

Registration Deadline: Second Friday in November

Student Name (Print):

Year: 2L 3L

HUID:

Email:

Faculty Supervisor (Print):

INDEPENDENT	IN CONJUNCTION WITH A COURSE OR SEMINAR
	Course or Seminar Name:
2 Writing Credits	2 Writing Credits
3 Writing Credits	3 Writing Credits

**PROPOSAL (REQUIRED):**

On a separate sheet of paper, briefly describe the topic and explain the approach you may take, the extent and type of research, your reason for interest in the topic, previous work you may have done in the area, and the written product you intend to produce (e.g., 60-page paper, research memo, etc.). **The Registrar's Office will not register your paper without a proposal attached to this form.**

**RESEARCH and IRB REVIEW:**

Research projects meeting the regulatory definition of "research with human subjects" require submittal to, and approval by, the Harvard University Area IRB. However, not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research and may not require review by an IRB. **Please see the reverse side for more information on what work meets the definition of research warranting IRB review.**

**NOTE:**

Winter term papers will satisfy your HLS written work requirement once the Registrar's Office receives the grade for your written work from your supervising faculty member.

*I have read the [relevant section of the Handbook of Academic Policies](#) and given my supervisor a copy of the [Guidelines for Faculty Supervisors](#).*

Student Signature:

Date:

*I have read this student's Winter Writing Program Proposal and the Guidelines for Faculty Supervisors, and I agree to supervise this project.*

Faculty Supervisor Signature:

Date:

**Faculty Supervisor, please note:** Your initials are required below if the student is doing research away from Cambridge.

**REQUIRED INFORMATION FOR WINTER TERM TRAVEL:**

Will this paper require travel off campus for research?  Yes  No If yes, where?

**HLS STUDENTS TRAVELING ABROAD MUST REVIEW AND COMPLY WITH INTERNATIONAL TRAVEL**

**REQUIREMENTS.** These involve completing pre-departure training (including attending one of the sessions in November) and an entry in the MyTrips platform, submitting an Assumption of Risk Form, and taking certain steps in relation to travel to areas categorized as high-risk. Further information can be found here:

<https://hls.harvard.edu/dept/ils/international-travel/>.

*I have reviewed the proposal to do research away from Cambridge. It is justified and fits within Winter Term.*

Faculty Supervisor's Initials:

While an activity may be considered research, it is important to highlight that not all research meets the threshold of “regulated research” requiring IRB review. The federal regulations have a very specific definition of what is considered regulated research that requires IRB review. The following provides a brief summary of the definitions used by federal regulations:

The federal regulations define *regulated research* as “a **systematic investigation**, including development, testing, and evaluation, designed to develop or **contribute to generalizable knowledge**.” Note that usage of the term “research” in the below text refers to regulated research.

What does a "systematic investigation" mean? A **systematic investigation** involves a methodical procedure and plan, is theoretically grounded, and specifies a focused and well-defined research problem or question, is informed by the empirical findings of others, is analytically robust, and provides a detailed and complete description of data collection methods.

What does "generalizable" mean? **Generalizable knowledge** is information that is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:

- Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
- Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

Note that publication or other dissemination of findings does not in and of itself make the activity “research.” It has been a long-standing myth that if you publish, IRB review is required. Examples of work that may not meet the threshold for needing IRB review include course projects where the primary intent is to fulfill course requirements and gain experience, program evaluations, case studies, oral histories, and journalistic activities.

For more information on activities that are not regulated research warranting IRB review, please see:

<https://cuhs.harvard.edu/winter-writing-project>

**If your activity meets the federal regulatory definition of regulated research, the next step is to determine whether your research involves human subjects.**

The federal regulations define a *human subject* as “a **living individual about whom** an investigator conducting research obtains (1) **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**.”

For more information on what constitutes a human subject, please see: <https://cuhs.harvard.edu/winter-writing-project>

- **WHAT IF I AM NOT CONDUCTING “REGULATED RESEARCH”?** There is no requirement for IRB review.
- **WHAT IF I AM CONDUCTING RESEARCH BUT IT DOES NOT INVOLVE HUMAN SUBJECTS?** There is no requirement for IRB review.
- **WHAT IF I AM CONDUCTING RESEARCH THAT INVOLVES HUMAN SUBJECTS?** IRB review is required.
- **WHAT IF I AM NOT SURE?** Instructions specific to the Winter Writing Project may be found here: <https://cuhs.harvard.edu/winter-writing-project>. The Harvard University Area IRB office may be reached at (617) 496-2847, by email at [cuhs@harvard.edu](mailto:cuhs@harvard.edu), or in person at 44R Brattle St, 2<sup>nd</sup> Floor, Cambridge, MA 02138.