



**University of Massachusetts Medical School**  
**Guidelines for Including UMW Students as Research Subjects**  
**(Draft v8.0; 8/12/15)**

Students of the University of Massachusetts Worcester (UMW) include those enrolled in any courses or programs of the School of Medicine, the Graduate School of Biomedical Sciences, and the Graduate School of Nursing. The purpose of these guidelines is to address the increasing concerns about protecting the rights and welfare of students who participate as human subjects in research conducted at the institution where they are enrolled. The main concerns include: (a) the potential for undue influence on the voluntariness of student participation, (b) the potential for breach of confidentiality, and (c) survey burden. These concerns must be weighed against student autonomy and the schools' obligation to respect the right of students to choose whether or not to participate in research.

**All human subjects research, including research involving students, must be submitted to the UMW Institutional Review Board (IRB) for review and approval prior to initiation.** Prior review and approval is required regardless of whether the research is deemed to fit an exempt or expedited review category or to require review by the convened IRB. In general, routine, scheduled course/instructor evaluations used for quality improvement would not be considered in the scope of educational research.

The individual schools within UMW will form a Coordinating Committee across the three schools, charged with the task of reviewing proposals that involve students as human subjects. Membership of the Coordinating Committee will include representatives from the Graduate School of Biomedical Sciences, School of Medicine, and School of Nursing, including faculty members and members of the student body. **Investigators (be they faculty or students) will need to consult this Coordinating Committee prior to submitting the proposal to the IRB, so as to be able to include accurate information regarding the study design, including subject recruitment, in the Investigator Study Plan.** This committee complements the IRB, as it focuses on issues such as the primacy of the curriculum, proper use and security of educational data, and faculty career development in the arena of educational research. The Coordinating Committee serves in an advocacy/advisory capacity only. Investigators conducting research that involves students from the UMW campus are required to submit a Statement of Intent, describing their project. The UMW procedures addressing this requirement and the Statement of Intent can be found on the Library website, under



libguides. Questions regarding this policy should be addressed to the Office of Educational Affairs at the school where the study is being conducted (GSBS, GSN, or SOM). A link to information regarding this process will also be posted on the Ancillary Reviews section of the Human Research Protection Program website, directing investigators to the Coordinating Committee, the Statement of Intent, and to this guideline. As the IRB does not oversee this process, questions regarding the Guidelines for Students as Research Subjects should not be directed to the IRB.

**A. Investigators should recognize the potential for undue influences and take steps to foster voluntary participation.**

Voluntariness involves the student's ability to freely choose to not participate in a study. Investigators can limit the potential for undue influence on participation in several ways.

First, an investigator should consider alternatives to directly recruiting UMMS students for a research study when he/she also teaches, academically supervises, or has any influence on that student's grades, academic success, or professional advancement, regardless of the level of risk in the proposed study. UMW students may be directly recruited by investigators or research personnel when such conditions do not exist. Investigators may enroll their own students as research participants if their students respond to indirect recruiting methods such as the posting of IRB-approved flyers or advertisements.

Second, students might feel unduly influenced to participate in a study that requires consent of all students in a group setting. Investigators should propose a strategy that provides for an individual student's ability to opt out of a study in a way that maintains his/her confidentiality and allows the student sufficient time to consider whether or not to participate. Data on students who opt out of a study must not be used.

Third, investigators should carefully consider the use of money, gift cards, raffles, or other incentives to encourage participation or continued enrollment in a research study. Consistent with the UMMS policy regarding incentives ([HRP-403 Worksheet: Payments](#)), the use of extra credit or grades as research incentives is generally prohibited as it has the potential to affect the voluntariness of participation in a study.

**B. Investigators should respect the sensitive nature of educational data by developing appropriate protections against breaches of confidentiality and obtaining informed consent from students to use their data for research purposes.**

When UMW students participate in any research, regardless of the level of risk, the investigators must provide the UMMS IRB with a specific plan to ensure that the confidentiality of these students, including their academic records, will be protected.

In research where the investigator/faculty member requires access to identifiable individual student academic records (grades), a consent process is required. Investigators/faculty should also not use their students' class assignments (e.g., journals, online postings, papers, etc.) in research without consent of their students.

Different studies will have different methods of obtaining informed consent. Depending on the nature of the study, the research may qualify for a waiver of written documentation of consent (see [HRP-303](#)) or even a waiver of informed consent (see [HRP-300](#)).

**C. Investigators should recognize the potential for survey burden.**

The timing of surveys, relative to other institutional processes, can have a significant impact on participation and institutional goals. Investigators should consider timing and content in relation to other surveys in process at the same time, and consult the coordinating committee regarding optimal implementation.

The activities of the Coordinating Committee for students as research subjects will abide by all existing school policies and procedures, as well as federal regulations regarding students enrolled in our educational programs, including FERPA.

*Note:* Because UMMS is a graduate school there is the assumption that all UMMS students are age 18 years of age or older; in the rare case where a UMMS student is under age 18, it will be necessary to obtain parental permission for the subject to participate or a waiver of parental permission. Information on the criteria for a waiver is available in the Standard Operating Procedures section of the IRB website (See [HRP-310 CHECKLIST: Children](#)).