The convened Board listens to the primary reviewer’s report and recommendation, asks questions of the investigator, discusses the protocol, and (having carefully read through the materials), votes to take some action on the protocol. We like to think that this group decision-making process is a rational one that (a) takes into account all available information, and (b) comes to a decision that is in some sense “optimal” in terms of weighing risks and benefits, and balancing the needs of human research protections and the research enterprise.

This view of decision-making dominated fields like economics and political science as well as psychology for many years, not to mention human research protections – the Belmont Report’s principle of beneficence is a call, after all, for a rational weighing of the costs and benefits of research. Statistical methods like Signal Detection Theory, Game Theory and Utility Theory were developed to formalize this approach and provide quantitative models of such optimal decision-making. But over the course of my career as a cognitive
psychologist, I’ve seen a radical change in this view, as theoretical and empirical work on human
decision-making has demonstrated that there are many factors – some cognitive and internal,
some social and external – that can bias, sometimes dramatically, our “rational” decision-
making, usually without any awareness on our part that they are having that influence.

One of the more powerful of these factors has been called the “framing effect” by
Daniel Kahneman and Amos Tversky, whose seminal work in the 1980s was the opening shot in
this transformation. (Kahneman, a cognitive psychologist, won the Nobel Prize in Economics for
his work in this area). In a series of simple and elegant studies, they showed that an apparently
trivial change in how a situation was described (or framed) could literally reverse the decision a
group would make about a life-or-death choice.

In one of their studies, a group of students was given a hypothetical scenario where an
emerging disease had been discovered in their community. If nothing was done, 600 lives would
be lost. The CDC had two potential courses of action – one (Plan A), a thoroughly studied
vaccine, was certain to save about 200 lives. The second (the riskier Plan B), a recently
developed drug, had a one-third chance of saving all the lives. What should they do? What
would you do?

The choices were designed to be exactly equal in terms of the “expected outcome” –
over the long haul, both would on average lead to 200 lives saved. Nonetheless, nearly three-
quarters (72%) of the students chose the less risky Plan A. Are people just biased to avoid riskier
actions when lives are on the line? No - the “kicker” in this study was a second group of
students, given identical information, but told that under Plan A, it was certain that “400 lives
would be lost,” but Plan B had a two-thirds chance of losing all the lives. This “framing” in terms
of losses rather than gains transformed the results – now, more than two-thirds (68%) of the
students chose the riskier path of Plan B! (see Kahneman & Tversky, 1984).
Kahneman went on to develop a broad theory of the psychology of gains and losses that helped establish the new field of “behavioral economics.” The lesson for us as the “deciders” is to be aware that (among other things), the way a problem is framed, or the language used to describe a situation, can sometimes have a dramatic (and essentially irrational) effect on the decision we’re likely to make – even when we have detailed quantitative information about risk and outcomes.

I started thinking again about these issues in the context of my own decision-making as an IRB person after the recent publication of a paper in the *Journal of Empirical Research on Human Research Ethics* (or JERHRE, as it’s affectionately called by its founder and editor, Joan Sieber). The paper was written by Ivor Pritchard (the former Acting Director of OHRP, and a philosopher by training), and is titled, “How do IRB Members Make Decisions? A Review and Research Agenda.”

Pritchard reviews numerous factors, including the Framing Effect, which can bias risk perception and subsequent decision-making. Factors that can lead to lower risk perception (and greater acceptance of risk) include familiarity with the risk, “availability” of the risk (how easy it is to think of the risky outcome occurring), the “voluntariness” of risk assumption (!), the degree of stigma, dread, or unpleasant affect associated with the risk, and the degree to which the decision-maker knows, trusts, or is affiliated with the person or institution posing the risk. Even gender and race have been shown to be factors (White males generally rate risks as lower).

Besides risk assessment, Pritchard reviews how individual differences in people’s decision-making style produces systematic differences in choice. He cites Barry Schwartz’s distinction between *Maximizers* – those who “tend to review all possible options . . . in the interests of making the “best” choice” – and *Satisficers* – “who are willing to choose an option as soon as they find one they consider to be ‘good enough.’” (p. 36). Pritchard sees the
composition of the IRB Board, in these terms, likely to influence the speed of approval, and the number of modifications required, and suggests that language in the regs themselves can bias one style or the other (compare \textit{Risks to subjects are minimized} [46.111(a)] to \textit{Risks to the subjects are reasonable in relation to anticipated benefits} [46.111(b)]).

A final factor is a social one – the impact of what others have to say, and how they are perceived by the Board member. My colleague Bob Sorkin (at one point Chair of the Psychology Department at UF), in the latter part of his career, extended Signal Detection Theory to group-decision-making, and wrote extensively about optimizing jury decision-making. So-called “Nonrational Group Processes” (see work by Robert Cialdini) played no role in Sorkin’s model (see Sorkin et al., 2004) – he was originally an engineer, and didn’t think such things could be quantified adequately to be represented within Signal Detection Theory, at least (despite his fame as a “human factors” psychologist!). But Pritchard notes five of these processes that, in the context of a convened meeting, could make one agree with another’s decision, even if that decision were not optimal: \textit{Reciprocity} (feeling obliged to repay others who have given them something); \textit{Commitment} (relying on a previous decision that seems relevant); \textit{Social Proof} (another’s choice demonstrates that making that choice is OK); \textit{Authority} (deferring to those perceived to be more knowledgeable or socially powerful); and simple \textit{Liking} (agree with those whom they know and like).

Pritchard’s article contains much more than what I’ve outlined here. He argues that psychological factors may be an important source of the much-discussed variability in IRB decision-making; considers the recent controversy over the value of “intuitive” decision-making (compare Gladwell, 2005, and Herbert, 2009), makes a number of recommendations for further research into how nonrational factors affect IRB decision-making, and discusses the practical implications of these nonrational factors on how IRB do, and should, go about their business. It’s
a good read, and an enlightening one; I hope you all can take a look at it. For now, to paraphrase Hill Street Blues’ Sgt. Esterhaus, Let’s be careful in there.

References


___

Revised Addendum A’s submitted with Continuing Review Reports will now require a proposed Project Revision for review. The Continuing Review Report has been revised to reflect this change.