Chapter 12
Introduction to Our Project: Understanding Ethically Salient Perspectives of Diverse Societal Stakeholders in Innovative Neuroscience Research on Mental Disorders

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Advancements in neuroscience hold great promise for reducing the burden of many of the most disabling conditions that threaten human health on a global scale, including mental illnesses and addictions. Increasingly, exceptionally innovative science inspires hope that these devastating brain-based disorders may be prevented, treated, and even cured. With its inception in 2014, the National Institutes of Health's (NIH's) Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative® began its 10-year project aimed at revolutionizing our understanding of the human brain through the accelerated development and applications of new techniques and technologies [1]. Through its funding of over hundreds of different scientists and engineers over the past 7 years, the BRAIN Initiative has encouraged researchers to better understanding how the brain works and how disease occurs, inciting hope for patients who live with brain-based diseases and disorders in the process.

Alongside the pursuit of innovative neuroscience come a suite of novel ethical considerations and challenges. Concerns surrounding the deepest questions about what defines humanity and personhood, what forms of novel inquiry may exceed ethically acceptable limits in society, and how to perform ethically sound studies with volunteers who may be vulnerable to exploitation in the research situation represent just a few of the ethical dimensions and implications of neuroinnovation. When the NIH's BRAIN Initiative announced in 2016 that it would be funding neuroethics research projects with the goal of identifying and analyzing the ethical

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issues implicit in innovative neuroscience research [2, 3], our Stanford University-based team developed a proposal for a project intended to accelerate neuroscience toward lessening the burden of mental illness and addiction through hypothesis-driven empirical ethics inquiry. This project, entitled "Enabling ethical participation in innovative neuroscience on mental illness and addiction: towards a new screening tool enhancing informed consent for transformative research on the human brain," was among the first four neuroethics projects funded by NIH as part of the BRAIN Initiative.

Central to our approach is the engagement of diverse stakeholders to gain greater understanding of the ethically salient dimensions of innovation in society—in this case, innovative neuroscience that focuses on important aspects of public health tied to mental disorders and addiction. The project has been led by one of us (LWR), following on years of similar hypothesis-driven investigative work exploring differences and similarities of stakeholders regarding ethical aspects of research and innovation that engage individuals who belong to vulnerable populations. Co-investigators for the project include Laura B. Dunn, M.D., Jane Paik Kim, Ph.D., Mildred Cho, Ph.D, and Casey Halpern, M.D. The combined expertise of the investigators on the team is quite diverse, with representation from two psychiatrists, a biostatistician, a bioethicist, and a neurosurgeon, and is further supported by an interdisciplinary research team with members with backgrounds in psychology, sociology, neuroimaging, public health, literature, and art history. The team additionally has enlisted an advisory board, which consists of bioethicists, physicians, and neuroscience researchers from universities across the United States. These individuals provide expertise and guidance regarding the development of interview and survey instruments and the interpretation of findings over the course of the project.

The chapters in this section detail the development, design, and deployment of our team's hypothesis-driven empirical inquiry into the ethics of clinical neuroinnovation and present initial findings from select portions of this BRAIN Initiative project. In order to provide the appropriate context for these findings, an overview of the rationale and methods for each aim of this project are discussed below.

Project Rationale

Innovative neuroscience research is imperative to address the suffering associated with mental disorders, including addiction. Studying these conditions poses great ethical challenges, however addressing these challenges after the fact or as a postscript could lead to potential harm to participants and a lack of public trust in research, thereby slowing advancement and innovation in the field. It is our team's belief that by preemptively identifying ethical issues in this emerging field, and giving the most vulnerable stakeholders a voice, innovative neuroscience inquiry can be accelerated and the burden of mental illness and addiction can be alleviated. The rationale for this project is therefore grounded in our team's prior empirical work with stakeholders in psychiatry research, as well as a novel theoretical model of ethical research participation.

Value of a Stakeholder Approach

Previous work completed by our team has demonstrated the value of approaches that are predicated on collecting the views of various stakeholders through surveys and semi-structured interviews (See Table 12.1). In a series of studies over the past two decades, Drs. Laura Weiss Roberts, Laura B. Dunn, and Jane Paik Kim, in collaboration with other investigators in psychiatry and bioethics, have used various

Table 12.1 Examples of stakeholder-based empirical ethics projects undertaken by our team

Topic	Awarding agency, type	Representative papers	Method used
Stakeholder perspectives on ethical challenges in algorithmic medicine [in progress]	National Center for Advancing Translational Sciences, R01	Kim [4]	Semi-structured interviews ($n = 40$) & online survey ($n = 420$)
Interactions between law enforcement and unhoused individuals with mental illness [in progress]	Dollard foundation	Lane-McKinley et al. [5]	[in progress]
Willingness of mothers to enroll children in research	Stanford University Department of Psychiatry and Behavioral Sciences	Kim et al. [6]	Online survey via MTurk ($n = 126$)
Research decision-making by caregivers of people with Alzheimer's	National Institute on Aging, R01	Dunn et al. [7, 8]; Overton et al. [9]	Surveys and in-depth interviews ($n = 142$)
Ethical issues in deep brain stimulation (DBS) research	Greenwall Foundation	Bell et al. [10]; Christopher et al. [11]; Dunn et al. [12]; Fisher et al. [13]; Leykin et al. [14]	Semi-structured interviews ($n = 26$)
Psychiatric genetics research ethics	National Institute of Mental Health, R01	Roberts and Kim, [15]; Roberts et al. [16–18]; Rostami et al. [19]	Structured interview ($n = 182$) & online survey ($n = 386$)
Psychiatric genetic research consent process intervention	Institutional funding	Kim et al. [20]	Simulated informed consent process and follow-up written survey ($n = 79$)
Use of genetic information in the workplace	Department of Energy, Small & Large Grants	Hoop et al. [21]; Roberts et al. [22–24]	Written survey and structured interview ($n = 63$) & online survey ($n = 570$)
Psychiatric research ethics: science & safeguards study	National Institute of Mental Health, K02	Roberts et al. [25–29]	Structured interview ($n = 60$) & written survey ($n = 69$)

(continued)

Table 12.1 (continued)

Topic	Awarding agency, type	Representative papers	Method used
Informed consent & surrogate decision-making in clinical care	National Alliance for Research on Schizophrenia and Depression	Roberts and Kim [30, 31]	Written survey (n = 52)
Vulnerability and informed consent in clinical research	National Institute of Mental Health, R01	Kim and Roberts [32]; Roberts and Kim [33–35]	Written survey and structured interview (n = 181)
Vulnerability and informed consent in clinical research: educational intervention study	National Institute of Mental Health/ National Institute on Drug Abuse, R01	Roberts et al. [36]; Roberts et al. [37–39]	Randomized educational intervention and follow-up written survey (n = 83)
Research participation and participant safeguards	National Alliance for Research on Schizophrenia and Depression	Kaminsky et al. [40]; Roberts et al. [41–44]; Warner et al. [45]	Structured interview (n = 63) & written survey (n = 73)

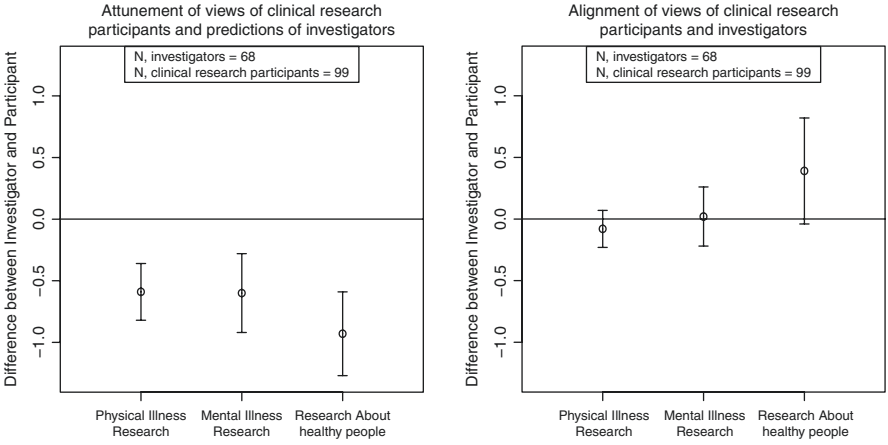

Fig. 12.1 Estimates of attunement and alignment, adjusted by covariates for the domain of "views regarding the importance of medical research." Whiskers indicate 95% confidence intervals. Reprinted from Journal of Psychiatric Research, 52, Roberts, LW, Kim JP, Do investigators understand ethically important perspectives of clinical research participants? A "piggy-back" study of attunement and alignment in serious illness research, Pp 36–43, Copyright 2014 with permission from Elsevier

stakeholder approaches to together provide substantial empirical data evaluating the abilities of people with mental illnesses to provide informed consent to research and correlate and predictors of these abilities [46–51], the impact of educational interventions on capacity to consent among people with mental illness [52, 53], the impact of differing levels of risk and compensation on potential participants' willingness to participate in hypothetical research protocols [54], and tools for assessing abilities of people with mental illness to consent to research [55] (see Figs. 12.1, 12.2, 12.3, and 12.4). These hypothesis-driven studies demonstrated the feasibility

Fig. 12.2 A comparison of perspectives on the ethical acceptability of mental illness research and the ethical acceptability of physical illness research. Adapted from Roberts, L. W., & Kim, J. P. Giving voice to study volunteers: comparing views of mentally ill, physically ill, and healthy protocol participants on ethical aspects of clinical research. Journal of Psychiatric Research 2014;56:90–97

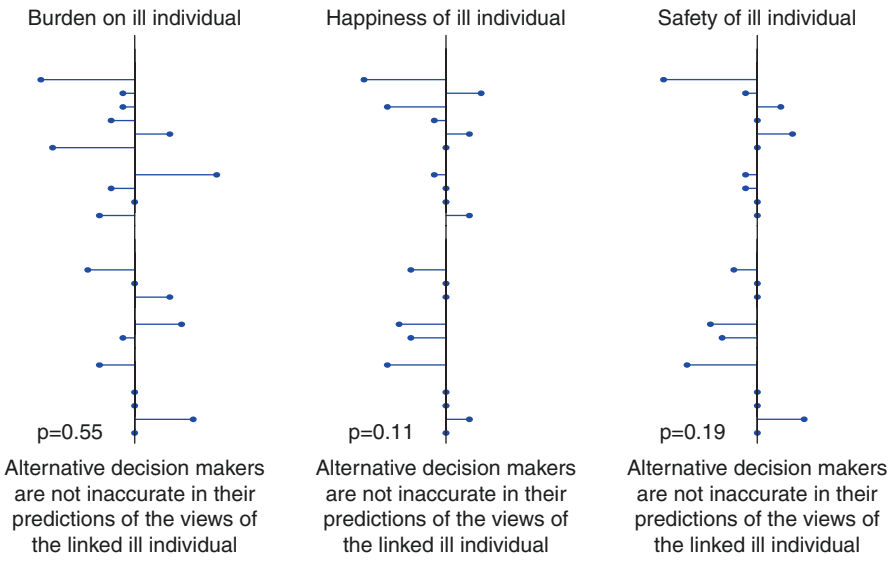

Fig. 12.3 Alternative decision-makers' predictions are attuned to the perspectives of ill individuals. Differences between the perspectives of ill individuals and the predictions of preferred alternative decision-makers (i.e., "attunement") were tested with two-sided paired t-tests and are graphically depicted here. *P* values were not adjusted for multiple comparisons as conceptual areas of interest (i.e., burden, happiness, safety) were identified a priori. Adapted from Roberts, L. W., & Kim, J. P. Attunement and alignment of people with schizophrenia and their preferred alternative decision-makers: an exploratory pilot study comparing treatment and research decisions. Journal of Psychiatric Research, 2015;71:70–77

	Healthy		Ill		*P* value
	N = 47		N = 100		
	strength of endorsement	sd	strength of endorsement	sd	
The researcher(s) tried to make sure:					
I felt comfortable	4.52	0.72	4.74	0.62	0.08
I really wanted to be in the study	3.91	1.11	4.35	0.99	**0.03**
I did NOT feel pressured	4.28	0.96	4.68	0.66	**0.01**
I felt I have choice about whether to drop out	4.76	0.64	4.75	0.62	0.08

Anchors for the survey items were as follows: 1 = Strongly Disagree; 3 = Equally agree/disagree; 5 = Strongly Agree.

Fig. 12.4 Comparison of informed consent questionnaire items directly assessing experiences of voluntarism in consenting to clinical research for both healthy and ill individuals. Reprinted from Journal of Psychiatric Research, 103, Roberts LW, Kim JP, Does informed consent given by healthy individuals when enrolling in clinical research feel less voluntary than for ill individuals? Pp 33–37, Copyright 2018 with permission from Elsevier

of performing empirical ethics research using a stakeholder-based approach, as well as the testability of ethics hypotheses regarding perspectives, attitudes, motivations, behavioral intentions, and decision-making. With this background and understanding, it was decided that a foundational aspect of our BRAIN Initiative project would involve an empirical line of inquiry directly with the stakeholders in neuroscience research—i.e., neuroscience researchers, Institutional Review Board (IRB) members, ethicists, patients with mental illness or addiction, and family members of patients with mental illness or addiction—in order to gain deeper insight into the ethical issues and processes that influence research decision-making.

Novel Theoretical Model of Ethical Research Participation: The Roberts Valence Model for Ethical Engagement in Research

The rationale for our project was additionally grounded in the understanding that ethical engagement of potentially vulnerable volunteers in human studies is predicated on rigorous, authentic informed consent processes that enable positive

influences on participation decisions and appropriately safeguard against negative influences [56]. Prior work has identified factors that influence research participation decision-making [57, 58]. Some affect a potential participant's decision-making favorably and appropriately; we call these "positive valence" factors (e.g., altruism; salience of the condition under study; accurate understanding of study procedures, risks, and benefits). Other influences are more ethically problematic; they may sway an individual toward participation by factors that have "negative valence" (e.g., desperation; lack of resources; threats to voluntarism) [59, 60]. Past research has examined positive and negative valence factors in isolation from one another or in relatively small combinations of factors [61–65]. The Roberts Valence Model for Ethical Engagement in Research, represented in Figs. 12.5, 12.6, 12.7, and 12.8, takes into consideration a fuller array of positive and negative valence factors in combination amongst research participation decisions.

It is expected that a decision to participate in research will be influenced by a number of factors, some "positive" and some "negative." The presence of negative

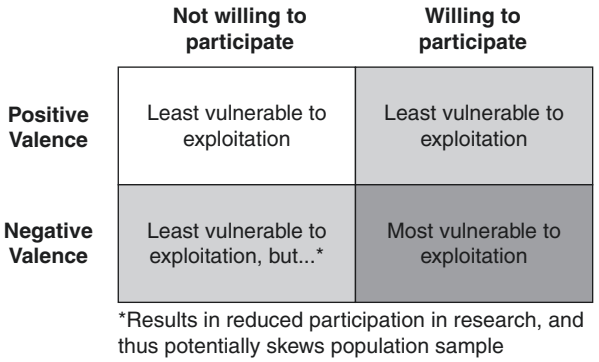

Fig. 12.5 Application of Roberts Valence Model of ethical research participation—a 2x2 construct

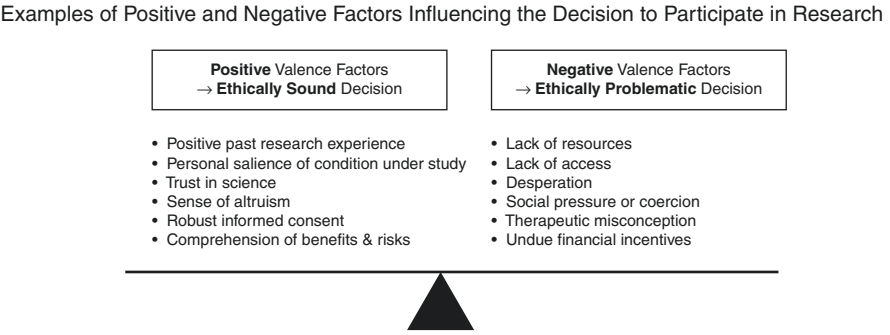

Fig. 12.6 Roberts Valence Model with examples of positive and negative factors influencing the decision to participate in research. Adapted from Roberts LW, Kasun M, Termuehlen G. Ethics in the mental health professions. IN: Roberts LW, Termuehlen G, eds. Professionalism and Ethics Q&A Self Study Guide for Mental Health Professionals, second Edition. Washington, DC: American Psychiatric Association Publishing: 2021, pg 112. Used with permission

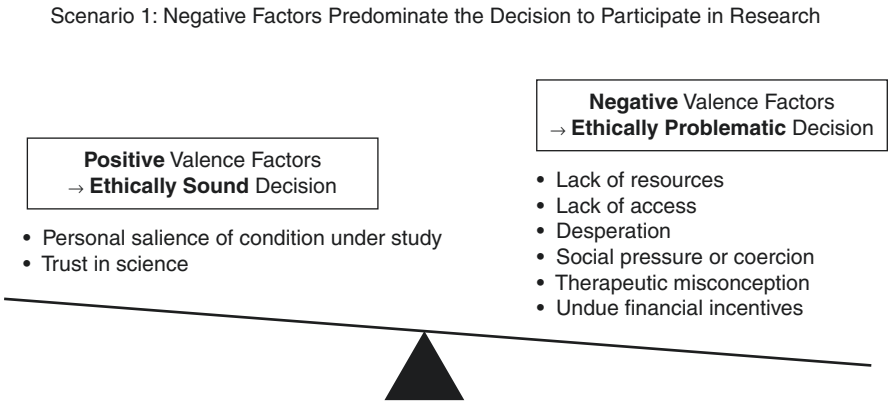

Fig. 12.7 Roberts Valence Model applied to a scenario in which negative factors predominate the decision to participate in research. **Negative** valence factors are predominant in the decision to participate, rendering the overall choice to enroll in research **ethically problematic**

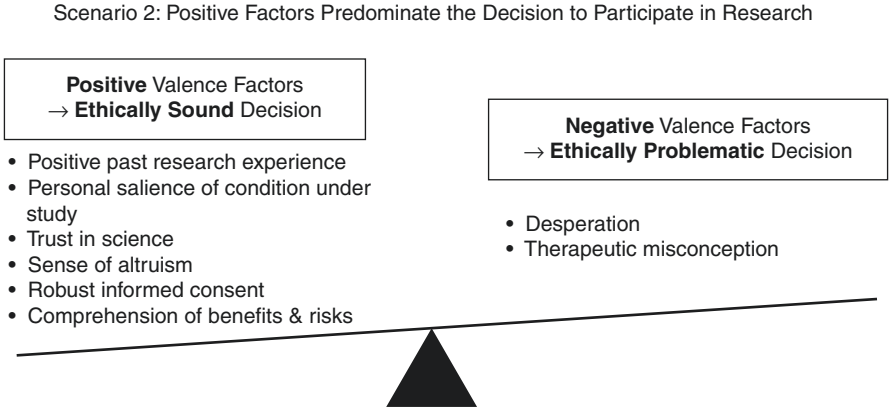

Fig. 12.8 Roberts Valence Model applied to a scenario in which positive factors predominate the decision to participate in research. **Positive** valence factors are predominant in the decision to participate, rendering the overall choice to enroll in research **more likely to be ethically sound**

valence factors is not in and of itself ethically problematic, but overly weighted negative valence factors are problematic. In ethically sound decision-making, negative valence factors will be at least balanced by positive valence factors. Ideally, positive valence factors will shape the decision to participate in research. Researchers can "tip the scale" through robust study-specific safeguards that ensure that positive factors outweigh negative factors.

By applying the Roberts Valence Model to our BRAIN Initiative project, we aimed to examine the influence of positive and negative valence factors on participation decisions of people with mental illness and addiction across a range of innovative neuroscience research. Understanding these valence factors is even more crucially important in cutting-edge research with as yet poorly understood risks and

benefits, and in research that involves vulnerable populations. Such efforts lessen the likelihood that volunteers' potential sources of vulnerability (e.g., desperation, misplaced hope, poor understanding, intractable pain, and coercion) are exploited in human research. More positively, attention to engagement with potential volunteers through optimal informed consent interactions and processes can ensure ethical participation of volunteers and enhance trust in science.

Notably, the Roberts Valence Model points to interventions and safeguards of value in ensuring ethical research participation. Because all risks cannot be eliminated or protected against, the safeguards themselves must be particularly well founded, especially when involving potentially vulnerable populations. At the same time, safeguards should not be so prohibitive that they hinder research due to biases about people with mental illness and addiction [66, 67].

Project Methods

The overarching goal of this BRAIN Initiative project was to encourage ethical engagement and innovation in neuroscience research in two main parts: first, by mapping a topography of salient ethical issues in highly innovative neuroscience research related to mental illness and addiction; and second, empirically examining influences on research decision-making in innovative neuroscience research in order to test a new evidence-informed conceptual model—the Roberts Valence Model of Ethical Research Participation**.** These goals are reflected in the methods for each project aim, demonstrated in Fig. 12.9 and discussed in detail below.

Prospective approval from the Stanford Institutional Review Board (IRB) for this project was received in October 2017 and was continuously maintained throughout the project period. All human subject participants engaged in an informed consent process before the start of any research procedures, and all collected data was de-identified prior to analysis and publication.

Aim 1

The first aim of this BRAIN Initiative project focused on *identifying the distinct ethical issues encountered in innovative neuroscience research related to mental illness and addiction* through the completion of semi-structured interviews with stakeholders. This stakeholder approach was based on our team's understanding that those best-situated to provide detail and insight regarding current, emerging, and possible future ethical issues are those whose careers and professional experiences encourage the development of first-hand views and opinions regarding neuroscience research ethics—namely, neuroscience researchers, ethicists, and IRB members. The rationale of interviewing these professional stakeholders was that it would yield novel data to map this new ethical terrain of innovative neuroscience research.

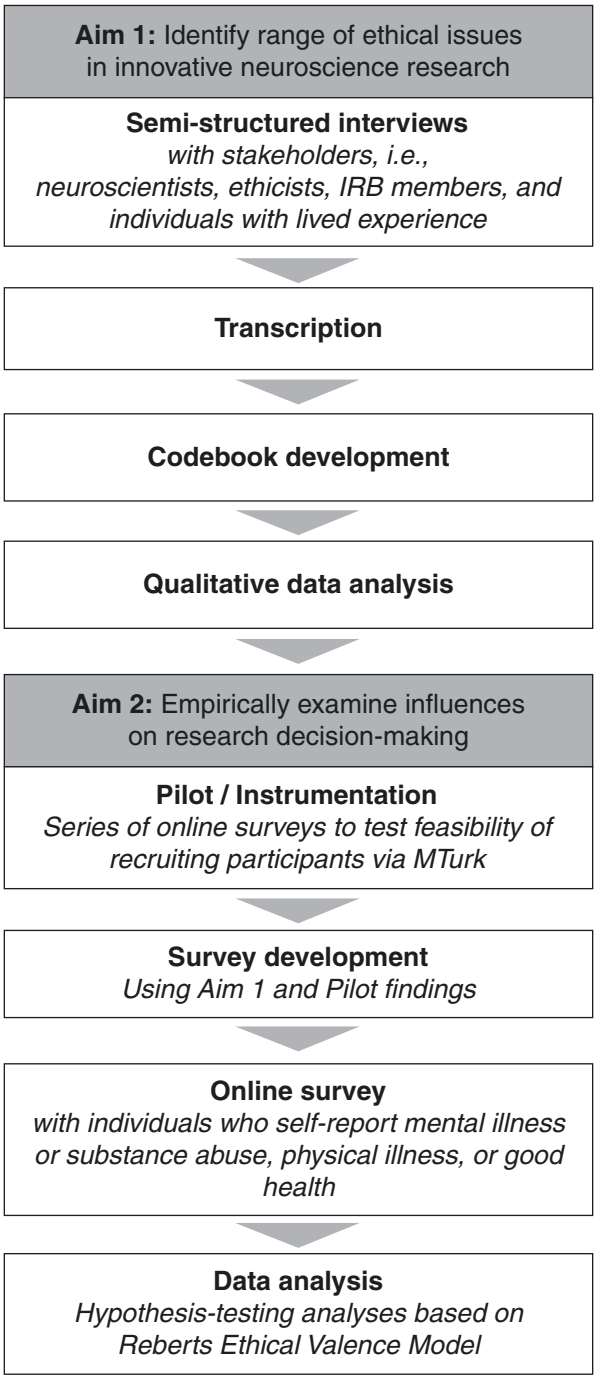

Fig. 12.9 Sequential design and methods for project aims 1 and 2

Furthermore, as reflected in the entries in Table 12.1, our prior empirical work has been centrally motivated by the need to give greater emphasis to underrepresented voices in research, including individuals who may be living with or at-risk for mental illness and individuals with multiple sources of vulnerability in the research situation. In order to elevate the voices of these populations, individuals who were living with a mental illness or addiction and immediate family members of individuals who were living with a mental illness or addiction were also included in this project aim. These individuals with lived experience belong to the groups who are most directly impacted by the processes of innovative neuroscience research, as it is these individuals who volunteer to take on the burden and risk of innovative research, and who stand to gain the most from advancements in treatment and care.

During this exploratory Aim 1, over 60 semi-structured interviews with stakeholders were conducted. The "professional" population consisted of over 40 neuroscience researchers, ethicists, and IRB members from Stanford and other universities across the United States. The "lived experience" population included over 20 individuals living with a mental illness or addiction and immediate family members of individuals living with a mental illness or addiction. Stakeholder interviews were designed to be semi-structured in order to facilitate exploration of unanticipated issues and in-depth understanding of the core topics being examined. One-on-one interviews, which typically lasted between 50 and 90 minutes, allowed for the eliciting of diverse, in-depth, and independent information from participants.

Interviews with "professional" participants (researchers, ethicists, and IRB members) were completed by a project co-investigator in-person at Stanford University or via a video call when necessary. Participants were queried regarding three organizing themes: (1) Experiences relevant to research ethics (e.g., specific examples of participant-related issues; experiences with institutional safeguards); (2) Perspectives on policy and implementation issues in neuroscience research; and (3) Differences between neuroscience research and other types of health research.

Interviews with "lived experience" populations (individuals living with mental illness or addiction and family members of individuals living with mental illness or addiction) were completed in-person at Stanford University by a trained team member. These interviews, while still administered in a semi-structured format, provided additional structured context regarding the field of neuroscience research for participants to reference throughout the interview. After a brief introduction to the field of neuroscience research, participants were queried regarding the following topics: (1) Interest in and knowledge of neuroscience; (2) Hopes and fears for neuroscience research; (3) Attitudes toward participation in medical research; (4) Opinions regarding hypothetical scenarios that included various real-world neuroscience research projects.

As discussed in more detail in Chap. 13, the audio and video recordings of all interviews were transcribed and then qualitatively coded and analyzed. This exploratory analysis identified key issues, claims, and concerns about the field of neuroscience research, portions of which are reported in the following chapters (See Chaps. 14, 15, and 16).

Aim 2

The second aim of this BRAIN Initiative project was to *empirically examine influences on research decision-making in innovative neuroscience research in order to test a new evidence-informed conceptual model—the Roberts Valence Model of Ethical Research Participation*. To fulfill the project's second aim, we developed a 463-item online survey to examine factors both negative and positive theorized to influence research decision-making by people with mental illness and addiction in the context of innovative neuroscience research, as compared with individuals with physical illness and in good health.

The qualitative findings from the first aim of the project provided insight into stakeholder perspectives, which informed the content of the structured survey in this quantitative second aim. The survey included over 20 validated personality, attitudes, and health instruments that evaluated relevant aspects of participants' experiences and perspectives on research and measured an array of both positive and negative valence factors theorized to influence willingness to participate. The main outcome measure of the survey included a series of research vignettes, which presented details regarding various innovative neuroscience research projects and served as the stimuli to which participants were asked to respond with respect to perceptions of risk and willingness to participate. These research vignettes were carefully developed by the team by drawing on our past work and applying findings from Aim 1. The use of these hypothetical research vignettes allowed our team to manipulate specific dimensions of the research in order to examine protocol-specific influences on decision-making in research. The Aim 2 survey was distributed online via Amazon MTurk (see Chap. 17) to nearly 1000 participants from across the United States living with mental illness or addiction, physical illness, or in good health.

Supplement

In September 2018, this project was awarded a one-year administrative supplement by the National Institute of Aging. The supplement allowed for the expansion of the Aim 1 and Aim 2 populations to include stakeholders in the field of innovative neuroscience research on Alzheimer's disease and related dementias (AD/ADRD). Over 30 AD/ADRD researchers, patients living with mild AD/ADRD and family members of individuals living with AD/ADRD were interviewed to supplement the Aim 1 populations from the parent award. An additional 240 individuals (60 individuals who were at-risk of AD/ADRD, 60 caregivers of individuals with AD/ADRD, and 120 controls) were recruited via Amazon MTurk and completed a modified Aim 2 survey regarding decision-making in innovative AD/ADRD research [68]. The results of this supplemental project are not represented within the scope of this book, and instead will be submitted to peer-reviewed publications for review and consideration.

Preliminary Findings

The following chapters in this section present qualitative findings from the Aim 1 semi-structured interviews, as well as quantitative findings obtained while piloting our survey methods for the Aim 2 online survey. Chap. 13 discusses detailed methods for the completion of our Aim 1 semi-structured interviews and delves into our process for developing and refining the codebook that was used to perform qualitative coding and analysis. Chapters 14–16 present the findings from our Aim 1 qualitative analysis, divided into thematic chapters that we feel best represent the voices and intentions of those we interviewed. Chap. 17 provides background regarding Amazon MTurk, a scalable online workforce that our team employed to recruit the populations necessary for the Aim 2 quantitative surveys, while the Appendix goes on to present findings that emerged while piloting our survey methods for the Aim 2 survey.

Looking Forward

With the completion of this foundational project, we look forward to applying our findings to the future development of a novel screening tool, which will be adaptable to a wide range of clinical research protocols and will aim to help investigators efficiently identify and address both positive and negative valence factors affecting participants' consideration of, or consent to, specific research protocols. In turn, this information will facilitate greater effort by investigators to provide and tailor additional participant safeguards on empirical and individualized bases (e.g., further teaching regarding study risks; clarifying the investigative or innovative nature of the research; helping participants better distinguish between research and treatment aspects; and helping participants identify other resources for treatment). We plan to expand research efforts in four lines of work:

1. Further testing of an evidence-informed conceptual model of ethical participation in research (the Roberts Valence Model) in additional populations, e.g., broader range of illnesses; greater diversity of age and ethnicity, and other research contexts, e.g., types of studies; different settings;
2. Implementation testing of the Roberts Ethical Valence screening tool in a range of studies;
3. Development and testing of interventions aimed at target areas identified by the tool;
4. Creation and dissemination of best practice recommendations from new knowledge, insights, and wisdom of neuroscientists, neuroethicists, and IRB members entrusted with safeguarding human subjects, generated from qualitative insights from interviews.

Innovative research fundamentally provides the possibility of transformative change, but as the parameters of research expand, the need for nuanced efforts to observe, anticipate, and minimize potential ethical issues becomes only more paramount. Our project, detailed here and in the following chapters, uses a stakeholder

approach to engage and explore these concerns empirically. Informed by what we learn from this project, we support the development of innovative research tools to support future innovative research endeavors.

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Further Reading

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