**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 as to whether your quality improvement/assurance project, program evaluation, or other activity requires IRB review.

**Human Subjects Research is defined in the federal regulations as:**

* ***Research*** ([45 CFR 46.102 (d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.102)): Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
* ***Human Subject*** ([45 CFR 46.102 (f)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.102)): Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

All Human Subjects Research (HSR) requires prior IRB review and approval, even if it meets the exemption criteria described in [HRP-423 WORKSHEET: Exemptions](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/). Use the usual IRB application materials, not this form, for exemption requests.

**The following types of projects typically do not require IRB review:**

* 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](mailto:privacy@umassmed.edu) with questions.
* 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
* 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>
* 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

**The following types of projects typically do require IRB review:**

* Plans to use patient data in comparative effectiveness analyses
* 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

\* **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 for a consultation of your draft (508-856-4261, [irb@umassmed.edu](mailto: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 lieu of an Investigator Study Plan.

For more information on how to submit a new study through eIRB, see [How to Create and Submit a New Research Study Submission](http://www.umassmed.edu/ccts/irb/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:

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

|  |  |
| --- | --- |
| Project Title: |  |
| Project Leader: |  |
| Funding/Sponsor: |  |
| Describe the purpose and main activities of the project: |  |
| Will the project be conducted to meet an external mandate (e.g., accreditation, CMS requirements)? If yes, please specify. |  |
| Will you interact with people or patients to conduct the project? If yes, who will you interact with? |  |
| Will you use patient information in any way? Will you collect private identifiable information from 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? |  |

\*([HRP-421 WORKSHEET: Human Research](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) can assist you in determining whether your project has human subjects or is research.)