

Chapter 1: Social and Behavioral Science R01s

Social and Behavioral Science Applications focus on a broad range of topics and use a diverse array of methods. NIH's Office of Behavioral and Social Science Research (OBSSR) defines social and behavioral research as:

Behavioral and social sciences research is a large, multifaceted field, encompassing a wide array of disciplines. The field employs a variety of methodological approaches including: surveys and questionnaires, interviews, randomized clinical trials, direct observation, physiological manipulations and recording, descriptive methods, laboratory and field experiments, standardized tests, economic analyses, statistical modeling, ethnography, and evaluation. Yet, behavioral and social sciences research is not restricted to a set of disciplines or methodological approaches. Instead, the field is defined by substantive areas of research that transcend disciplinary and methodological boundaries. In addition, several key cross-cutting themes characterize social and behavioral sciences research. These include: an emphasis on theory-driven research; the search for general principles of behavioral and social functioning; the importance ascribed to a developmental, lifespan perspective; an emphasis on individual variation, and variation across sociodemographic categories such as gender, age, and sociocultural status; and a focus on both the social and biological contexts of behavior.

The core areas of behavioral and social sciences research are divided into basic or fundamental research and applied research. The basic and applied research distinction serves more of an organizational function for purposes of this definition, rather than representing firm boundaries within the field. Indeed, many studies have both basic and applied components. Moreover, basic and applied research is often complementary. Basic research frequently provides the foundation for subsequent applied research, and applied research often influences the direction of basic research.

In general, social and behavioral science applications differ from biomedical proposals in that they tend to focus on broader and more complex questions than projects that explore a single set of chemical interactions, identify gene markers for a specific disease, or develop a computer model for disease development. While clinical trials also include social and behavioral science interventions, the process for understanding why a particular support system for caregivers or an evidence based intervention to reduce diabetes and obesity is different from a blind drug trial. This chapter outlines the kinds of social and behavioral science projects funded by NIH, which Institutes and Centers fund the most proposals of this nature, and provides some general tips for successful proposals.

THE R01 MECHANISM FOR SOCIAL AND BEHAVIORAL SCIENTISTS

An R01 project explores a specific research question that can provide insights into fundamental categories for health research or which provides insights on issues of public health, health disparities, health access, or clinical practice. A number of other topics can be explored through an R01, but to receive funding from NIH, the topic needs to meet a need expressed by NIH or address a critical health issue. R01s are not exploratory grants, but rather a mechanism to gather data on a specifically defined research question that is clearly defined as a gap in current knowledge or to test a research hypothesis or evidence based intervention. R01s are designed to build on prior research and investigators at the early stages of developing an idea should look at grant mechanisms designed for exploratory or pilot research like K awards, R03 or R21.

Since NIH is known for its biomedical and clinical research, social and behavioral scientists often believe that they have an uphill battle for funding. While social and behavioral science grants are still a small proportion of NIH grants, they are a growing part of the NIH portfolio. The broad range of methods used by social and behavioral scientists are increasingly understood and welcomed at NIH. However, social and behavioral scientists need to clearly explain how their research questions and methods contribute to the NIH enterprise. As Dr. Mark Luborsky and Dr. Andrea Sanker remind us, it is important for potential investigators to understand the cultural forces at NIH and see themselves as contributors to NIH's larger project of improving health and public health.¹

¹ Luborsky, M. and Sanker, A. 2006. Cultural Forces in the Acceptance of Qualitative Research: Advancing Mixed Method Research. In Curr, L., Shield, R. and Wetle, T eds. Improving Aging and Public Health Research: Qualitative and Mixed Methods. Washington DC: American Public Health Association.

Who Funds Social and Behavioral Science Projects and How Many are Funded?

Social and behavioral science applications are less than 20 percent of the R01 grants funded by NIH each year, but both the absolute number of proposals and their percentage of funded projects has steadily increased in recent years. As table 1 demonstrates, social science grants were only 11 percent of successful proposals in 2001, but have been 17 percent of funded projects in the last two fiscal years. Funding for social science projects in fiscal year 2014 is 1.5 times the amount of funding from 2001, despite recent cuts at NIH. Funding for social and behavioral science projects has expanded while the overall amount of funding for NIH R01 grants has remained roughly the same over these fourteen years. This suggests that well designed social and behavioral science projects are welcomed at NIH.

Table 1: NIH R01 Funded Applications 2001, 2011-2015 (source NIH Reporter)

Fiscal Year	Projects	Total Funding	Social Science Projects	Total Funding	% Social Science
2001	6,754	\$2,200,951,267	764	\$284,238,684	0.11
2011	5,429	\$2,307,395,380	811	\$397,482,880	0.15
2012	5,367	\$2,296,668,319	915	\$461,823,653	0.17
2013	4,906	\$2,045,111,857	849	\$414,138,514	0.17
2014	5,030	\$2,227,126,594	841	\$429,970,501	0.17
2015	839	\$371,724,028	3	\$1,515,291	0.00
Total	21,571	\$9,248,026,178	3,419	\$1,704,930,839	0.16

To succeed, applicants need to clearly and concisely present an idea that fills a gap in existing research and has a measurable public health impact. This is true for any kind of grant, not just social and behavioral science projects. Table two gives the number of applications, the number of projects awarded funding, and the success rate for funding for all R01 applications from 2011-2015. Comparable information was not available for social and behavioral science projects. As table two demonstrates, only 14 to 15 percent of new applications are funded each year. The percentages are higher for applications that are continuations of ongoing projects (competing renewals), suggesting that it is even harder to get a new idea funded. As

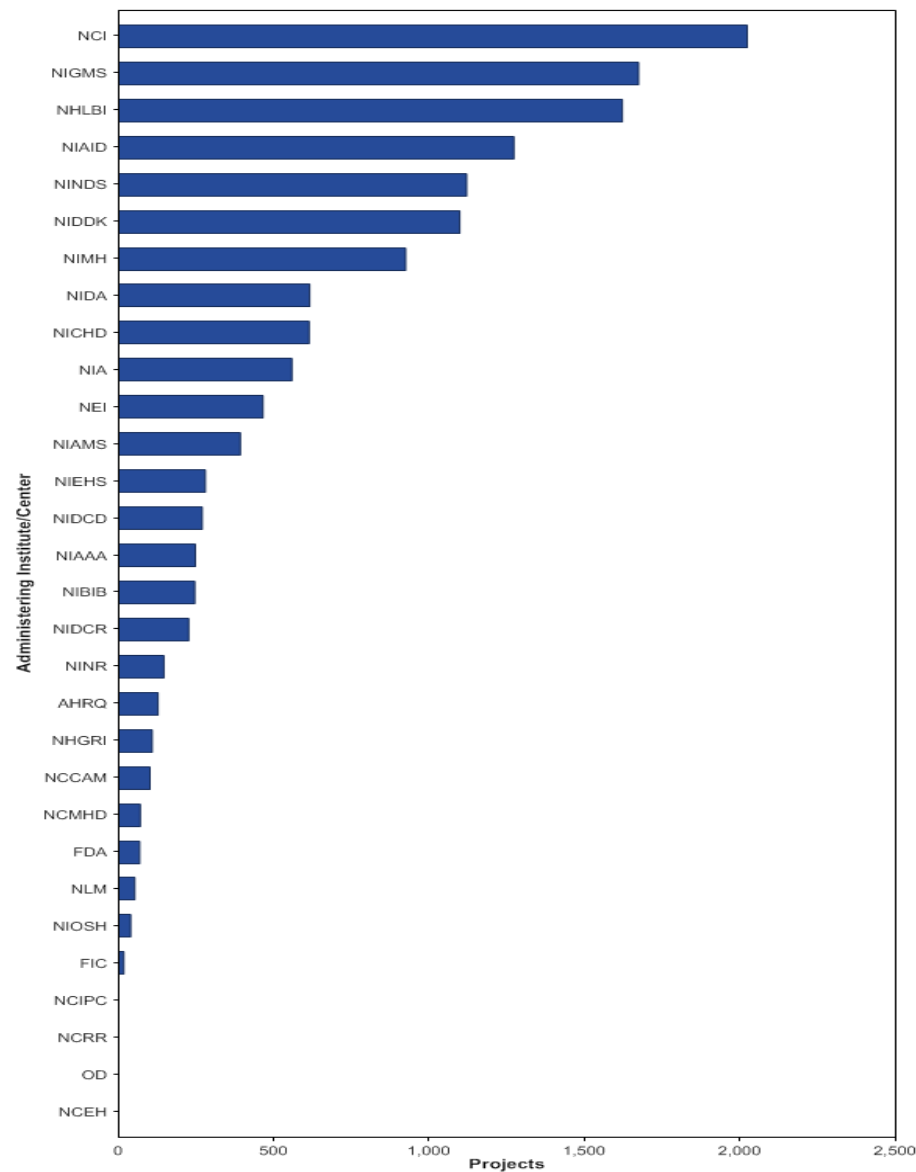
documented in PIAs guide on resubmitting proposals that have been turned down (see *Revising and Resubmitting NIH Proposals* <https://principalinvestigators.org/product/revising-and-resubmitting-nih-proposals-guide/>), proposals that have been resubmitted after being turned down a first time also have a much better chance of funding. This means that researchers need to carefully develop their proposal if they are to have any hope of funding. They also need to be prepared to submit it several times before it is funded.

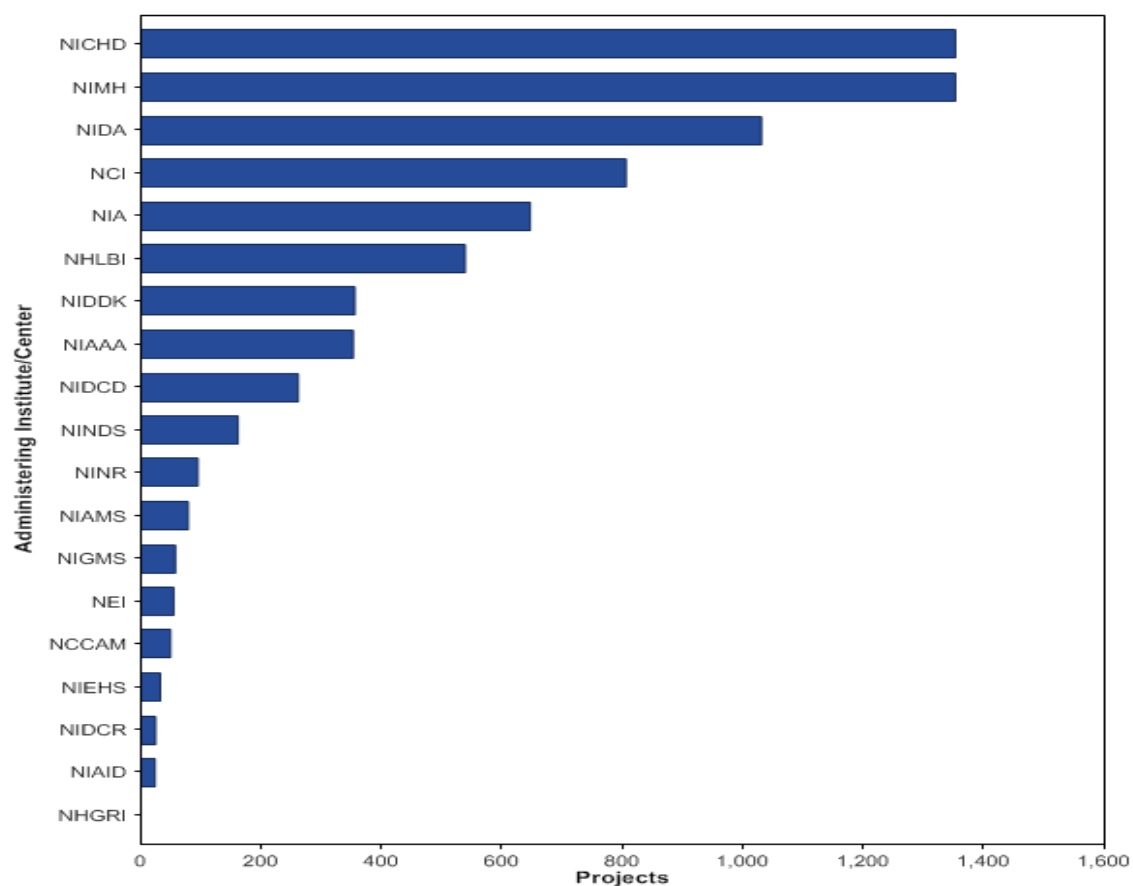
Table 2: Success Rates for R01 Applications 2011-2015 (source NIH Reporter)

Fiscal Year	2011		2012		2013		2014	
Grant Type	New	Competing Renewal	New	Competing Renewal	New	Competing Renewal	New	Competing Renewal
Applications	23,383	5,111	24,637	4,780	23,323	4,529	23,004	4,241
Awards	3,543	1,710	3,700	1,653	3,341	1,421	3,566	1,467
Success Rate	15%	33%	15%	35%	14%	31%	15%	35%

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Figures 1 and 2: Number of Grants Funded by Each Institute Overall and for Social Science





Figures 1 and 2 show the number of grants funded from 2011-2015 for each of the Centers that fund R01s. As these two figures demonstrate, the Institutes that fund the most grants overall are not the same ones that fund the largest number of social and behavioral science applications. NIGMS, with the most grants overall only funded 72 social and behavioral science proposals over this five year period. NCI, often considered the largest and most influential Institute is number two in the number of grants overall, but sixth in number of social proposals, with under 200 funded in the last five years.

National Institute of Mental Health (NIMH) funds many more social and behavioral science proposals (775), than any other Institute. This is unsurprising given its focus on mental health. However, as figure 2 and table 3 demonstrate, a wide range of Institutes fund social and behavioral science research. The bulk of proposals are funded by NIMH, NIDA, NICHD, NIA, NIAAA, NCI, NINDS, NHLBI, NIDDK, and NINR. Most of this guide will focus on the top six Institutes in number of social and behavioral science applications funded given their importance in funding social and behavioral science research.

That said, some of these Institutes and Centers have fewer social and behavioral research funded grants because they are smaller overall rather than because they are less interested in social and behavioral science projects. For example, National Institute on Nursing Research (NINR) and National Institute on Minority Health and Health Disparities (NIMHD) are relatively small Institutes which are friendly to social and behavioral science approaches.

While the top six Institutes have more money to give away, researchers should look at the whole range of Institutes when deciding which might be interested in their project. In some cases, you might consider asking that more than one Institute consider a proposal that responds to the priorities of both Institutes. In that way, you are dividing the amount of money requested from each and doubling your chance for funding. As with all applications, you should talk to appropriate program officers in each target Institute or Center to find out if this is a good idea.

As discussed in more detail in the next chapter, researchers need to first figure out what Institute would be most interested in their project. In order to figure this out, it is helpful to ask two questions:

1. Does my research topic address the main mission and goals of this Institute or Center?
2. Does this Institute or Center have a track record of funding social and behavioral science projects? Have they funded anything like my project in the past?

In order to answer these questions, researchers are encouraged to do research themselves on projects funded through NIH using the NIH reporter (<http://projectreporter.nih.gov/reporter.cfm>). While the tables and figures presented here looked at funding for social and behavioral research at all Institutes and Centers that use the R01 mechanism, researchers can do their own queries on particular Institutes of interest. Finding out that an Institute funds a significant number or proportion of grants on your topic would be a first step. Next, query the proportion of grants that use social or behavioral science methods. If they fund your topic and

appear to fund social and behavioral projects regularly, they would be an appropriate Institute to approach and explore their interest in funding your project.

Table 3: Number of Social Science Applications Funded by Institute/Center 2011-2015 (source NIH Reporter)

Administering Institute/Center	Projects	Total Funding
NIMH: National Institute of Mental Health	775	\$403,203,869
NIDA: National Institute of Drug Abuse	488	\$241,440,336
NICHHD: Eunice Kennedy Shriver National Institute of Child Health and Human Development	388	\$199,217,518
NIA: National Institute on Aging	294	\$153,830,359
NIAAA: National Institute on Alcohol Abuse and Alcoholism	208	\$94,098,036
NCI: National Cancer Institute	186	\$99,024,477
NINDS: National Institute of Neurological Disorders and Stroke	182	\$72,636,018
NHLBI: National Heart, Lung and Blood Institute	161	\$102,811,144
NIDCD: National Institute on Deafness and Other Communication Diseases	138	\$59,232,660
NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases	132	\$68,452,224
NINR: National Institute on Nursing Research	104	\$53,420,923
NEI: National Eye Institute	93	\$36,322,485
NIGMS: National Institute of General Medical Sciences	72	\$26,218,644
NIMHD: National Institute on Minority Health and Health Disparities	40	\$15,519,245
NIEHS: National Institute of Environmental Health Sciences	37	\$21,173,417
NCCIH: National Center for Complementary and Integrative Health	31	\$16,075,360
NIAID: National Institute of Allergy and Infectious Diseases	27	\$14,123,893
NIDCR: National Institute of Dental and Craniofacial Research	15	\$8,565,947
NIBIB: National Institute of Biomedical Imaging and Bioengineering	13	\$5,798,376
FIC: Fogarty International Center	10	\$1,502,316
NIAMS: National Institute of Arthritis and Musculoskeletal and Skin Diseases	10	\$5,858,678
NLM: National Library of Medicine	8	\$2,973,950
NHGRI: National Human Genome Research Institute	6	\$3,007,212
OD: Office of the Director (Crosscutting projects)	1	\$423,752
Total	3,419	\$1,704,930,839

What Kinds of Social Science Projects are Welcomed at NIH?

NIH funds a broad array of projects coming out of social and behavioral sciences. The important thing for a prospective applicant to remember when considering seeking funding from NIH is whether or not your project responds to a need in the health sciences that is of importance to the NIH and the Institute you hope will sponsor your project. As such, the first step involves exploring NIH priorities in the same way as someone doing biomedical or clinical research would

do. Successful applicants and peer reviewers interviewed for this manual stress that social and behavioral scientists need to get beyond their disciplinary concerns and look at how their research contributes to finding concrete answers to critical health issues. As one senior scientist who regularly reviews for NIH commented, “[Applicants need to] show that you are part of the general conversation about what needs to be known and have your [unique] way of doing [research]. We [social scientists] ask big, exciting, questions rather than [explore the] specific next minor step in brain imaging.”

In general, social and behavioral science approaches can respond to one of several clear needs funded by NIH. Some social and behavioral science proposals provide general background research on critical health issues, exploring general population patterns, the ways health issues are understood by consumers or practitioners, the social categories of health and the dynamics of health access. On a more practical level, social and behavioral scientist provide data on why and how an intervention does or does not work. In either case, the research fills a gap in scientific or practical knowledge of a particular health problem. As such, social and behavioral science research can provide the categories needed to develop standardized measures or tools. Other examples of ways that social and behavioral scientists can contribute to the NIH mission include describing the environment for a particular health intervention, explaining how a target population for a public health initiative understands the issue, illuminating novel ways to implement evidence based health practices, or showing how caregivers go about juggling caregiving responsibilities and other aspects of their lives. These are only a few ways that social and behavioral science can contribute to NIH’s mission.

The key is identifying a specific research topic that contributes to solving or understanding a concrete health issue of interest to NIH. Successful applications identify a compelling need and show how the research will meet that need throughout. For example, priorities mentioned by program officers that fund social and behavioral science proposals included:

- Public health oriented projects, emphasis on prevention and screening and what can be done in primary care to either prevent disease (screening) and careful follow up of survivors of serious illnesses.

- Service delivery to improve population health.
- Develop tools and questions about what people are perceiving. To quote one program officer: *“Measurement people need valid categories which social science can get at. The final product is new constructs, factors, dimensions that can be extended through further work.”*
- Creating measures, critiquing existing measures.
- Focusing on psycho-social issues, but also physiological issues and risk.

NIMH recently shifted its scientific approach to ask all applications to identify targets/mechanisms of change. To quote a program officer:

- *On services or systems levels – what does this intervention do to manifest change? What is the unique target or mechanism that turns the key?*
- *Identify what it is that is the ‘magic – or unique ingredient’ that enhances child or adult mental health outcomes.*

Both program officers and researchers highlighted that social and behavioral science proposals usually have a stronger theoretical framework than most clinical and some biomedical studies. As such, these studies look at the fundamental theory that influences understanding the social determinants of disease and the effectiveness of interventions. For example, while at NIH, I developed a model to disseminate evidence based health interventions based on several social science theories and theories of the dissemination of innovation. This merging of theory and practice is particularly important in successful social and behavioral science proposals.

Social and behavioral scientists use a broad range of methods in their work. While quantitative studies are more familiar to many peer reviewers, NIH funds a wide range of methods, including qualitative research, multi-methods studies, economic research and social network analysis. While those conducting qualitative research still sometimes face challenges in the review processes, in recent years NIH and its reviewers have become more familiar with qualitative research. Sometimes reviewers ask for qualitative components. While researchers still need to ensure that reviewers are available that understand their methods, this is less of a problem now. That said, several program officers stated that they prefer multi-

methods projects to purely qualitative research. Methods and how to present them will be discussed in detail later in this manual.

NIH also welcomes a broad range of research topics, as long as they are related to NIH's primary mission of improving health and healthcare and its current specific goals. The same is true of the various Institutes and Centers that fund social and behavioral science research. The key to a successful proposal is defining a clear, measurable research question that solves a compelling health issue. The following are titles of social and behavioral science research projects funded as R01 projects from 2011-2015. They demonstrate a small portion of the range of current projects:

Project Title	Administering IC
DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES? http://projectreporter.nih.gov/project_info_description.cfm?aid=8468334	NHLBI
EXPLORING EXPERIENCES OF DISCLOSING HIV-POSITIVE STATUS WHILE IN PRISON http://projectreporter.nih.gov/project_info_description.cfm?aid=8465343	NIDA
A MOBILE PERSONAL HEALTH RECORD FOR BEHAVIORAL HEALTH HOMES http://projectreporter.nih.gov/project_info_description.cfm?aid=8495589	NIMH
STRESS-INDUCED MARIJUANA SELF-ADMINISTRATION: ROLE OF SEX AND OXYTOCIN http://projectreporter.nih.gov/project_info_description.cfm?aid=8561004	NIDA
UNDERSTANDING HOW PERSONAL NETWORKS CHANGE http://projectreporter.nih.gov/project_info_description.cfm?aid=8506360	NIA
FAMILY OUTCOMES IN AUTISM SPECTRUM DISORDERS http://projectreporter.nih.gov/project_info_description.cfm?aid=8524248	NIMH
SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES http://projectreporter.nih.gov/project_info_description.cfm?aid=8505856	NIDA
A RANDOMIZED CLINICAL TRIAL OF CULTURALLY TAILORED MI http://projectreporter.nih.gov/project_info_description.cfm?aid=8438022	NIAAA
THE AUTISM IMPACT MEASURE: A NEW TOOL FOR TREATMENT OUTCOME MEASUREMENT http://projectreporter.nih.gov/project_info_description.cfm?aid=8575724	NIMH
THE TIMES ARE CHANGING: A QUALITATIVE STUDY OF OLDER AND YOUNGER MARIJUANA USERS http://projectreporter.nih.gov/project_info_description.cfm?aid=8458476	NIDA
DISPARITIES IN CANCER SCREENING: THE ROLE OF MEDICAID POLICY http://projectreporter.nih.gov/project_info_description.cfm?aid=8562222	NCI
COMMUNICATION AND ECONOMIC OUTCOMES FOR CANCER SURVIVORS http://projectreporter.nih.gov/project_info_description.cfm?aid=8501827	NCI
NEIGHBORHOOD FACTORS AND CHILD MALTREATMENT: A MIXED METHOD STUDY http://projectreporter.nih.gov/project_info_description.cfm?aid=8558865	NICHD

These examples include broad brush explorations of the environment that impacts on health, such as the influence of neighborhood factors in child maltreatment and the role of parks and recreation departments in health disparities. Some explore family, work and other stressors on health issues like substance abuse or disclosing HIV status – a first step in ensuring treatment for people in prison. One explores the impact of public policy on prevention initiatives. In each case, the study shows how broader factors influence outcomes for health interventions.

Others provide specific background information needed to develop new tools and interventions. Exploration of how social networks change demonstrates the kinds of people resources that may be available to assist with a health problem and the influence of illness on social networks. Knowing how networks work helps providers developing interventions relying on social networks to understand what kinds of support is possible from the ill person's friends and family. Networks analysis combined with research on the impact of caregiving stress on those networks can show the potential outcomes of expecting members of a social network to provide support to someone who is ill. Likewise, exploration of the impact of autism on the family members of an autistic person or the impact of communication on cancer survivors shows how critical it is to take these factors into account in the treatment of these conditions.

Still other funded studies use social or behavioral science methods to implement or evaluate a new tool or intervention. This includes electronic health records, tools to measure the impact of autism on the person with a disability and his or her family, and clinical trials.

Several of these studies will be used throughout this guide as examples of strategies to write a successful proposal. Each share a clearly defined research question that meets a need for the Institute that funds it. In exploring whether NIH is the right funding source for your project, it is important to remember that R01s are not limited to a few types of studies like clinical trials or investigations of the social constructs behind a health condition. NIH Institutes will consider a broad range of projects. However, the project does need to clearly address a specific

health issue of interest at the present time with an innovative approach and clear outcomes. The remainder of this manual will outline ways to achieve this goal.

The Role of OBSSR

OBSSR was established in 1995 in the NIH Office of the Director to provide a centralized voice to promote social and behavioral science research at NIH.

OBSSR's mission is:

(1) to integrate a behavioral and social sciences perspective across the NIH; (2) to disseminate behavioral and social sciences research findings; and (3) to provide advice to and communicate with the NIH Director, Congress, other government agencies, the research community and the general public on matters regarding behavioral and social sciences research.

OBSSR's role is to promote social and behavioral science research throughout NIH. As such, it does not usually directly fund research projects and is not a place to look for funding for your R01 project. However, OBSSR has joined with other Institutes to sponsor cross-cutting requests for applications on particular topics. For example, OBSSR is currently sponsoring a targeted R01 PAR-11-314 "Systems Science and Health in the Behavioral and Social Sciences (R01)" (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-122.html>). These cross cutting Requests for Applications (RFA) are usually funded through other Institutes, but OBSSR usually plays a role in developing the review process for applications and selecting the final funded projects.

OBSSR has four core activities:

1. Developing and setting an agenda for national health research priorities in the social and behavioral sciences
2. Briefing the Director of NIH on progress related to behavioral and social science research and related issues
3. Promoting dialogue between social and behavioral scientists and the public
4. Training and career development for behavioral and social scientists

OBSSR's primary activities involve developing publications, conferences, educational materials, talks and other activities to improve behavioral and social science research on health issues. They also work behind the scenes to promote use of behavioral and social science research throughout the Institutes at the NIH. They develop forums and materials to explain findings from NIH sponsored behavioral and social science research to the general public and other scientists.

For a researcher looking for resources, OBSSR is a good place to look for background materials on research methods and cutting edge findings in the field. Generally, a researcher looking for funding for their grant would not contact OBSSR unless they were interested in a specific cross-cutting RFA developed by OBSSR. However, OBSSR may be able to suggest appropriate Institutes for a project if the researcher is having trouble identifying which Institute or Center might be interested in their topic.

Myths and Realities of Peer-review of Social Science Proposals at NIH

Many social and behavioral scientists believe that their proposals have a harder time getting funding at NIH because so many of the reviewers are biomedical or clinical scientists. While this may be true in some fields, increasingly NIH has developed review panels and lists of potential reviewers with a wide range of behavioral and social science expertise. Presuming that the applicant clearly outlines the methods and topics they plan to use and requests reviewers with this expertise in their cover letter, NIH will do its best to find appropriate reviewers. If the application is turned down because the reviewers did not have expertise in the topic or methods, this is grounds for automatic reconsideration of the proposal in the next round of reviews.

Given the diversity of social and behavioral science methods, the nature of the research questions, and the range of topics, social and behavioral scientists do need to do some extra work to present the case for their research. For example,

it is harder to explain how you will measure the impact of economic conditions on health access or the outcomes of a tool to identify stressors for families with an autistic child than to outline a series of experiments and their hypothesized outcomes. Methods sections need to provide more detail than in well-known biomedical experiments because many on the review committee may not be familiar with this kind of research. Cover letters are essential for behavioral and social science research, as this is where you explain the types of people who should review your work.

All of the seasoned reviewers, funded researchers and program officers interviewed for this guide mentioned that the biggest barrier for many social and behavioral science proposals is their expectation that they are going up against a biomedical scientific community that does not understand their work. Proposals that focus on explaining why social and behavioral science is generally important or spend a lot of time criticizing other methods or theoretical approaches are seldom funded. Your proposal is not the place to fight internecine battles within your discipline of theory or method.

Instead, social and behavioral scientists need to realize that they have been part of the research conversation for many years. While the goal of any proposal is to show how a research strategy fills a gap in current knowledge, it is best to explain how your project augments or builds on knowledge from other disciplines. A successful proposal will demonstrate knowledge of a research topic from a variety of disciplines, including biomedical research, and show how this research will advance knowledge or solve a particular health problem.

The remainder of this chapter briefly outlines how social and behavioral science applications are different than biomedical or clinical proposals. It offers some general tips for a successful proposal. The manual then provides detailed advice on developing various aspects of the application.

HOW IS A SOCIAL OR BEHAVIORAL SCIENCE APPLICATION DIFFERENT FROM A BIOMEDICAL PROPOSAL?

While all NIH proposals contain the same general elements, the content of a social and behavioral science application differs in many aspects from a biomedical or clinical proposal. The items to emphasize may differ and you will need to assemble a different kind of team than a biomedical proposal. The types of research partners and the supporting documents you need to collect from them will vary as well. Here are a few key elements to pay attention to when developing your proposal.

Different Aims, Goals, and Justifying Your Project

Whether you are exploring a big question like the impact of public policy on health care access or evaluating the implementation of an evidence based tool based on social or behavioral science measures, you need to clearly show that your project meets a specific need with measurable outcomes. Since social and behavioral science research project goals are often not as concrete as biomedical research, your proposal needs to show that you have identified a clear problem that can be studied in the time frame and resources of a three to five year research project. One senior researcher commented that many applicants “commit suicide by being all over the map in describing the problem or what they want to do.” As Chapter 3 discusses in detail, a successful proposal clearly and concisely defines a problem, outlines related literature from all disciplines and demonstrates throughout how the proposed project will fill a gap in our knowledge or provide a concrete solution to this problem.

Likewise, aims need to be clearly stated and involve specific goals. If you normally do not use hypotheses in your research, it is helpful to present aims in similar language. The aims and goals need to be theoretically grounded and clearly linked to the research problem you present in your significance section.

The Kinds of People Necessary for a Successful Research Team Differ

Given the nature of social and behavioral science research, the key team members are likely to be more diverse than a laboratory project or a clinical trial. If your project uses multiple methods, you will need to include people with expertise in each of those methods on your team. While you may want to include senior, well-known researchers on your team to ensure that NIH knows your project has the track record to succeed, they may serve better as members of advisory committees than co-PIs. For more information on developing interdisciplinary team projects, see Principal Investigators Associations' guide, *Interdisciplinary Research Teams: The Scientist's Guide to Building Strong, Productive Teams* <https://principalinvestigators.org/product/interdisciplinary-research-teams-guide/>.

Often, projects involve clinical components or are hosted by community organizations. Staff at these organizations may be important to include on your research team. You may need more outside consultants to help with participant recruitment, media or web design for dissemination. Instead of hiring a few graduate students to work in a lab, your data collection and analysis staff may include clinicians, tape transcribers, experts at social network analysis or geographical information systems, and so forth. For example, one study of women's health hired a nurse practitioner as a key researcher to collect data. Studies based at hospitals or clinics will want a clinical staff person to serve as a co-PI or key team member to facilitate various aspects of the research and demonstrate the clinical applications of findings.

Your proposal will need to show that you have thought through what personnel need to be on your team and demonstrate how those people will help you successfully complete your project throughout the proposal. At the leadership level, this will involve bringing in key research staff with a range of needed skills and a track record of working together. Your proposal will need a discussion or chart showing how the various research team members will work together to complete the project. If team members cannot demonstrate prior experience collaborating on research, it may be helpful for those team members to perform some pilot research or publish a co-authored research article before submitting the proposal.

Given that some reviewers may not be familiar with social and behavioral science research, you may need to describe in some detail what each person will do and why it is important to include them. This is done in the bio-sketches, discussion of the data collection methods and analysis strategies, and the budget justification.

The Resources and Institutional Supports Needed for a Successful Project Differ

NIH looks at the resources of the university or institution hosting the research as much as it looks at the ability of the researchers to carry out the project. This involves both having the facilities to do the project and providing the researcher with sufficient support to do their work. In a biomedical study, the institutional resources section focuses on laboratories, equipment, and other materials needed to carry out the project. Social and behavioral science projects may also need concrete resources like office space, lab rooms to conduct interviews and focus groups, computers with specialized software, and other equipment. However, these resources are not the only things to include in a social science proposal. For social and behavioral scientists, institutional resources that provide access to research communities like a hospital or university outreach projects to a specific neighborhood with the target population may be more important. A functional human subject review system is also vital for any project involving specific people as research participants. Adequate libraries and access to national data sets are also important institutional supports. Your proposal will need to document these resources in their institutional resource statement.

One of the key supports a university or other institution needs to give a social or behavioral science researcher is time and a commitment to facilitate carrying out the project. If the university or institution has a medical facility or outreach project in a local community, they need to demonstrate that appropriate staff will facilitate the PI gaining access to research subjects through their facilities. Reviewers will look for concrete commitments for course releases or other research buy-outs to ensure that the researcher has the time to complete the project. If the project

involves using students in service learning classes to complete parts of the research, the institution needs to show that those classes will take place. Service learning courses are for credit classes that use actual research or service projects as part of the class work. For example, students in a research methods class may collect data, or students in a public health course may observe a clinic and write up their observations as their class paper.

Another resource that needs to be documented by the institution is access to people resources to help complete the project. This may involve committing graduate assistant to a project and covering part of their costs. If the university or institution has a center that conducts statistical analysis, provides GIS services, or has other resources needed by the project, letters indicating center staff willingness to participate in the project may be important to include.

Any project that involves a medical facility or community organization outside of the PI's institution will need to demonstrate that these institutions are willing to participate in the project and have the resources in the form of facilities and staff to be part of a project. For example, a project involving a community clinic will need to provide a support letter indicating their willingness to host the project and identify staff that will participate in it. They will also need to demonstrate they have the resources to participate. For example, if a project plans to use medical records from a clinic, but those records are incomplete and only on paper, the project will have difficulty carrying out the research. If clinic staff are supposed to present opportunities to participate in a smoking cessation intervention to appropriate patients, but they are disinterested in the project and too busy to mention it, the researcher will have a hard time finding participants. Researchers need to clarify what kinds of support they will need from community organizations hosting research and document that they have that support in their application.

Methods Differ and the Ways to Explain Them to Reviewers also Differ

Since the review panel will include biomedical researchers and clinicians likely to be unfamiliar with social and behavioral science methods, applicants will need to take extra care to explain their methods. As discussed in Chapter 5, researchers may need to use more detail in describing their methods than a biomedical proposal. Another common strategy may include using references to methods articles or texts as documentation of the efficacy of methods.

While reviewers can usually clearly see how a particular experiment will prove or disprove the aim of a biomedical project, the relationship between social and behavioral science methods and the aims of the project may be less clear. Each discussion of methods needs to be clearly tied back to the aims and initial research question, showing how this method will provide important data to answer the research question or demonstrate solutions to a specific health problem.

Program officers and peer reviewers interviewed for this manual highlighted that multi-methods are often beneficial in social and behavioral science projects. Applicants will both need to explain multiple methods and show how each method contributes to answering the research question. Proposals using several methods will also need to include a clear research plan which shows how data from different methods are related to each other, when each component will be collected, and how findings from different methods will be synthesized into the final product.

Researchers should never use appendices to expand on their research methods. However, many social and behavioral researchers will need to use the appendices to include research protocols like questionnaires and interview guides for focus groups or in-depth interviews. These materials will need to be prepared in advance or outlined for inclusion in the proposal.

Pilot Studies and Other Supporting Research also Need to Be Produced and Presented Differently

R01 projects are not the place to explore a research topic for the first time. These applications need to build on earlier research conducted by the researcher or others. Pilot studies use a small number of subjects to explore the research question. They show that the project is feasible and suggest potential outcomes. Since collecting pilot data takes time and is expensive, PIs who want to do R01 research must often think ahead several years in order to complete pilot studies and publish the results. This may include seeking funding through the PIs institution, other sources, or other mechanisms at NIH designed for exploratory research like the R21 or R03.

Presenting pilot data may be tricky. While the pilot needs to demonstrate that the research can be conducted and indicate some potential findings, it cannot be large enough to suggest that the research has already been done. The proposal needs to clearly show that the pilot leaves unanswered questions that need to be answered through a larger research study.

Researchers may also use data from related studies conducted by themselves or others instead of pilot data. For example, a researcher who has explored caregiving strategies for children with autism among children associated with a single specialized school may want to expand to children in an array of public and private schools or in another state or city. The data from the study in the single school would serve as pilot data. Multi-site studies of health care systems may propose extending work done by an advisor or member of the research team in another state. In this case, the researcher should present how the new data will expand on earlier research.

The Role and Risks to Human Subjects Differ Significantly from Biomedical Projects and Need to Be Explained in a Different Way

Unless the project uses deidentified data collected by someone else or involves study of policy, a social and behavioral science research project will need to be reviewed by its institution's human subjects review committee (IRB) before it begins. As discussed in Chapter 6, NIH will want to know that you have thought through the risks to human subjects in your study and have an adequate IRB committee available to review the proposal. The project will not need IRB approval before it is funded.

The potential risks of a medical procedure or new medication may be clear to a researcher, but a social or behavioral science project can create a number of additional risks. Will discussion of certain subjects create emotional problems for participants? Will participation in a project identify participants as belonging to a minority group or having a particular disease that may cause stigma in their community? Will an intervention take time away from work or other essential activities, harming participants' quality of life? What if data from the project was leaked, could it result in participants losing jobs, insurance, or something else they need? Social and behavioral science proposals need to outline each of these types of risks and explain why it is important to do the project anyway. For more information on developing human subjects review applications for social and behavioral scientists, see Principal Investigators Associations' guide *Qualitative Research & IRB: A Comprehensive Guide for IRB Forms, Informed Consent, Writing IRB Applications and More* <https://principalinvestigators.org/product/qualitative-research-irb/>.

NIH encourages expanding medical research to include people from different racial and ethnic groups, women, and other marginalized populations often left out of health studies. Social and behavioral science projects are often seen as having the contacts to reach these kinds of populations. In addition, studies increasingly include populations that may not be in a position to make decisions for themselves like people with intellectual disabilities, autism, dementia, children or prisoners.

Regardless of the nature of the special population, the applicant will need to fill out forms that show that they have included these populations or explain why they are not included. For protected populations (pregnant women, children, prisoners, people with impaired decision making ability) special human subjects review will also be required. These elements will need to be included in the proposal's sampling plan, human subjects statements, and forms of various special populations.

The Physical Resources Needed to Carry Out the Project are Completely Different

Rather than labs and specialized equipment, social and behavioral science projects need completely different physical space. At the host institution, this will include office space, conference rooms, interview rooms, and places to securely store data and mobile equipment like tape recorders and laptops. The project may also require specialized printers, software, media equipment and studios, or access to statistical centers or GIS labs. These resources will need to be carefully planned and outlined in the institutional resource section, budget, and budget justification. These elements will be discussed in Chapter 7.

Partnerships with research sites are particularly important for social and behavioral science projects. In addition to willingness to host a project, a host site may also need to reserve workspace, office space, or secure filing cabinets to store data or research materials. These facilities and partnerships should be outlined in the research plan. Assurances that these resources will be available should be included in support letters from host sites.

Investigators Need to Pay Particular Attention to Which Panel Reviews Their Application, the Branch and Institute Identified for the Application, and the Expertise on the Review Panel

Given the diversity of social science and behavioral science research questions and methods, PIs need to take extra care to ensure that their application is assigned to the right Institute and reviewed by a research panel with appropriate expertise. Talking with program officers and doing research on review panels is particularly important for social and behavioral science researchers. These topics will be discussed in Chapters 2 and 9. Including a cover letter that identifies the appropriate Institute, suggests review panels, and clarifies the expertise needed to review your proposal is particularly important for social and behavioral science proposals.

SOME KEY OVERALL STRATEGIES FOR A SUCCESSFUL SOCIAL SCIENCE PROPOSAL

The remainder of this manual discusses strategies to write a successful R01 proposal in detail. This section offers some overall tips recommended by program officers, reviewers, and successful applicants to write a winning proposal:



REMEMBER:

Be sure to link every section back to your research question.

- **Your title is important.** The title is the first thing a reviewer will see and will also be used to assign your project to a review panel. The title needs to be concise, interesting, and clearly describe your project. Authors should continue to craft their title throughout proposal development and share it with others to see that it clearly expresses your research idea and has impact.
- **Choose a compelling, timely research topic.** Your research topic should not only meet a need expressed through NIH and the Institute's priorities, but it should address a need that is on the minds of reviewers or the general public. For social and behavioral science projects this is particularly important. Can you link your research to a policy initiative like the Affordable Care Act? Has the population been in the news like the increase in autism, the aging population, problems with people vaccinating their children, or violence like the Sandy Hook killings? While not all important research topics have this kind of media cachet, if your topic does address an issue of public interest, use it in your significance section.
- **Be sure to link every section back to your research question.** Your application should tell a story about why a particular problem needs further study and how your approach is the best way to research this topic. Each section should describe the aims in exactly the same way and show how each element contributes to that aim.

- **Proposals with the highest success rates speak about what’s already known, what needs to be known, and how to get there.** An NIH proposal is not the place to claim that no one has ever done research on this topic before or explore completely new ground with methods seldom used. Completely new ideas are rarely funded at NIH. Proposals need to show innovation, but also demonstrate knowledge of the existing literature and build on existing research. Successful researchers go over their proposal to ensure that it answers four questions: 1) What do we know about this topic?, 2) What are the gaps in existing knowledge that need to be filled?, 3) How does this project and these methods fill that gap?, and 4) What is the impact of this project on public health or a particular health issue?
- **Writing needs to be clear, concise, and written for an educated audience that may not be familiar with your topic or methods.** One program officer explained that she tells applicants that they should “*pretend you are writing for your dentist – someone who is educated, but is not in your field.*” Review panels always include clinicians, epidemiologists and others from different fields than the applicant. Any NIH proposal needs to explain each aspect of the proposal in language that can be understood by people who are not familiar with your methods or the problem you plan to address. Do not use jargon or get caught up with disciplinary arguments. Remember that you only have twelve pages to explain the significance, approaches, and analysis you plan to use. Using plain, concise language is particularly important given the page limits.
- **Follow the directions.** NIH staff expressed over and over that they are frustrated by otherwise good applications that are eliminated because they did not follow NIH’s careful, explicit directions. Be sure that the fonts and margins fit the stated requirements. Follow all directions for page length, materials in various sections, appendices, support letters and so forth.



TIP:

One program officer explained that she tells applicants that they should “pretend you are writing for your dentist – someone who is educated, but is not in your field.”



REMEMBER:

Allow enough time to write and review your proposal.

- **Assemble your team before you begin writing.** NIH looks carefully at who you include in your team and their track record of working together. The team should be assembled before writing your proposal and contribute to developing it. Preferably, you have worked with these people before. If you haven't, it may be important to do a small project with them before developing an R01 and publish the results.
- **Allow enough time to write and review your proposal.** Social and behavioral science proposals can often take six months to write given the need to find materials, complete pilot data, assemble the research team, identify host sites, and give time for adequate proposal review, and get institutional approvals. Experienced researchers and reviewers stress that it is important to find outside reviewers for your proposal and give them adequate time to review it. Team projects should include review from each member of the research team and their institution. Institutions also have their own review timelines. It is important to know these up front and factor them into your proposal development timeline.
- **Find a mentor to help you develop your idea.** Even the most experienced researchers can benefit from the advice of others in developing their proposals. More junior researchers are particularly encouraged to find a senior colleague with a track record of NIH funding to help them develop their proposal.
- **Be prepared to submit your idea more than once.** Given that only 15 percent of new R01 proposals are funded the first time, be prepared for the need to revise and resubmit your project. It is helpful to look at reviews as a critique of your work that provides insights into issues you may have missed. It is equally important to discuss reviews with your program officer and follow their advice in revision. ■