**Not sure if you need IRB approval?**

Use this form if you are seeking a written determination that your activity is Not Human Subjects Research or you are unsure whether your quality improvement/assurance project, program evaluation, or other activity requires IRB review.

**Human Subjects Research is defined in the federal regulations (45 CFR 46.102):**

* ***Research*** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
* ***Human Subject*** means a living individual about whom an investigator (whether professional or student) conducting research:

(1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

**The following types of projects typically require prior IRB approval:**

* Plans to use patient data in comparative effectiveness analyses
* Plans to use retrospective patient data to contribute to generalizable knowledge
* Plans to implement an untested clinical intervention that is hoped to improve patient care
* Projects that involve randomization, even if they involve standard of care
* Projects that involve scale or instrument development

All Human Subjects Research (HSR) requires prior IRB review and approval, even if it meets the criteria described in [HRP-423 WORKSHEET: Exemptions](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/). **For all human subjects research, submit a completed** [**Investigator Study Plan**](https://www.umassmed.edu/ccts/irb/forms_templates/) **and any supporting documents.**

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|  | **DO NOT USE THIS FORM FOR EXEMPT RESEARCH** |

**DO use this form for activities that are not human subjects research at all. The following types of projects typically do not require IRB review:**

* Analysis of pre-existing anonymous data sets or public data sets
* Analysis of coded specimens or data from an external source when (i) there is written documentation that the code will never be broken for you and (ii) the external source is not one of the key personnel on a federal grant funding the analysis
	+ See the NIH online decision tool: <https://humansubjects.nih.gov/questionnaire>
* Program or course evaluations, unless they are designed to contribute to generalizable knowledge
* Classroom exercises conducted solely to fulfill course requirements or to train students in the use of particular methods or devices
* A single patient case study (Note that ethical obligations and [HIPAA](http://www.umassmed.edu/ccts/human-research/privacy-and-security/) regulations still apply). To be authorized to access the patient’s protected health information, project personnel must either provide direct care for the patient or have obtained written authorization from the patient. Email privacy@umassmed.edu with questions.
* Quality improvement or quality assurance projects when they are not designed to contribute to generalizable knowledge; examples include:
	+ A provider or group monitors its infection rates or other outcomes solely to detect possible problems and to change its practice in response
	+ A provider or group implements an existing evidence-based practice project or plan, assesses its performance against the given benchmarks, and works with the permission of an individual or institutional body that has the authority to mandate changes in clinical practice and concurs that the activity is QA/QI
	+ A clinic surveys its patients to identify ways to reduce no-shows
	+ A review of pharmacy records to conduct a cost/benefit analysis for formulary selections

\* **Instructions** \*

To request a written determination that your activity is Not Human Subjects Research or to request an assessment as to whether your project requires IRB review:

* Answer the questions on the next page.
* If this is your first time using this form, we invite you to contact the IRB to request a consultation of your draft (508-856-4261, irb@umassmed.edu).
* Submit this document through the eIRB system as a new study. You will upload this document to Section 7.0 Attachments in the Investigator Study Plan slot.
* Upload any supporting documents that may be available – even if in draft form. Providing surveys, permission forms, statements of work, proposals, etc., helps the IRB assess the activity. Permission forms, recruitment materials, etc. cannot say that the IRB has reviewed the activity.
* Students/Residents/Fellows/Trainees must list their Faculty Advisor as Active Study Staff and as an Additional Contact, or as Principal Investigator.

For instructions on how to submit a new study through eIRB, see [How to Create and Submit a New Research Study Submission](https://www.umassmed.edu/ccts/irb/eirb2/job-aids-ii/). You will still need to Edit Research Staff and Edit the Consumer/Lay Summary to submit.

Regardless of whether an activity is determined to be HSR, project personnel must: (i) follow institutional security policies and guidelines and (ii) follow HIPAA regulations for protecting any protected health information, including ensuring that appropriate agreements are in place prior to sharing any individual or identifiable information outside of the institution. Contact the following offices for more information:

* <https://www.umassmed.edu/it/> -- Information Technology Security
* <https://www.umassmed.edu/bridge/> -- Material Transfer Agreements
* <https://www.umassmed.edu/privacy> -- Data Use or Business Associate Agreements

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| --- | --- |
| Project Title: |  |
| Project Leader: |  |
| Faculty Advisor (if applicable): |  |
| Funding/Sponsor:  |  |
| What is the purpose of the project?  |  |
| Will the project be conducted to meet an external mandate (e.g., accreditation, CMS requirements)? If yes, please specify. |  |
| What are the project activities/procedures? |  |
| Will you interact with employees, students/trainees, patients or others? If yes, please specify.  |  |
| Will you use, access, collect, or generate *identifiable private information*+ related to employees, students/trainees, patients or others? If yes, please specify. |  |
| Do you believe this project involves research\*? If not, why not? For example, does it fit any of the examples on Page 1 of projects that may not require IRB review?  |  |
| Who will the results be shared with and how? Include local and external parties. |  |
| If the project is externally mandated or contract-based, will the activities be limited to those needed to fulfill the mandate or contract? Or will the team take the opportunity to address other topics/questions of interest? |  |

+ *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. (45 CFR 46.102)

\*See the definitions on page 1 or use [HRP-421 WORKSHEET: Human Research](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) to help determine whether your project has human subjects or is research.