National Science Foundation, Institutional Review Boards, and Political and Social Science

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ll projects involving human subjects must either (1) have approval from the institution's (i.e., college or university) Institutional Review Board (IRB) before issuance of a National Science Foundation (NSF) award, or (2) affirm that the IRB (or an appropriate authority designated by the institution) has declared that the research is exempt from IRB review as established by Section 101(b) of the Common Rule before issuance of an NSF award. In a nutshell, these two requirements summarize NSF policy regarding research proposed by a political science principal investigator (PI). If the PI's research involves human subjects, NSF requires either IRB approval or the IRB's declaration that the research is exempt from review. It is important to understand that the institution's IRB has the authority to approve the research proposal's design as it relates to human subjects.

As the grantee, the institution is responsible—along with the PI—for the protection of the rights and welfare of any human subjects involved in research, development, and related activities supported by the award. Accordingly, the institution is interested in protecting its integrity. In protecting the integrity of the institution, the institution also protects the PI by granting institutional validation. The PI should view the IRB as an ally rather than an adversary. The university and the PI share a desire to produce ethical research. Consequently, the IRB and Sponsored Research Office (SRO) officials can be of great assistance to PIs in the review process, particularly in clarifying research protocols and designs that adequately protect human subjects.

Historically, social scientists have used survey, observation, and ethnographic research methods as the primary research methodologies—these are nonexperimental approaches (Heimer and Petty 2010; Plattner 2006; Schrag 2011; Seligison 2008; Winslow 2006). Given these methodologies, IRBs have granted much social-science research "Exempt" status. Because survey, observation, and ethnographic approaches in certain instances may involve minimal risk to human subjects, IRBs additionally have granted "Expedited" review to many social-science research projects. Increasingly, social scientists have embraced experimental and causal-inference approaches that are associated more closely with biomedical and behavioral science (e.g., field, laboratory, and survey experiments) (Druckman et al. 2011). However, this embrace of experimental approaches renders the review process more crucial in validating that experimental social-science research interventions "do no harm" to human subjects. These interventions are still generally less intrusive to human subjects than interventions traditionally associated with biomedical research. Nevertheless, advances in social-science experimental and causal-inference approaches raise new challenges for institutions and IRBs because these approaches involve procedures that are sometimes more invasive than nonexperimental social-science procedures.

THE RATIONALE FOR OVERSIGHT

The fundamental goal of institutional oversight remains the same: projects involving research with human subjects must ensure that those subjects are protected from research risks in conformance with the federal policy known as the Common Rule (Code of Federal Regulations 45 CFR 690.101-124). The fundamental principle of human-subjects protection is that people should not be involved in research without their informed consent and that subjects should not incur increased risk of harm from their research involvement. Regulations on the philosophical principles of humansubject protection are contained in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Social and behavioral scientists are subject to the same regulations as biomedical investigators. The protection of human subjects is paramount. Nevertheless, the Common Rule requires that institutions and IRBs match the review to the potential risk of harm to subjects. The Common Rule specifies the following broad classes of research involving human subjects as "exempt" from the policy's oversight (45 CFR 690.101):

- Institutions can determine whether the research is "exempt" or qualifies for "expedited" (the IRB chair or a designee reviews the proposal for the committee) or full-board review.
- Research using surveys, observational or ethnographic methods, cognitive and educational tests, and so forth can be "Exempt" if (1) the information would not allow subjects to be identified, (2) the disclosure of the data would not place the subject at risk of harm, or (3) the survey is not to be administered to children or other vulnerable populations.

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Under provisions of the Common Rule, concerns about experimental social-science interventions force IRBs to reevaluate (1) the risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (2) the appropriate guidelines for the selection of human discuss the nature and rationale for the project with the IRB chair.

Working with the institution's IRB is essential because NSF program officers cannot waive the applicability of the Common Rule to research activities. In most cases, the

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subjects for participation in such research, and (3) the nature and definition of informed consent in various research settings. On the one hand, IRB evaluations for experimental social science will be much like IRB evaluations for biomedical and behavioral sciences. In short, IRBs apply the Belmont principles to experimental social-science research with the same rigor as for biomedical and behavioral-science research.

On the other hand, this extension of biomedical-level evaluation to experimental social science creates several problems: (1) the IRB review may be too severe because it is program officer accepts the validity of an IRB certification. In rare cases, the program officer may decide that more oversight for the protection of human subjects is necessary before an award is recommended. The program officer cannot impose less oversight than the institution's IRB requires. If the program officer demands greater oversight, she may ask the NSF's Division of Grants and Agreements (DGA) to impose additional conditions before making the award. Otherwise, the program officer may ask the DGA to include additional conditions in the award at the time of funding.

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conducted by individuals who generally review more intrusive experimental research; (2) the IRB may assign social-science reviewers who are more comfortable with nonexperimental social-science methodologies; and/or (3) the IRB may extend the experimental protocols to social-science research that uses nonexperimental approaches. These problems may lead to delays that threaten completion of the research or to denial of proposed research because IRB reviewers are unfamiliar or uncomfortable with political science methods.

COORDINATING WITH LOCAL IRBs

Whereas a research proposal submitted to the NSF can be reviewed without IRB approval, projects involving human subjects cannot be recommended for an award until the NSF program officer receives certification of IRB approval. Researchers should file their proposal with their institution's IRB at the same time they submit it to the NSF so that the approval procedure will not delay processing of the award. It may be in the PI's interest to confer directly with the IRB chair to facilitate the process. In the situation in which an institution's IRB will review only those projects that have been designated to receive federal funding, PIs should seek IRB approval of their research projects as soon as possible. It is not uncommon for an IRB committee to require changes to the submission. If the changes are minor, it is most efficient and effective to make the required changes. If the required changes involve fundamental changes to the proposed research, it is useful to In many cases, research may take place at multiple sites or be conducted by PIs at multiple institutions. A collaborative proposal (a proposal with PIs from more than one institution) is an example of multisite research. In general, the IRB at each institution should review the collaborative project for human-subjects implications. In some cases, the review of the lead grantee institution's IRB can serve as the full review of the project. This condition may apply if the non-lead institution agrees to rely on the lead institution's determination (45 CFR 690.107). This arrangement is called an IRB Authorization Agreement.

In another case, multiple-site research may involve research in foreign countries. IRBs in foreign countries are not always required to review the research for human-subject implications if no IRB exists or if the foreign IRB agrees to rely on the US IRB's determination. The US institution's IRB review is always primary and often sufficient.

On its website (www.nsf.gov/bfa/dias/policy/human.jsp), the NSF provides the following information concerning the protection of human subjects:

- The Common Rule on Protection of Human Subjects is available at www.nsf.gov/bfa/dias/policy/docs/45cfr690. pdf.
- Guidance about the regulation is available at www.nsf. gov/bfa/dias/policy/human.jsp.
- Information on Frequently Asked Questions is available at www.nsf.gov/bfa/dias/policy/hsfaqs.jsp. This webpage

also provides links to vignettes, as well as "Problems and Advice on Dealing with Them."

- Vignettes concerning IRB–PI disputes are available at https://collaboration.inside.nsf.gov/sbe/Protection%20 of%20Human%20Subjects%20Resources/Human%20 Subjects%20Vignettes%20with%20Answers.pdf.
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research is available at www.hhs.gov/ohrp/humansubjects/guidance/ belmont.html.

In summary, advances in social-science experimental and causal-inference approaches raise new challenges for institutions and IRBs because these approaches involve procedures that may be more invasive than nonexperimental socialscience procedures. The NSF requires either IRB approval or an IRB's declaration that the research is exempt from review. IRBs and SRO officials can be of great assistance to PIs in clarifying research protocols and designs that adequately protect human subjects. Nevertheless, problems may arise if the IRB review is too severe because (1) it is conducted by individuals who generally review more intrusive experimental research, (2) social-science reviewers are uncomfortable with experimental social-science methodologies, or (3) experimental protocols are applied to nonexperimental research. These problems may lead to delays that threaten the completion of the research. Working with an institution's IRB is essential because NSF program officers can neither waive the applicability of the Common Rule to research activities nor impose less oversight than the institution's IRB requires.

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Diversity and Inclusion Programs

The American Political Science Association has several major programs aimed at enhancing diversity within the discipline and identifying and aiding students and faculty from under-represented backgrounds in the political science field. These programs include:

Ralph Bunche Summer Institute (RBSI) (Undergraduate Juniors)

The RBSI Program – celebrating its 30th anniversary—is an annual five-week program designed to introduce undergraduate students from under represented racial/ethnic groups, or students interested in broadening participation in political science and pursuing scholarship on issues affecting under-represented groups, to the world of graduate study and to encourage application to PhD programs. Application deadline: January of each year. For more information, visit <u>www.apsanet.org/rbsi</u>.

APSA Minority Fellows Program (MFP) (Undergraduate Seniors or MA Students)

(Fall Cycle for seniors and MA Students, Spring Cycle for PhD students) MFP is a fellowship competition for those applying to graduate school, designed to increase the number of individuals from under-represented backgrounds with PhD's in political science. Application deadline: October and March of each year. For more information, visit <u>www.apsanet.org/mfp</u>.

Minority Student Recruitment Program (MSRP) (Undergraduates and departmental members) The MSRP was created to identify undergraduate students from under-represented backgrounds who are interested in, or show potential for, graduate study and, ultimately, to help further diversify the political science profession. For more information, visit <u>www.apsanet.org/msrp</u>.

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