

Registration Deadlines:

Fall-Spring groups: September 17th, 2021 / Spring groups: February 4th, 2022

Student Name: _____ **Year:** 2L 3L LLM

HUID: _____ **Email:** _____

Faculty Supervisor: _____

Writing Group Title: _____

Writing Credit: Writing credits can be applied to the fall, winter, or spring terms. Please select the number of writing credits AND the term(s) where the writing credits will be applied.

2 Writing Credits	Fall	Spring	Winter
3 Writing Credits	Fall-Spring	Fall-Winter	Winter-Spring

PROPOSAL (REQUIRED): Briefly describe the topic and explain the approach you may take, the extent and type of research, 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.*

Please review the requirements for participation in [Upper-Level Writing Groups](#), as well as the guidelines for written work in the [Handbook of Academic Policies](#).

By signing below, you agree to read and abide by the terms for Writing Group and Written Work registration.

Student Signature: _____ **Date:** _____

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

J.D. & LL.M. WRITING GROUP REGISTRATION

Please note the following regarding HUMAN SUBJECT RESEARCH:

If your research involves human subjects as defined below, 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.

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.

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 or for information on activities that are not regulated research warranting IRB review, 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, or in person at Smith Campus Center, 1350 Massachusetts Ave, Suite 935 (9th floor), Cambridge, MA 02138.