiality agreement.

Projects that are not research must still protect privacy. Site policies, HIPAA, and FERPA continue to apply.

6. Attestation

By signing, I confirm that:

- The information on this form accurately describes the project as planned.
- I will contact the HSC before changing the design, for example by adding comparison groups, new data collection, or a new intervention.
- I understand that an NHSR determination is not IRB approval and applies only to the project as described.
- I am responsible for obtaining any approvals required by the project site.

Investigator	Signature: Taylor Morgan	Date: 12/01/2026
Faculty advisor (student projects)	Signature: Casey Lee	Date: 12/01/2026

7. HSC Use Only

Determination	☐ Not Human Subjects Research: not research (QI, program evaluation, evidence-based practice) ☐ Not Human Subjects Research: research not involving human subjects ☐ Human subjects research: submit a protocol in Cayuse ☐ Consultation needed
Consistency check	☐ Section 3 answers match the design questions ☐ Mismatch noted (consult with investigator)
Reviewer, date, and letter issued	
Log number and notes	

EXAMPLE

Definitions and Guidance

Anonymous. No identifiers are collected, and information cannot be linked to an individual by the project team or others.

Confidentiality. Protecting identifiable information collected from or about individuals against unauthorized access, use, or disclosure, and limiting access to authorized individuals (45 CFR 46.111(a)(7)).

De-identified. Information from which identifying details have been removed so that individuals cannot readily be identified. No key or link back to individuals is available to the project team.

Extra data principle. Collecting additional data or conducting analyses beyond those necessary for local QI or operational purposes may indicate that an activity is designed to produce generalizable knowledge. Such activities need further review. (Adapted from VA guidance on operations activities.)

Generalizable knowledge. Knowledge intended to apply beyond the individuals or setting studied, such as theories, principles, or statements of relationships. QI findings may be transferable to similar settings, but transferability is not the same as generalizability (AACN, 2026).

HSC and IRB. The Human Subjects Committee (HSC) is Idaho State University's Institutional Review Board (IRB). A determination that an activity is not human subjects research (NHSR) is not IRB approval; it establishes that IRB review is not required under the applicable human subjects research regulations.

Human subject. A living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction, or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (45 CFR 46.102(e)).

Privacy. An individual's interest in controlling access to themselves and their personal information. Privacy concerns how individuals are approached, observed, or asked to provide information, whereas confidentiality concerns how information is protected after collection.

Quality improvement (QI). An activity designed to improve a specific program, clinical practice, educational process, or service through the application and evaluation of existing evidence. QI primarily seeks improvements in a local setting. Program evaluation and evidence-based practice projects often have similar purposes.

Research. A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(l)).

Systematic investigation. A planned activity involving organized data collection and analysis to answer a question or evaluate outcomes. Research and QI can both be systematic, so being systematic alone does not make an activity research.

Vulnerable populations. Individuals or groups who may be particularly susceptible to coercion or undue influence in research, including children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons. Including them does not by itself make a project research, but for research it may affect the level of review and protections required.

What does not determine research status. Presenting or publishing findings, labeling an activity as QI, or using surveys, interviews, or statistics does not by itself make an activity research. Purpose and design are what matter.

Examples

- **Likely QI (clinical).** A clinic adopts an evidence-based depression screening tool at annual visits and monitors screening rates from its own records.
- **Likely QI (educational).** A department revises a gateway course and compares pass rates with previous semesters to decide whether to keep the changes.
- **Likely research (educational).** An instructor randomly assigns course sections to two teaching methods to test which is more effective beyond the local course.

If your project does not clearly fit either category, contact the HSC. A brief conversation is often the fastest route.

Presenting or publishing a QI project

Suggested wording: "This project was reviewed by the Idaho State University Human Subjects Committee (HSC), the university's Institutional Review Board (IRB), and determined not to be human subjects research."

Resources

- OHRP Decision Charts (2018): https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html
- OHRP QI FAQs: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html
- ISU HSC: https://www.isu.edu/research/research-integrity-and-compliance/human-subjects/human-subjects-committee/
- AACN (2026). The Doctor of Nursing Practice: Current issues and clarifying recommendations.