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Implementation of NIH Inclusion Guidelines: Survey of NIH Study Section Members

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Abstract

In March of 1994, the National Institutes of Health (NIH) released guidelines mandating the inclusion of women and minorities in clinical research. Four years later, the NIH released similar guidelines mandating the inclusion of children. These “inclusion guidelines” were created to increase the representation of women, minorities and children in clinical research to address potential harms (real and perceived) created by their exclusion or omission. As designated in the guidelines, Institutional Review Board (IRB), NIH Scientific Review Groups (SRG) and NIH program staff all have responsibility for the evaluation of Principal Investigator (PI) adherence to the inclusion guidelines. The purpose of this survey was to assess the experience with and attitudes of NIH Scientific Review Group (SRG) members with the implementation of these justice-based policy recommendations.

The results of the survey identify one clear measure of success regarding the implementation of the NIH guidelines; SRG members indicate the guidelines are in part responsible for their attention to the inclusion of women, minorities and children in clinical research. In addition, SRG members believe that gender and race are important factors when assessing the diversity of study samples and that the current NIH guidelines are adequate for encouraging their inclusion. As a proxy measure of success, SRG members believe that PIs responsible for protocols reviewed by their study group are generally compliant with the inclusion guidelines. Future research ought to explore whether IRB members and NIH program officers find PIs to be compliant as their projects get underway. In addition, more research ought to be conducted to assess the downstream effects of this important social policy.

Keywords

NIH Inclusion Policy; Study Section Members; Attitudes and Opinions about Implementation

Introduction

In March of 1994, the National Institutes of Health (NIH) released guidelines mandating the inclusion of women and minorities in clinical research.[1] Four years later, the NIH released similar guidelines mandating the inclusion of children.[2] These “inclusion guidelines” were created to increase the representation of women, minorities and children in clinical research to address potential harms (real and perceived) created by their exclusion or omission. As designated in the guidelines NIH Scientific Review Groups (SRG) share the responsibility for the evaluation of Principal Investigator (PI) adherence to the inclusion guidelines with local Institutional Review Boards (IRBs) and NIH Program Staff.[1,2]

In general, SRG groups are responsible for the peer review of research applications submitted to the NIH and their decisions determine whether an application ought to be considered for funding by a particular NIH institute, center or division (ICD). The SRGs assessment of a PIs adherence to the inclusion guidelines are incorporated into their scoring of the application. A decision by the SRG to penalize an application for non-adherence to the policy (raising the priority score of the grant) can determine whether a particular application is considered for funding. Their willingness to use this power may be related to their attitudes regarding what human factors are important to diversity in study populations and whether they consider the NIH policy useful in encouraging such diversity. The purpose of this survey was to: describe the experience with and attitudes of SRG members toward the inclusion guidelines and to identify characteristics of respondents that predict their attitudes towards the policy.

Background

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research produced the Belmont Report which set out three basic principles to guide the conduct of human subject research; respect for persons, beneficence and justice. [3] The principle of justice as articulated in the Belmont Report was concerned with the protection of vulnerable populations from exploitation.[4] In the interim, the principle of justice has been re-framed to promote equitable access to the benefits of research.[5,6]

Advocates used this re-framed principle of justice to advocate for the inclusion of women, minorities and children in clinical research, focusing on the limited generalizability of results from research conducted with heterogeneous subject populations and on the potential ethical harms of failing to address the systematic exclusion of particular classes of people.[6–8] Efforts to increase the number of women enrolled in clinical research began with recommendations by the NIH Women's Advisory Committee in the 1985 and culminated in 1994 with a Congressional mandate that NIH funded biomedical and behavioral research (with special emphasis on Phase III clinical trials) include women and minorities.[1,6,9–13]

It is important to note that the adoption of these guidelines was not uniformly supported at the time and the utility of the minority guidelines continue to be an active topic of debate.[14–21] At the time the women and minority guideline was adopted Controlled Clinical Trials published an article on the guidelines authored clinical trialists affiliated with the NIH and a number of articles in response.[22] Some argued that the underlying premise that women had been systematically excluded from trial participation was false.[23,24] Others argued that the requirement for the “appropriate representation” minority groups in study populations was both vague and impractical and such a goal supported the false premise that only research that included specified proportions of minority group members would be generalizable to the population.[23,25–27] Still others noted that efforts to increase number of minority group members in clinical research supported the notion that race was a biologic rather than social construct.[28] It is not clear whether these scientific arguments and others were discounted or disregarded, but the implementation of the guidelines is at least evidence that the ethical argument in favor of inclusion had more influence with policy makers at the time. Building on the momentum generated regarding the inclusion of women and minorities, Congressional hearings were held in 1995 regarding the inclusion of children in research culminating in the adoption of the ‘Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects’ in 1998.[2]

It is the responsibility of IRBs, SRGs and NIH program staff to evaluate whether the Principal Investigator (PI) submitting an application to NIH for funding is compliant with the inclusion guidelines.[1,2] SRG members are scientific experts from academia, industry and non-profit research organizations. The primary role of SRGs is to assess the scientific merit of research

proposals to the NIH based on the NIH-defined criteria of significance, approach, innovation of proposal, quality of the investigator, and scientific environment. In addition, SRGs must include an evaluation as to whether the PI(s) has met the requirements of the NIH guidelines to include women, minorities and children.[1,2,29,30] Reviewers are instructed to increase the score of a proposal if “inclusion of these groups is inadequate to answer the scientific objective of the proposed study” and justification for their exclusion is inadequate. (The higher the score, the less likely the proposal will be funded) The SRG has discretion as to the amount of weight to give to this deficiency (i.e. there is not a standard reduction suggested); further, the SRG has the option of designating a protocol as unacceptable if it substantially fails to conform to the guidelines.[29]

Methods

Sample

The Office of Extramural Research (OER), NIH website[31] provides a narrative describing the purview of each SRGs and posts member rosters from recent meetings. Eligible subjects were sampled from SRGs that have responsibility for reviewing research proposals that may include human subjects. Six SRGs who appeared to regularly review human subject research but had not met in the last calendar year and six SRGs for which no current roster of members was posted were excluded from the sample. A master list of all eligible members for inclusion was created. All Committee Chairs were included in the sample (n = 70). A random sample of 746 members was created from a list of close to 1400 non-Chair members.[32]

Recruitment

Once the random sample was created, complete mailing addresses were collected via a comprehensive web-search (e.g. Google and/or Institutional Faculty/Employee Databases). All eligible subjects were mailed a letter describing the study and a hard copy of the questionnaire. The first mailing was sent in April 2003 to coordinate with reviews scheduled for and conducted in January–March 2003. Two weeks after the first survey package was sent a reminder postcard was sent to all non-responders. Four weeks after the original mailing, a second mailing with a letter and copy of the survey was sent.

Each subject was given a unique identifier (UI) in order to track and follow-up with non-responders. When the survey was returned it was dated and given a new number in order of receipt date. Once processed it was impossible to link survey responses with an individual respondent.

Survey

Survey domains and questions were developed based on documents that detail SRG responsibilities regarding the implementation of the NIH Guidelines.[29,31] Drafts of the survey were reviewed by an expert in survey design and cognitive interviews were conducted with three colleagues who had served on an SRG. Survey domains included: Basic details about their SRG experience, attitudes about diversity in general and diversity in study samples, experience with implementation of each of the set of NIH guidelines and basic demographic information including their area of expertise.

All respondents were asked to complete the demographic questions and survey questions regarding their attitudes and opinions about evaluating the diversity of study samples.

Independent variables of interest are:

- Gender,

- Race/ethnicity,
- Personal experience with research,
- Completion of an ethics course,
- IRB service,
- More than five years experience on an SRG,
- SRG chair service,
- More than 50% of protocols reviewed as most recent SRG meeting included human subjects,
- Agreement with the importance of gender, race, age, socio-economic status (SES) and genotype in the assessment of the diversity of a study population, and
- Which subject factor is most important in assessing the diversity of a study population.

Dependent variables of interest:

- Whether the guidelines are in part responsible for the amount of attention given by their SRG to inclusion of women, minorities and children;
- Whether they believe investigators whose grant applications are reviewed by their SRG consistently address the inclusion of women, minorities and children in their applications;
- Whether the number of women, minorities and children included in clinical research has increased as a result of investigator compliance with the guidelines;
- Whether subject factors related to diversity are frequently discussed during SRG meetings; and
- Whether current NIH policy regarding factors related to the diversity of a study population is adequate.

Data from returned surveys were entered into an Excel database and later uploaded into STATA, version 7.0, statistical software for analysis.[32] Descriptive univariate analysis was conducted followed by bivariate analysis. A number of questions required respondents to indicate whether they “strongly agree, agree, neither agree nor disagree, disagree or strongly disagree” with statements about the study sample diversity and the NIH guidelines. Based on the characteristics of the variable distributions, these responses were collapsed such that those who were neutral, disagreed or strongly disagreed were combined and compared with those who strongly agreed or agreed.

Results

Response

Two postcards were returned as ‘undeliverable’. Twenty-five subjects either returned blank surveys or sent an e-mail noting they did not believe they were eligible for participation. A total of 425 completed surveys were returned (overall response rate = $425/746 = 56.9\%$).

Independent Variable: Demographics

Of the 425 respondents, two-thirds (66%) were male and 85% were white. Seventy-nine percent of respondents held a PhD and 77% reported personal experience conducting research. Sixty-nine percent of respondents completed an ethics course and 28% have served on an IRB.

Eighty-seven percent of respondents were members of standing committees and had a mean tenure of 2.9 years on their current committee. The remaining 13% were members of Special

Emphasis Panels (SEPs). SEPs are brought together for the review of a particular set of research proposals or for the review of protocols submitted in response to a particular request for applications (RFA) or request for proposals (RFP) that requires expertise not available on standing committees. Fifty-four percent of respondents reported they have more than 5 years of cumulative experience on an SRG. Twenty-three percent of the sample is Committee Chairs. Ninety-five percent of respondents reported their SRG meets three times a year and 65% attended a committee meeting less than two months prior to completing the survey. (See Tables 1 and 2)

Independent Variable: Opinions about Evaluating the Diversity of Study Samples

Ninety-seven percent ($n = 415$) of the sample responded when asked whether they agreed that particular human characteristics – gender, race, age, socioeconomic status (SES) and genotype – were important when evaluating the diversity of human subjects to be included in a study sample. Results are presented in Table 3.

Respondents were also asked to identify which of the above factors was the most important when evaluating the diversity of a study population. Thirty respondents refused to answer this question, a number noting that no one factor can be identified as “most important.” (See Table 3) Non-white respondents were more likely than white respondents to agree that gender ($p = .025$) or race ($p = .025$) was the most important factor. Female respondents were no more likely than male respondents to agree that gender or race was the most important factor ($p = .121$ and $p = .577$).

Dependent Variable: Attitudes, Beliefs and Opinions about Inclusion Guidelines

Respondents who indicated that they reviewed human subject research at their last meeting ($n=375$; 88% of sample) were asked to indicate their level of agreement statements about the guidelines regarding the inclusion of women, minorities and children.

1. Whether the guidelines are in part responsible for the amount of attention given by their SRG to inclusion of women, minorities and children. The majority of respondents agreed that the inclusion guidelines were in part responsible for their study sections' attention to the inclusion of women (84%), minorities (88%) and children (77%) in human subject research (See Table 4). Respondents were more likely to agree that guidelines were in part responsible for SRG attention to inclusion of minorities if they had taken an ethics course ($p = .018$) or if they had served on an IRB ($p = .026$).
2. Whether they believe investigators whose grant applications are reviewed by their SRG consistently address the inclusion of women, minorities and children in their applications. The majority of respondents agreed that investigators whose grant applications are reviewed by their study section consistently address the inclusion of women (84%), minorities (83%) and children (72%) in their grant applications (See Table 4). Those who reported having conducted research themselves; having taken an ethics course or that more than 50% of the proposals reviewed at their last committee meeting proposed to include human subjects were more likely to agree that investigators are consistent with the minority ($p = .001$; $p = .001$; $p = .03$) and gender ($p = .000$; $p = .004$; $p = .001$) guidelines.
3. Whether the number of women, minorities and children included in clinical research has increased as a result of investigator compliance with the guidelines. Just over half of the respondents agreed that the number of women (54%) and minorities (56%) included in clinical research has increased as a result of investigator compliance with the inclusion guidelines. Only thirty percent of the respondents agreed that the number

of children included in clinical research had increased as a result of investigator compliance with the guidelines (See Table 4).

4. Whether subject factors related to diversity are frequently discussed during SRG meetings. Respondents also were asked whether the factors of gender, race age, SES and genotype are frequent topics of discussion in reference to the diversity of study samples proposed in proposals under review during study section meetings.(See Table 5)
5. Whether current NIH policy regarding factors related to the diversity of a study population is adequate. In follow-up, respondents were asked if they believed that the current NIH guidelines adequately address the importance of each of these factors in evaluating the diversity of study samples (See Table 6).

Discussion

The results presented here indicate that the NIH inclusion guidelines may have had an influence on the attitudes of SRG members in a number of ways. First, the majority of respondents indicate that gender and race are the most important factors when assessing the diversity of study samples and that the NIH guidelines regarding the inclusion of women and minorities are adequate to encourage their inclusion. Second, the majority of respondents also indicate that age is an important factor when assessing the diversity of study samples and that the current NIH guidelines are adequate. What is not clear, given the way in which the question is asked (importance of age rather than inclusion of children or older adults), is whether respondents believe that variation in age or inclusion of more younger or older subjects is important. Given respondent agreement that NIH guidelines regarding age are adequate, we can conclude that respondents are satisfied with the emphasis of the current guidelines that encourage the inclusion of children. Respondents were not asked if they believe it would be important to encourage the enrollment of older adults (for which NIH has no policy to encourage enrollment), which may become more important as the population ages.

Of note, SRG members do not agree that SES is as important a factor as gender and race in assessing the diversity of a study sample. There is compelling evidence that socio-economic status (e.g. income, education, occupation) is a strong determinant of health status.[33–39] That is, in general, poor socioeconomic status predicts poor health status.[39] Since socio-economic status is a clear predictor of health status, the socio-economic status of research subjects should be collected to assess both who gets into clinical trials and the role of socio-economic status on clinical outcomes. In addition, there is evidence from the epidemiologic literature that race/ethnicity is often used as a proxy measure for socio-economic status.[40–47] There are clear disadvantages to making biological assumptions about outcomes that vary by race/ethnicity; such assumptions can distract scientists from examinations of other risk factors such as socioeconomic status that may be as or more relevant to health status[28,40, 42,45,48,49], promote the idea that there **are** biological differences among racial/ethnic groups unrelated to socio-economic status,[28,36,40,42,48] 3) result in missed opportunities to appropriately target public health interventions meant to reduce health disparities.[42]{ { 1625 Lillie-Blanton, M. 1996; } }

Many argue that information on race should be collected as long as investigators define what concept they are measuring when they collect information on race/ethnicity.[41,43,46,47,50–52] Race used as a social variable can capture status differences among racial groups in the United States, racism, and the differential treatment that can result from racial discrimination. [34,37,42,43,47,50,53–56] Collecting information on race is important, they argue, because racial disparities in health persist, and we need information on differential outcomes to target

social interventions. But these goals are hindered by imprecise definitions of race and the historic use of race alone in exploring health disparities by social class.[40]

In addition, the SRG members report that they believe the guidelines have influenced outcomes relevant to the successful implementation of the inclusion guidelines. More than two-thirds of the respondents indicated that gender and race and the diversity of study samples were frequent topics of conversation in their study sections and the majority of SRG members agreed that the guidelines were in part responsible for their attention to issues related to the inclusion of women, minorities and children in human subject research. SRG members in this sample generally agreed that PIs of grant proposals have been consistent in their compliance with the inclusion guidelines. One limitation of the role of SRG members ability to assess PI compliance is that they only review the PIs' *intent* to adhere to the guidelines as described in their grant application.

Those SRG members that have experience conducting research, report having reviewed human subject research or have taken an ethics course are more likely to agree that investigators have been consistent with the inclusion guidelines. None of these respondent characteristics predict agreement that investigators have been consistent in their compliance with the guidelines regarding the inclusion of children. In a multiple regression model, only having taken an ethics course was found to be predictive of agreement with investigator compliance with the guidelines regarding the inclusion of minorities and children. It is not clear why having taken an ethics course would be predictive of PI compliance with the inclusion of minorities and children but not women. As noted above, having taken an ethics course may indicate respondent familiarity with the history of research ethics and the importance of the equitable distribution of the benefits and burdens related to enrollment in research study that they may be more aware of or sensitive to the inclusion guidelines. At the same time, it is not clear why this ethical knowledge would lead respondents' to positive assessment of investigator compliance with the guidelines, or why respondents wouldn't positively assess PI compliance with the gender guidelines.

About half of the SRG members in the sample agree that the inclusion guidelines have resulted in an increase in the number of women and minorities enrolled in clinical research (54% and 56% respectively). Less than a third of SRG members (30%) indicate that the guidelines encouraging the inclusion of children has lead to an increase of children in clinical trials. The amount of agreement regarding this outcome may be related to the SRG members' hesitance to support a statement about an outcome which is distal to their role in the assessment process. There are a number of possible reasons for the difference in the SRG members agreement with the influence of the guidelines on the number of women and minorities included in clinical trials as compared to the number of children. One reason may be that SRG members are aware of the dramatic success of a number of Food and Drug Administration (FDA) guidelines and initiatives (e.g. Pediatric Rule and Pediatric Exclusivity Provision) to increase the enrollment of children in research.[57–62] While challenges remain regarding the optimal labeling of drugs, attention to off-patent drugs used routinely in children, and the systematic collection of data on race and ethnicity, the FDA initiatives are responsible for the inclusion of thousands (and potentially tens of thousands) of children in clinical research.[58,60] By comparison then, the role of the NIH guidelines on the increase in the number of children enrolled in clinical research has been minimal.

Corbie-Smith, Durant and St. George found in their survey of National Heart, Lung and Blood Institute (NHLBI) funded principal investigators that 69% agreed that the inclusion guidelines had been successful in increasing gender diversity and 55% agreed the guidelines had been successful in increasing the number of minorities enrolled in clinical trials.[63] Compared to the results presented in this paper, PIs are more likely than SRG members to agree that the

guidelines have been successful in increasing the number of women., PIs and SRG members were similarly unenthusiastic about the influence of the guidelines on increasing the number of minorities in research.

It is important to note that there are alternative ways to assess whether the implementation of the guidelines have been successful. For example, the NIH Office for Research on Women's Health (ORWH), the NIH office responsible for monitoring compliance with the guidelines. According to the ORWH's last fiscal year report 2003 & 2004,[64] 57.5% of human subjects enrolled in all clinical studies were female, 52% were White, 8.9% were African American, 28% were Asian and 1% were American Indian/Alaska Native and Hawaii/Pacific Islanders combined. 4.8% of human subjects were of Hispanic/Latino ethnicity. The number of women and minorities enrolled in research has remained stable since the system has been in place, however.[64–69] In addition, there was no rigorous accounting system in place prior to the implementation of the 1994 guidelines. Therefore, the ORWH numbers cannot be used to argue the guidelines have been successful.

Other investigators have attempted to assess the influence of the guidelines on the inclusion of women and minorities by conducting literature searches and assessing if and how data regarding the sex and race/ethnicity of study populations is documented. Geller, Adams and Carnes conclude as a result of their review of 69 Federally-funded studies published in high impact medical journals in 2004 that there is inadequate compliance with the NIH guidelines. [1615 Geller, S.E. 2006;][70] Using similar methods applied to articles published in six leading journals in 1999, Rochon et al conclude that articles reporting the results of NIH-funded research were more likely to report minority group status of study populations as compared to non-NIH funded research. [71] Walsh and Ross applied similar methods to articles from July 1999-June 2000 reporting results of research projects in three general pediatrics journals and found that that almost two-thirds of studies included information on the race/ethnicity of participants.[72,73] Such studies have more potential than the ORWH data to indicate the influence of the guidelines on the inclusion of women and minorities in research if studies were conducted to assess the diversity of study populations before and after the guidelines were implemented.

It is also important to note that SRGs are not the only groups responsible for the assessing PI adherence to the guidelines. The Institutional Review Board (IRB) has the opportunity to assess individual PI compliance with the guidelines in the process of their annual review of approved protocols. NIH project officers review recruitment reports submitted annually by PIs and are therefore another source of information on PI compliance with the guidelines. There is currently no empirical data available regarding whether or how often IRBs or NIH project officers assess PI's success in recruiting as diverse a population as proposed or whether the continuation of the IRB approval or continuation of funding is contingent on evidence of success.

At least one potential limitation of this study is that while an effort was made to assure confidentiality, because the project was funded by the NIH, respondents may have been less critical of the guidelines than they would have been if the study was funded by non-NIH funds. This funding arrangement may have also influenced SRG members' willingness to return the survey in the first place.

Conclusion

This survey identifies one measure of success regarding the implementation of the NIH guidelines; SRG members indicate the guidelines are in part responsible for their attention to the inclusion of women, minorities and children in clinical research. In addition, SRG members believe that gender and race are important factors when assessing the diversity of study samples

and that the current NIH guidelines are adequate for encouraging their inclusion. As a proxy measure of success, SRG members believe that PIs responsible for protocols reviewed by their study group are generally compliant with the inclusion guidelines. Future research ought to explore whether IRB members and NIH program officers find PIs to be compliant as their projects get underway. In addition, more research ought to be conducted to assess the downstream effects of this important social policy. For example, whether PI compliance with the NIH guidelines leads to evidence in the research literature that women, minorities and children are well represented in clinical trials, whether research results vary by sub-groups and whether the conduct of such research results in the adoption of treatment recommendations tailored for different populations.[73,74]

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Table 1

Demographic Characteristics of Respondents (n = 425)

Sex	Male	66%
Race	White	85%
PhD Trained		79%
Personal Experience with Conducting Research		77%
Completed an Ethics Course		69%
Served on an IRB		28%

Table 2

Experience as SRG Member (n = 425)

Member of Standing Committee	87%
Mean Tenure as SRG Member	2.9 years
More than 5 Years Experience as SRG Member	54%
Chair of SRG	23%
SRG Meets three times a year	95%
Attended SRG meeting less than 2 months ago	65%

Table 3

Important Factors when Evaluating Diversity of Study Samples (n = 415)

Factor	Agree	Neutral/Disagree	Most Important
Gender	90%	10%	45%
Race	82%	18%	26%
Age	75%	25%	19%
SES	54%	46%	6%
Genotype	37%	63%	5%

Table 4

SRG Member Agreement with Role of NIH Guidelines (n = 385)

	Gender	Minority	Children
Guidelines in part responsible for SRG attention to inclusion of women, minorities and children	84%	88%	77%
Grant applications reviewed by their SRG consistent with inclusion of women, minorities and children	84%	83%	72%
The number of women, minorities and children has increased as a result of PI compliance with NIH guidelines	54%	56%	30%

Table 5

Which Factors Related to Diversity were Discussed Frequently at SRG Meeting (n = 385)

Factor	Agree	Neutral/Disagree	Can't Evaluate
Gender	69%	26%	4%
Race	68%	28%	4%
Age	48%	47%	4%
SES	26%	69%	5%
Genotype	17%	70%	14%

Table 6

Adequacy of NIH Guidance for Factors Related to Diversity (n = 385)

NIH Guidance Adequate Regarding:	Agree	Neutral/Disagree	Can't Evaluate
Gender	88%	8%	4%
Race	84%	12%	5%
Age	70%	25%	5%
SES	28%	63%	9%
Genotype	24%	53%	23%