

# It's Not Our Job: A Referral Guide for IRBs

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IRBs are often handed problems that they have neither the authority nor the resources to resolve effectively. The IRB may be the only body within the institution that perceives and understands the problems that a given project may raise. It may be the body that would be blamed if the problem manifested itself in a way that came to the attention of other authorities within the institution, in the press, or within OHRP. Yet, the IRB may have no power to take appropriate action, or to enforce its demands. Alternatively, it may not have the expertise to evaluate the problem. To illustrate:

*An IRB chair receives irate phone calls from university staff members about a highly personal and invasive questionnaire they've been handed by some students, querying them about the politics of their office. The questionnaire is ostensibly anonymous, but asks for respondents' job title. The survey is represented as a class project, but it obviously is the project of the entire class, and presumably of the professor. The IRB has never seen the project, and the university does not require review of classroom research projects.*

*The IRB has rejected a highly inappropriate and illegal survey which asks school children questions about sexuality, and does not seek parental permission as "most of the parents of those students do not understand English." When the IRB rejected the project, it gave the investigator a long list of requirements to meet to make the project acceptable. Later, another faculty member informed the IRB Chair that the professor has given the survey to one of his student teachers to administer as part of her student teaching duties.*

*The IRB reviews a protocol that is technically adequate but is sure to land the university on the local newspaper's front page because of the political incorrectness of the research hypotheses and methods.*

*The IRB reviews a protocol involving a piece of equipment that could conceivably pose a physical danger to participants. However, no one on the IRB feels qualified to understand or evaluate the equipment or the risks it may pose.*

*An investigator proposes to use a non-patented new high-tech device that he has borrowed from another colleague. It appears that perhaps a licensing arrangement should be executed, and that possibly the researcher should require subjects to sign a non-disclosure statement. However, the IRB is not sure about just what should be done.*

*An IRB receives protocols from graduate students whose advisor clearly has spent no time giving assistance or supervision, and is perhaps incapable of doing so. While the proposed research will not harm subjects, it clearly is poorly designed and useless.*

The first two examples involve unethical research that technically is not under the IRB's purview, though arguably these projects represent an attempt to circumvent the IRB. The third problem is a political and public relations issue; it is not the IRB's business, but someone ought to know about it if only to prepare the institution to respond to the embarrassment that will ensue. The fourth and fifth are problems beyond the technical expertise of the IRB. The sixth is a no-win situation; the IRB would be over-reaching if it stepped in and advised the students as their

professor should have, and cruel to punish the students by rejecting the research or demanding that they request better treatment by their professor. When faced with such problems, the IRB can choose between various unattractive courses of action:

- It can try to step in and reach beyond its authority, and perhaps be accused of over-reaching, or find that it has no power to enforce its demands.
- It can “tattle” to someone who probably has the authority to make and enforce the demands that seem appropriate to the IRB. However, that authority may not wish to be involved.
- It can ignore the issue, placing the institution, subjects, or others at risk.

Taking any of these courses of action may undermine the credibility and authority of the IRB. Alternatively, the IRB could anticipate such problems by developing a decision and referral matrix, and having that matrix ratified by the appropriate responsible officer, e.g., the provost, or governing body of the institution, e.g., the Academic Senate. How would this work?

First, the IRB would take stock of the kinds of problems it has faced or may face, in which it has no clear mandate or authority to act but where “something ought to be done.” The problems should be organized by type, with a few illustrative examples of each. Obviously these types and examples of problems will vary depending on the nature of the research that is reviewed, and the nature of the institution. For example, a medical school may have several categories of safety issues which should be referred to safety specialists of various kinds. An industrial IRB may have one or more categories of concerns about company intellectual property interests that should be referred to its legal office, or its publication or patent committees. In any event, the IRB should then consider which office(s) in the institution might have the authority to handle such problems, or that should at least be alerted of the problems. The matrix might resemble, somewhat, the example that appears in Table 1

	<b>Examples Of Each Kind of Issue</b>	<b>Possible Referrals</b>	<b>Contact PI or Referral?</b>	<b>Report Back to IRB?</b>
Legal Issues	Conceivably the researcher could uncover reportable criminal activity in family research (e.g., child or elder abuse).	Nursing, Social Work, attorney	Both	Yes
	If a project involves intellectual property, conceivably a non-disclosure agreement should be signed by subjects, and a licensing agreement might be needed between the researcher and the inventor of the device.	attorney	Both	?
Sharing of Data, Sites or Subjects	A professor wants access to student's confidential research data with identifiers attached.	Chair, Dean, Provost	Ref'r'l	No
	Professor wants to re-contact subjects to whom student researchers have promised confidentiality.			
	Professor wants to piggyback on another's study.			
Safety Issues	Equipment appears to be unsafe.	Equip. Tech.	Both	Yes
	Procedure might cause illness.	physician	Both	Yes
Circum- venting of IRB	Professor assigns students, as a class exercise, to conduct risky research on campus staff.	Dean	Ref'r'l	No
	IRB rejects illegal research on school children A student teacher is then given the questionnaire to administer to the students he is teaching.	Dean	Ref'r'l	No
PI Ignorant of IRB	A non-social/behavioral science department is doing research with human subjects but doesn't consider it appropriate to go through IRB.	Dean	Both	No
Other Stake- holders	The research may have harmful implications for other stakeholders in the research process, such as members of the subjects' community.	Community relations office, PI	Both	
Research Risk	The proposed treatment may hold risks the IRB cannot assess.	Consul-ant	Both	Yes
Public Relations	The research could seriously embarrass the department or university.	Provost, President	Ref'r'l	No

**Table 1.** Some kinds of issues that might be referred elsewhere, possible referrals, whether PI, other referral or both are contacted, and whether the PI is required to report back to the IRB when matter is settled.

Having devised the referral matrix, the next step is to confer with each respective administrator to whom the IRB would consider referring problems. The appropriate approach might be to introduce the problem either as one that has occurred at one's own institution in the past, or as one that has occurred elsewhere and is likely to arise some day at one's own institution. Then, ask: "If this problem comes to the attention of this IRB, to whom should we refer it?" It might be necessary to explain that the problem is beyond the purview of power of the IRB to solve. Chances are this will be seen as a friendly gesture from an IRB that does not want to over-reach and that respects other offices within the institution. It will result in a decision of where the problem should be referred.

After the IRB has gotten informal approval of the referral system, it is useful to get the "buy in" of the entire institution to this procedure. Perhaps the most democratic way to achieve this is to approach the head of the governing body, e.g., the chair of the Academic Senate or the Provost of a university, the Dean of a medical school, or the president of a corporation, and seek ratification of the procedure that has already been put in place informally. Since no one wants an IRB to try to seize power that should conceivably belong to elsewhere, chances are the idea will be seen as attractive by the head(s) of the organization. Besides, the problems represented in the matrix are ones the institution can scarcely afford to ignore. If it is asserted that the IRB should be responsible for any of the problems, the IRB must be prepared to ask the governing bodies to officially sanction giving the IRB the power and resources to handle that responsibility effectively. Either way the IRB's problem is solved.

A referral matrix such as this was developed and used most effectively in a human subjects committee of which the author was chair. The referral matrix was reviewed from time to time with the relevant offices. A few items were added and a few modified since its inception. The matrix was published on the IRB's web site so that any member of the institution could refer to it. The web site stated that the IRB is mandated to make such referrals when triggering circumstances arise. The referral system has worked well, and saved the IRB and the rest of the institution a lot of strife.