

**DRAFT**  
**Undergraduate Research in the Social Sciences  
and the Institutional Review Board at Brown**

Report of an *ad hoc* faculty subcommittee of the Research Advisory Board

submitted by:  
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This report describes the activities, findings, and recommendations of an *ad hoc* subcommittee of the Research Advisory Board (RAB) formed during academic year 2007/08 to study the relationship between Brown's Institutional Review Board (IRB) and undergraduate research at Brown. The subcommittee was convened on the recommendation of the faculty executive committee (FEC), and approved by RAB chair, Vice President Clyde Briant.

The original recommendation from the FEC was made in response to concerns expressed by some faculty members that IRB practices were having a dampening effect on some research activities, particularly involving undergraduate projects in the social sciences. Our subcommittee members appreciate the importance of undergraduate research as a characteristic feature of the Brown experience, and this was a strong motivating factor in our decision to undertake the study. At our first subcommittee meeting we agreed to focus on a single aspect of IRB operations, namely undergraduate research in the social sciences, because it was the area of most concern raised by the FEC and because it raises a well-defined set of questions the committee could realistically address during this academic year. The report below gives a faculty perspective on this issue – while we spoke with representatives of the administration as part of our information gathering process, the recommendations below are those of our faculty subcommittee alone, and are submitted to the full RAB for further consideration.

### **Subcommittee Activities and Findings**

#### *Activities*

In the fall of 2007 a special meeting of the FEC was devoted to discussion of IRB issues. The meeting was attended by three members of our subcommittee as well as faculty members outside the FEC invited to air grievances or issues related to the IRB and the social sciences. At that meeting, a number of faculty members expressed the view that the IRB was having a dampening effect on undergraduate research in certain

topical areas and disciplines. Some faculty members expressed the view that IRBs at Brown and many other institutions were medically-oriented bodies, whose formal procedures were not fully appropriate for the often lower-risk activities in the social sciences. Further, there was a view expressed by some faculty members that the University may have some flexibility in the interpretation of the federal guidelines governing the IRB that it was not fully using, but which could help alleviate the dampening effect on undergraduate research in some areas.

Following the meeting and over the course of the 2007/8 academic year, our subcommittee held a variety of face-to-face and phone meetings to collect information that would become the basis for this report. A particular interest of the subcommittee was to gather a more representative set of faculty opinions than was possible at the special FEC meeting by interviewing a range of social science faculty members across campus including those selected by us and outside the group who have been publicly voicing IRB grievances. Individual meetings were held with concentration chairs and senior seminar instructors, who observe significant numbers of students involved in senior theses, and with administrators in the Office of the Vice President and the Dean of the College. Phone inquiries and web research was carried out to obtain information on policies and practices at peer institutions.

#### *Current policies and practices at Brown*

Before presenting the findings, it will be useful to briefly review our understanding of Brown's existing policies and practices regarding undergraduate research and the IRB. The federal government requires IRB review of federally funded research on human subjects, and Brown has a single board for reviewing cases and ensuring ethical conduct in both biomedical and social sciences projects. The IRB has some flexibility in choosing the proper degree of oversight for different projects, which can be classified as "exempt", "expedited", or requiring "full board review" (see the attached table on human research protocols identified as undergraduate projects in the last five years). Brown voluntarily signs a statement that the same guidelines will be applied to its non-federally-funded research on campus as well. Much of the controversy surrounding undergraduate work lies in whether the work meets the federal definition of "research," which is not necessarily the same as the everyday usage of the word, and is defined by the federal government as follows:

*Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.*

In practice this abstract definition does not answer many of the questions students and faculty members have, and needs a clear and more specific local interpretation. Brown's current practice is that the faculty advisor serves as the principal investigator and makes the determination whether or not a student's work is "research on human subjects," using the above definition and additional information available on the Research Protections Office (RPO) website. The IRB staff members provide consultation and advice. Until recently, students were allowed to serve as principal investigators. Brown now requires the faculty advisor to be the principal investigator, make the determination as to whether the project requires IRB review and be the responsible party in the review process and the project execution. One of our first findings was that many faculty members do not understand the current practice, or know how to work successfully within it, and some possible reasons for this are discussed in the next section.

#### *Findings from faculty interviews*

The subcommittee found that there is a wide variation in cultures and practices among the relevant departments and programs and a correspondingly wide range of experiences with the IRB. Our IRB practices have been evolving, and many faculty members are not aware of the current practices and local interpretation of the federal guidelines. Furthermore, some faculty sponsors of student research do not have externally funded research, and have little or no experience or prior contact with the IRB.

Many faculty members from the social sciences report some aspect of the IRB to be or to have been a burden, and a significant fraction feel that IRB practices are having or have had some dampening effect on the quality or availability of undergraduate research opportunities. There is the widely held belief that many social science projects typically consisting of interviews or surveys, have a low intrinsic risk. Most faculty members, however, do recognize the existence of some risk, depending on the nature of the activity, and the need for some type of oversight. Many faculty members believe that the formal and rigidly structured IRB process is not an optimal way to oversee and regulate undergraduate work, due to variable levels of organization, knowledge, and professionalism among the undergraduates, and the special time constraints associated with the undergraduate senior year.

To give an example, a Brown junior may spend a semester abroad, return in the fall of the senior year, and begins to contemplate a senior thesis topic. A topic may be chosen that is quite separate from any faculty member's research and leverages the student's recent foreign experience, but any information or data taken while abroad is excluded because it occurred before IRB involvement. The student may choose to return to the

foreign location to gather data with a proper (approved) experimental plan, but must define the thesis, develop the protocol, potentially iterate with the IRB, gain approval, and schedule the trip over January or spring break to complete the thesis. Students who begin late, or are not sufficiently organized and focused may find it difficult to complete the thesis on time. Students who change their research protocol violate IRB rules and may have their studies and theses invalidated. These obstacles can lead the student to drop the research topic or abandon the honors thesis.

The committee has the impression that the ability of students to successfully navigate this process during the hectic senior year is highly variable. For undergraduates this is often their first experience with research or with project activity of a large scope, and as such some students are able to function as young research professionals and others not. In some cases the student research is closely tied to, or an integral part of, the ongoing research of a faculty member, and the faculty member is able and willing to provide significant support for the IRB process. In some cases the student work may even fall within an existing IRB protocol for the research group. In other cases, the student work is quite independent and separate from the faculty advisor's research. These student-initiated and student-led projects form the majority of cases where the IRB process can be problematic, since they are not strongly connected to the "professional" research programs of the university that benefit from the combination of faculty expertise and commitment, graduate student involvement, external sponsorship, and existing IRB protocols. It may be useful to see the IRB process as a requirement primarily directed toward *research professionals*, and it is thus not surprising to encounter some difficulties when it is applied to undergraduate students engaged in student-initiated, student-driven research.

Some departments have cultures and practices that enable students to complete a timely IRB review. In Education, for example, many theses deal with minors, and as such the department uses IRB review extensively and senior thesis students begin early, in the junior spring semester, and receive significant departmental support. Other departments and programs have very different cultures, and overall the student/IRB experience is variable. Many departments offered our subcommittee anecdotes of cases gone awry for one reason or another, with disappointed students, students unable to find advisors for projects, and the general avoidance of some topics that are perceived to require IRB review. We also note there were reports of slow turnaround at the IRB, though they date from at least several years ago, and several faculty members mentioned that the problem appears to have been fixed and the current board achieves acceptable turnaround times.

It is important to know that Brown's current practice is to allow the faculty advisors to determine if a student project meets the federal definition of research, and the committee found that *many student-initiated and student-led projects that are not closely tied to faculty research and are not designed with journal publication in mind as an end product, are currently being classified as NOT constituting research under the federal guidelines and are NOT receiving IRB review.*<sup>1</sup> This practice is prevalent to the point of standard practice in certain departments and programs, while other departments or programs do not appear to know about this option. Interestingly, while this option eliminates the challenge of navigating the IRB process in the senior year, it leaves some students with no education or training in human subjects work whatsoever, and some departments/programs expressed to our subcommittee the desire for some university system to help provide these students with at least introductory knowledge of the issues and pitfalls of human subject work in cases where IRB review does not occur because the federal definition is not met. Other departments have internal methods courses, which they feel satisfy this need in a more discipline-specific way and do not see a need a university-wide system.

#### *Information from peer institutions*

Members of our subcommittee contacted faculty colleagues at other institutions, and Regina White requested input from compliance professionals at several universities. Between 10 and 15 contacts were made either by phone or email. The results range from those at Princeton, where all seniors write a thesis and must obtain IRB approval if they deal with human subjects, to the University of Chicago, whose separate board for the social sciences reports that they "do not generally regard undergraduate theses as research under the federal guidelines" but recognize exceptions where undergraduate thesis work does indeed require IRB review. As far as we know, the University of Chicago was the only institution that articulates such a position, and appears to be the only university with a policy and practice that guides students away from the IRB more than Brown's current policy and practice. Brown's current policy and practice is to allow the faculty advisor to make this determination, but we do not currently explicitly advise faculty members that undergraduate theses "are not generally regarded as research under the federal guidelines", which might steer an even larger fraction of projects away from IRB review.

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<sup>1</sup> Other projects fall outside the federal definition because they do not meet the "human subjects" criterion. Information useful for making the determination of whether a project deals with "human subjects" is found on the Research Protections Office website, and is not dealt with in this report.

## **Policy Options for Brown**

Based on the above findings, the committee considered three possible policy options that could improve our current situation:

**Option A.** Brown adopts IRB review as the standard procedure for undergraduate theses and non-classroom projects dealing with human subjects similar to Princeton. This policy would clarify much of the current confusion about whether IRB review is needed. It would, however, also increase the IRB case flow and, if not managed carefully, could exacerbate the problems or perceived problems that initiated this review by increasing the number of students and faculty affected. This option would require significant planning and communication, a possible additional investment in IRB staff, and significant changes in the way some departments currently manage their undergraduate theses programs. It also runs the risk of reducing resources available to process and review large externally-funded applications with significant human subjects involvement and potential risk to safety and confidentiality. The committee felt this could be a viable option, and many universities appear to take this approach, but there was little support for this option in our faculty interviews. This is a stricter local interpretation than the one we have now, and there may be significant faculty resistance to its adoption.

**Option B.** Continue the current system, but clarify several points and communicate the policy more explicitly to avoid faculty and student confusion. Brown's current practices, in which many undergraduate projects are not submitted to the IRB based on the faculty advisor's determination that they do not constitute "research" under the federal guidelines, are among the most flexible we encountered, and if regularized and communicated may avoid many of the complaints currently being raised by faculty members. If this option is chosen, we recommend two sets of changes:

(i) minor changes be made to the ORP website to clarify and communicate the existing policy (see details in the Appendix)

(ii) a simple mechanism be set up so that students on non-IRB-reviewed projects (whose faculty advisors have deemed their project not to meet the federal definition of "research") receive some basic education and training in the interaction with human subjects. As an example, the existing on-line CITI (collaborative Institutional Training Initiative) training could be required of all undergraduate students carrying out theses or independent study projects dealing with human subjects. This would provide students a baseline knowledge of and sensitization to the issues as a

substitute for IRB review, and would serve as an education and risk management tool that would be a minimal burden to students or faculty members. A suggestion was made to develop or a new condensed version of CITI training (“CITI-light”) targeted at undergraduates. This option should be discussed, but the majority of the committee felt that the full six-hour CITI training is not an unreasonable time commitment in light of the fact that it would serve as a substitute for the development, submission, and likely revision of an IRB protocol.

(iii) RPO outreach to departments (especially UG Concentration advisors and perhaps departmental chairs) and the Dean of the College Office to communicate the changes and offer help to advisors and students.

**Option C.** Adopt and communicate a policy in which non-federally-funded undergraduate work is not subject to IRB review, but rather to some other educational and oversight system tailored for undergraduates, to be defined. This would require that Brown no longer “check the box” that indicates its internal policy of voluntarily applying the federal guidelines to non-federally-funded research.

#### *Discussion*

Options A and C are simple to communicate and simple for the faculty and students to understand (in essence either we use the IRB for undergraduate projects (A) or we do not (C)). Option A, however, does not have faculty support at this time, and the committee could not find another university that has adopted Option C. (Note that our peer-review study was limited in the number of universities approached.) Brown could set up a system for Option C, but it would require careful study since we would be at the forefront of changes in IRB practice. A reasonable approach might be to discuss Option C as a longer-term alternative with the discussion centering on what new and innovative review structure Brown could put in place that would optimally designed for undergraduates. We only note that a properly executed Option B would achieve most of the goals of Option C. The only *incremental* effect of Option C would be to provide an alternative review system for the subclass of undergraduates engaged in publishable, but non-federally-funded research, who would be required under Option B to submit IRB protocols.

#### **Recommendations**

1. The committee recommends Option B as the best near-term solution for Brown and requests that it be considered at meetings of the full RAB and the FEC. This option includes the web changes as suggested in the Appendix and the implementation of University wide introductory training for students whose projects fall outside the IRB.

RPO, the Dean of the College, and Departments can work together to establish resource materials on procedures, time line, and illustrative protocols for undergraduates. For example, the honors thesis advisors can share examples of successful protocols with students in a specific field.

2. We recommend the IRB subcommittee of the RAB to consider the following issues:

- (a) the form of the baseline required training for all undergraduate students working on human subjects as outlined under Option B (if Option B is chosen). The subcommittee recommends the on-line CITI training for this baseline requirement, or a “departmental equivalent” for those departments with required methods courses that achieve the same goals in a more discipline-specific manner.
- (b) the longer-term possibility of developing Option C as described above
- (c) other IRB related issues beyond undergraduate projects as the subcommittee sees fit, which may include:
  - special challenges for researchers working in developing countries
  - inter-institutional projects that involve multiple IRBs
  - the possible benefits of separate IRB panels to review (i) biomedical, and (ii) behavioral and social sciences research.

**APPENDIX**  
**Specific suggested modifications to the RPO website section on the IRB  
if Option B is chosen**

The Research Protections Office has clearly devoted much time and effort to providing web-based information to help students and faculty understand the IRB process. If Option B is chosen, a continuation of our current practice, we recommend that a small set of changes to clarify the particular issues discussed in this report that deal with undergraduate activities. We first recommend that a prominent statement on undergraduate work be placed under the header “Does my project require IRB review?” with the following approximate content:

**Undergraduate projects and theses** pose unique issues and may or may not require IRB review. In particular, student-initiated and student-led projects and theses in the humanities and social sciences that are not intended for peer-reviewed journal publication may fall outside the federal definition of “research” and thus not be subject to IRB review. It is the faculty advisor’s responsibility to determine, in consultation with the student and the IRB staff, if this is the case for any given project. We recommend the faculty advisor contact the RPO staff at the earliest possible time to obtain advice and information to help in this determination.

We note the following small error. The pdf file on “Frequently asked questions” under the header: “Do projects conducted by Brown students require IRB approval” contains the statement that: “Brown University considers thesis and dissertation work to meet the definition of “research,” requiring IRB approval if it deals with human subjects.” In fact this is in conflict with our current practice, which is that undergraduate thesis and dissertation work may or may not be “research” depending on the nature of the work, and the distinction in practice often hinges on the publication intention as described above. We recommend this section be revised.

We also recommend removal of the phrase: “presentation at a professional conference, or placement of a report in a library” found in the web-section describing “generalizable.” This raises issues about where theses are kept, and if their archiving constitutes “dissemination” and where reports may be sent or kept, and what sort of oral communication may be defined as a conference presentation. Brown’s current practice is to allow undergraduate thesis work to fall outside of the federal definition of “research”

if they are not targeted for publication, so to be consistent with this existing practice, we recommend that “publication in a scholarly journal” be the sole form of dissemination mentioned in this section.

We further recommend that the statement that the faculty advisor makes the determination of whether a project is submitted to the IRB be moved from a small-font footnote on the page “Does my project need IRB review” to a more prominent position at the top of that page.

We finally recommend a few other cosmetic changes to the website. On the RPO home page, there is a link entitled: “Does my project require IRB review?”, which leads to a page with the same title followed by two links giving “Examples of activities likely to be defined as research for IRB purposes” and “Examples of activities likely NOT to be defined as research for IRB purposes”. These examples are useful, but the main information giving the answer to the question (“Does my project require....”) is not apparent on that page. In fact that information lies on another page, which one reaches by clicking the title “Does my project require....” which itself turns out to be a (non-obvious) link. The next page has the same structure, with the main question appearing to be a header, but in fact being a link to the answer at a deeper web level. The result is a deep, multilayered tree structure that the subcommittee found confusing. This could be easily remedied by consolidating all of the information on “Does my project require IRB review” onto one page, or at least adding “click for more information” to the headers, which are in fact links. It could be made further transparent by removing the dictionary definitions and associated discussion of “systematic” and “generalizable,” which add verbiage, but are not key to clarifying Brown’s local interpretation or answering the practical the questions most users will have.