# Registration Deadlines - Fall: Second Friday in October / Spring: Second Friday in February

Student Name (Print):        Year: 2L 3L

HUID:       E-mail:

Faculty Supervisor (Print):

| **INDEPENDENT** | **IN CONJUNCTION WITH A COURSE OR SEMINAR**  Course or Seminar Name: |
| --- | --- |
| 1 Writing Credit  2 Writing Credits  3 Writing Credits | 1 Writing Credit  2 Writing Credits  3 Writing Credits |
| Fall Term  Spring Term | Fall Term  Spring Term |

# 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., 30-page paper, research memo, etc.). **The Registrar’s Office will not register your paper without a proposal attached to this form.**

# HUMAN SUBJECT RESEARCH:

**If your research involves human subjects as defined on page 2 of this form, you will need to have your project reviewed by the Harvard University-Area IRB.** The IRB review process requires time; if your project will or might involve human subjects, you must begin the review process well before the term in which you are planning to conduct your research.

**PLEASE NOTE:**

* **Please review the guidelines for written work found in the** [Handbook of Academic Policies](http://hls.harvard.edu/dept/academics/handbook/rules-relating-to-law-school-studies/requirements-for-the-j-d-degree/j-d-written-work-requirement/)**.**
* Independent Writing:
  + Registering for 1 Writing Credit independent of a course **will not**, by itself, fulfill the written work requirement.
  + Registering for 2 or 3 Writing Credits independent of a course **will** fulfill the written work requirement.
* Written Work done In Conjunction with a Course or Seminar:
  + Registering for 1, 2, or 3 credit(s) **will** all fulfill the written work requirement.
* Your written work requirement will not be satisfied until the Registrar’s Office receives a passing grade for your written work from your supervising faculty member.
* [RA work for credit](http://hls.harvard.edu/dept/academics/handbook/rules-relating-to-law-school-studies/additional-academic-opportunities-j-d-and-graduate-programs/additional-written-work-opportunities/) should meet the written work guidelines as outlined in the Handbook of Academic Policies.

**I have read the above and agree to the terms.**

**Student’s Signature:** **Date:**

**Faculty Supervisor Signature:** **Date:**

### **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) **data through intervention or interaction** with the individual ***or*** (2) **identifiable private information**” (45 CFR 46.102(f)(1)(2)).

*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 Smith Campus Center, 1350 Massachusetts Ave, Suite 935 (9th floor), Cambridge, MA 02138.