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Continuing a collaboration between the *Journal of Empirical Research on Human Research Ethics* (JERHRE) and Public Responsibility in Medicine and Research (PRIM&R), we are once again pleased to publish empirical research poster abstracts from the 2017 PRIM&R annual conference, Advancing Ethical Research, held November 5 to 8 in San Antonio, Texas.

Informed Consent Process When Conducting Genomic Research in Populations Characterized to Have Low Literacy Levels

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Keywords
genome wide association studies (GWAS), sickle cell disease, Human Hereditary and Health in Africa (H3Africa)

Background

Conducting genomic research in low- and middle-income countries cannot be underestimated because of the high disease burden found in these countries and because genomic approaches can be a powerful tool in improving population health. However, conducting genomic research in populations with low literacy presents specific challenges in obtaining quality informed consent.

Method

This study was designed to explore the challenges associated with obtaining a valid informed consent when conducting genomic research with populations characterized as having low literacy levels. Qualitative methodologies were used to collect information including focus group discussions, in-depth interviews, and participant observations. This study was embedded in a genomic study on sickle cell disease conducted at a hospital. Participants were recruited using purposeful sampling. In total, there were 47 participants. Five focus group discussions were conducted with at least six participants in each, and 17 in-depth interviews were conducted. All the interviews were recorded using digital recorders and also captured in the field notes. All data were analyzed using thematic content analysis.

Findings

The findings indicated that literacy level was not a key factor influencing participants' understanding. However, adequacy of the information provided to the participants and the methods used to communicate the information were important contributing factors to help participants' understanding. The preferred mode of the provision of information was through group sessions in the presence of nurses or doctors. The benefits of the research and returning results were considered by the participants to be important sections of the consenting process.

Discussion

As a qualitative approach was utilized, the results cannot be generalized to the population. This study was also a hospital-based study and that, in some ways, might have an influence on the results. The relevance of the findings to other types of studies (non-genomics) requires further investigation. Gaining informed consent in populations with low literacy levels requires novel approaches to ensure that the information is fully comprehended. Our research indicates that individuals with low literacy levels require special consideration in the method for delivering materials and information. Group sessions with trusted medical personnel present are desirable for the target population. Using group sessions requires careful consideration to protect the identity of potential participants. The findings from this study will be used to develop a tool and strategies to guide researchers in the context of genomic research.

Declaration of Conflicting Interests

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Insider Experiences: United States Military Service Members as Participants in Health Research

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Keywords

military research, research participants, research experiences, human subjects research, qualitative research

Background

U.S. military service members may be vulnerable to coercion, undue influence, and exploitation surrounding participation in health research due to factors such as military hierarchy, physical and psychological conditions, and impaired decision-making capacity. Knowledge of their research experiences may provide insight into ethical concerns and may help future research design.

Method

After receiving institutional review board (IRB) approval, we sought a demographically diverse, purposeful sample of individuals currently serving in the U.S. Armed Forces (Army, Navy, Air Force, Marine Corps). Semistructured, individual interviews, completed in person or by telephone, focused on service members' experiences as participants in research and related insights. Using qualitative description methods, we analyzed interview data from 18 service members who had participated in at least one health research study within the last 3 years. Service members had each participated in one to three studies, for 34 total research participation experiences in 27 separate studies. Through an iterative process of descriptive coding, qualitative content analysis, and constant comparison, we identified and categorized service members' experiences of participation in health research into themes.

Findings

Experiences spanned six themes: (a) "being broken" described stigma associated with health problems that impacted, or were perceived to impact, one's work performance, and was accentuated due to participation burden; (b) "cautious distrust" described the assumption by service members that their privacy would not be maintained and that it was unwise to divulge certain information despite reassurances; (c) "connecting" described service members trusting researchers due to shared experiences and good communication; (d) "peeling back the scab" described re-traumatization experienced during research procedures, including surveys and interviews; (e) "opportunity to tell my story" reflected the importance of sharing significant experiences through research participation; and (f) "forgotten research" described studies that service members did not recall having had participated in until reporting and discussing other research experiences. No service members reported coercion, undue influence, or pressure to participate; all were aware of options regarding disenrollment and felt confident to do so if desired.

Discussion

The study has several limitations. Most service members in this study (89%) had >10 years of military experience, most (94%) were ≥30 years old, and most (67%) had academic degrees. Only one Air Force member participated. No Marine Corps members participated. Experiences of younger, less experienced service members may differ. To our knowledge, this study is the first to report service members' experiences as health research participants. Based on findings, recommendations for researchers, clinicians, and ethicists include the following: (a) reduce participation burden, particularly time away from work, to avoid heightened stigma experience; (b) avoid providing reassurances regarding privacy/confidentiality that cannot be upheld; (c) collaborate with and include researchers/clinicians who share similar experiences with participants and seek to establish trusting relationships through effective communication; (d) anticipate emotional distress and incorporate appropriate supportive measures/resources; (e) evaluate effectiveness of storytelling interventions; and (f) incorporate tangible objects and information regarding study findings to make research participation more memorable.

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Using Advanced Statistics to More Accurately Predict IRB Outcomes

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Keywords

institutional review board (IRB), time to approval, full board review

Background

Time to approval for institutional review boards (IRBs) has been scrutinized in recent years. The IRB review process is complex and input from different sources, and interpretation of different regulations, is often required. A simple count of days to approval may not be an accurate reflection or estimation of the time required.

Method

Data from 224 studies reviewed by the full IRB were collected beginning in July 2016. Time to approval was assessed by days with the study team and days with the IRB. Dependent variables collected included the department of the principal investigator (PI), type of sponsorship, involvement of Food and Drug Administration (FDA) regulated drugs or devices, IRB panel assignment, number of stipulations, number of times a submission was returned, single versus multicenter studies, and length of the consent form. A univariate analysis was used to make initial correlations. Significant variables were then entered into a multivariate regression analysis to determine the strongest correlates with each component of the time to approval.

Findings

The initial multiple regression model for IRB days included variables that were statistically significant in the univariate model. The items were IRB panel assignment, department of the PI, number of stipulations, and the number of times a submission was returned. IRB panel assignment ($p < .0001$), number of stipulations ($p = .0014$), and the number of times a submission was returned ($p = .0008$) were significantly correlated with the number of days with the IRB in the multivariate analysis. The initial multiple regression model for study team days included variables that were statistically significant in the univariate model. The items were IRB panel assignment, number of sites involved, number of times a submission was returned, and the length of the consent form. The number of sites involved ($p = .0046$) and the number of stipulations ($p < .0001$) were significantly correlated with the number of days with the study team.

Discussion

Additional work is needed to determine different characteristics across IRB panels, and to establish more consistent review patterns. The number of stipulations was significantly correlated with both study team and IRB days. Additional analysis to determine the types of projects or departments with high numbers of stipulations is warranted. The number of stipulations and the number of times that an application must be returned may be viewed as a surrogate measure of the quality of a submission. Studies of high quality showed significant correlation with improved time to approval. In addition, multicenter projects added significantly to the days of the study team, likely caused by additional approvals required by sponsors, coordinating centers, and contract research organizations. Institutions should be able to replicate the methods of this project to assess weaknesses and areas of improvement within their research portfolio.

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Inconsistencies Among IRB/Ethics Committee (EC) Approvals When Determining the Risk–Benefit Category for Research With Children

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Keywords
research with children, institutional review board (IRB), ethics committees, research ethics, 45 CFR 46 Subpart D

Background

United States 45 CFR 46, Subpart D provides institutional review boards/ethics committees (IRBs/ECs) and investigators with the permissible approval categories for research with children based on potential risks and direct benefits of the study. However, the selection of the approvable category for the same study differs greatly among IRBs/ECs.

Method

We utilized the Division of AIDS Protocol Registration System, which prospectively collects from all its U.S. and international clinical research sites the reviewing IRBs'/EC's letters of approval with the risk–benefit categories for research with children. This system collected ~1,200 IRB/EC approvals documenting the risk category from ~100 pediatric multisite studies from January 2010 through May 2017. Included in this dataset are the 30 studies with the highest number of IRB/EC approvals. These approvals came from commercial and institutional IRBs/ECs in the Americas, Asia, and Africa from 534 IRB/EC meetings. The data were summarized, analyzed, and described. The data were arranged using a brief study descriptor and the tally of the research category designations given by the reviewing local IRB/EC for each study. Each study descriptor includes study phase or design, type of intervention, and population. Note that some of the approvals did not include a category of permissible research with children or were classified only as greater than minimal risk.

Findings

The data indicated that eight studies of the 29 (27.6%) reviewed at 88 of the 517 IRBs/ECs (17.12%) were consistent in their determinations; for example, for one study, all 19 IRBs/ECs designated the study as "§46.405-Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects." However, for the other 22 studies (75.9%), there were inconsistencies among IRB/EC approvals when determining the risk–benefit category. Eleven of 517 IRB/EC approvals (2.0%) included different category designations for studies with more than one risk–benefit ratio, for example, studies with placebo and active study product groups. Inconsistencies were found in research with both complex and simple study-designs. We also found many IRB/EC approvals without a specific designation of a risk–benefit category.

Discussion

Due to the descriptive and retrospective nature of data collection and the analyses, we did not seek statistical significance. The results/conclusions and discussions may reflect a certain level of bias. Also, the selection of the sampling may have its own restrictions. We believe that IRBs/ECs used component analysis in 11 (2.0%) of the IRB/EC approval documents that included different category determinations for studies with more than one risk/benefit ratio for the same study with different treatment groups. However, we do not have the documentation to validate this belief. We believe some of the causes for the inconsistencies are limited IRB/EC training and expertise, lack of clarity and insufficient information in research documents, and unmet local cultural and economic matters. Suggested actions include the following: (a) research teams should provide information about potential risks and direct benefits as per the sponsor's/institution's policies/procedures (e.g., Division of AIDS-Policy-Enrolling Children in Clinical Research: Protocol Document Requirements); (b) clinical sites/local-investigators should add supporting information about locality to Standard Operating Procedures/Guidance for submission to IRBs/ECs of research with children (e.g., how would the research impact the local-population?); and (c) IRBs/ECs should secure the experience and knowledge needed to review research with children as per the U.S. regulations (e.g., IRB/EC coordinators/external consultants should assign reviewers based on background, experience, and knowledge). These preliminary findings could be assessed in the full-set of IRB/EC approvals (~1,200) in a follow-up activity.

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Negotiating Change: A Qualitative Analysis of Meeting Discussions During the Implementation of an Electronic IRB Work Management System

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Keywords
institutional review board (IRB), transition, culture, electronic system, meeting discussion

Background

Implementing an electronic work management system has been demonstrated to reduce institutional review boards' (IRBs) costs and turn-around time. However, little is known about how IRBs adapt to the culture change (including changes in terminology, processes, and group interactions) that is an unavoidable result of changing the way work is done.

Method

This research study used mixed social science methods to observe how two groups of Human Research Protections Program (HRPP) professionals, IRB staff, and reviewers communicated about the implementation of an electronic IRB system and negotiated a new IRB culture around the institution's new electronic system. The researchers observed bimonthly IRB staff meetings (approximately 15 staff members) and weekly IRB meetings (approximately 90 IRB members) between September 2013 and August 2014, which represented the first year after the new electronic IRB system was implemented. They took notes during the meeting of any problems that were brought up regarding system design, implementation, IRB processes, or IRB policies. In addition, the observer selected a word from a list of emotions that they felt best described the overall emotional climate of the meeting. Observations occurred at 20 IRB staff meetings and 44 IRB meetings.

Findings

Overall, 21% of the staff meeting discussions that related to the new electronic system were about technical glitches being experienced, 21% were about the design of the system, 21% were about procedural issues the staff was experiencing, and 19% of the discussions surrounded office policies. The emotional tone of IRB staff meetings was initially enthusiastic and interested. Over the course of the year, staff appeared disinterested and occasionally even angry. During IRB meetings, 32% of the panel's discussions pertaining to the new electronic system involved training about computer literacy and system navigation. Twenty-one percent of the discussions were about individual review procedures; 13% were about how the panel's meeting processes should incorporate the electronic system; 13% related to the design of the system; and 11% were about efficiency and paper review processes. All of the IRB committees raised approximately the same number of issues, but the committees that had structured education initiatives had approximately 5% less group discussion and more positive emotional tones during the meetings.

Discussion

This was an observational study at one institution, so these results are subjective and have limited generalizability. IRB staff meetings were focused on solving problems and ensuring consistent IRB office processes, while IRB members focused on navigation of the system and learning how the system worked. This shows that the needs of IRB staff and members are different, but future research to verify these results is needed. Another conclusion of this study is that committees that engaged in early discussions about shared processes were able to adapt more easily. This proactive leadership and open negotiation of procedures facilitated greater engagement of the committee members, and meetings were evaluated to have more interest and enthusiasm.

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User Attitudes Towards Implementation of a Commercial Electronic Review System at a Naval Medical Center

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Keywords
institutional review board (IRB), change implementation, institutional culture, electronic review, commercial off-the-shelf software

Background

Switching from paper to electronic institutional review board (IRB) submissions can be difficult for any institution. Challenges with training and novel software can result in resistance toward implementation of any electronic system. Following initial roll-out, the IRB office wanted to measure user perception of efforts to relieve frustration for new users. To streamline future training and implementation of electronic review systems, this study utilized a non-validated questionnaire to measure attitudes following initiation of the commercial electronic review system, in a military treatment facility. The questionnaire was distributed to 800 system users and included 17 Likert-type, frequency, binary, and open-ended questions. It measured the effects of culture, technology expertise, and age on acceptance of the system. Certain cultural characteristics have been shown to inhibit feedback (Scott, 2005). The investigator hypothesized that, due a distinctive cultural difference, military members will exhibit less resistance to the commercial electronic review system than civilians, that training issues can significantly affect use of electronic systems (Tonneson, 1999), and that commercial electronic review system training will be easier for those who regularly use various technology platforms. Finally, the investigator hypothesized that millennials should have an easier time using the system than their colleagues. Secondary measures included differences in training preferences and users' opinions regarding helpful support.

Findings

Out of 800 users contacted, 51 surveys were completed, for a response rate of 6.3%. Contractors and civilians made up 57.1%, while military members made up 42.8% of responders. Users were divided into two age groups; <40 (49%) and ≥40 (51%). Three negatively prompted Likert-type questions were aggregated to measure responses across our three variables. An ANOVA compared responses for the Likert-type scale, and a statistical difference was found ($p = .008$), indicating a difference among the groups. A TUKEY post hoc analysis found that military members differed from contractors ($p = .038$) and civilians ($p = .016$). Although respondents were unanimously negative, military members exhibited significantly more resistance to system implementation. The t test demonstrated no difference between social media users and non-users, and no difference was demonstrated between age groups.

Discussion

A low response rate may make conclusions less valid. A larger sample would allow for stronger comparisons between civilian and contractor groups. Likewise, these groups sometimes overlap, making interpretation subjective. Various social media platforms were grouped for analysis due to the low number of responses. A single social media platform with features comparable with the commercial electronic review system would be ideal for further comparison, instead of grouping several different platforms with various features. There was no difference in opinions of the system from users that used various social media. Most users disliked the new system implementation process. They did not find the system intuitive; they also indicated that they would change system design and request additional training. Unexpectedly, military members were less inhibited to report resistance than civilians or contractors and were significantly more frustrated than their counterparts. Overall, military physicians were less likely to use the system on a regular basis, though using the system more frequently led to less frustration. Alternative training initiatives for sporadic users should be explored. Social media use and age were not appropriate measures in a population where baseline technology skills are expected. The commercial electronic review system is no longer used at the studied institution but lessons learned from this survey will be valuable for the implementation of future systems.

Authors' Note

I am an employee of the U.S. Government. This work was prepared as part of my official duties. Title 17 U.S.C. 105 provides that "Copyright protection under this title is not available for any work of the United States Government." Title 17 U.S.C. 101 defines a U.S. Government work as a work prepared by a military service member or employee of the U.S. Government as part of that person's official duties. The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the U.S. Government. Research data

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A Conscientious Consenting Process for Research in Drug-Using Populations

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Keywords

cannabis, cocaine, consent, intelligence quotient (IQ), misconception

Background

Research study purpose misconceptions, known as therapeutic misconceptions, have been extensively examined in individuals seeking treatment for a disease or disorder. However, a more general comprehension of the purpose and procedures of a research study during the consent process has not been examined, particularly in a vulnerable population such as nontreatment seeking individuals, despite the fact that conducting research on novel treatment interventions among nontreatment seekers, particularly illicit drug users, is prevalent.

Method

This secondary data analysis was comprised of 64 current drug-using men (34 cocaine users; 30 cannabis users) who were interested in participating in other (parent) studies examining the effects of potential treatment medications on behaviors related to drug use. These participants completed a "consent form quiz" after reading the study consent form. The quiz allowed investigators to asses a participant's comprehension of the study purpose and procedures. After the research staff scored the short, 12-question quiz, an investigator reviewed the quiz results with participants during a subsequent consent discussion to ameliorate any study misconceptions prior to the participant signing the consent form. Correlations (using the Pearson product–moment correlation coefficient) between a participant's demographic information, including age, years of education, weekly primary drug use, years of primary drug use, self-reported impulsivity, and IQ measures (i.e., the Wechsler Adult Intelligence Scale (WAIS) and Stroop tests), and a number of incorrect answers on the consent form quiz, were examined. The group was then split by primary drug of choice (cocaine vs. cannabis) to explore group differences (using the Student's *t* test) in demographics and consent form quiz responses. Of importance, no participants were consented while acutely intoxicated, as determined by members of the clinical and research team.

Findings

Overall, the number of incorrect answers on the consent form quiz negatively correlated with IQ scores ($p < .05$) and positively correlated with years of primary drug use ($p < .05$). When the groups were split by primary drug of choice, number of incorrect quiz answers were negatively correlated with IQ scores in cocaine users ($p < .05$) but not cannabis users ($p > .05$). We found that cocaine users answered a range of zero to six questions wrong and cannabis users answered a range of zero to two questions wrong on the quiz, with 59% of the cocaine users and 43% of the cannabis users answering at least one question wrong. In addition, cocaine users were older, were less educated, scored lower on the IQ tests, and used their primary drug of choice longer (in years) than cannabis users ($p < .05$ for all), though, surprisingly, they used their primary drug of choice less times per week than the cannabis users ($p < .05$).

Discussion

These findings show that a nontreatment seeking drug-using population may have difficulties with comprehension of the nature of a research study due to a variety of reasons, possibly due to their drug use, particularly in long-term cocaine users. This suggests the importance of determining study misconceptions on an individual basis during the consent process and engaging participants in a consent discussion, prior to study participation, to eliminate misunderstandings and prevent undue influence. Future studies should address the following issues: (a) It would be important to determine if these findings were similar in female and nondrug users. Although females were not excluded from the parent studies, the number of female participants increased the sample size by 50% in the cannabis group (i.e., 31 females), while only increasing the cocaine group by approximately 10% (i.e., five females), thereby leading

to notably unequal sample sizes (61 vs. 39, respectively). To better match groups in terms of sample size, females were excluded from this secondary data analysis. In addition, control groups were not included in either of the parent studies, though the issue of comprehension of the consent process and study design would likely be more of a concern in the potentially more vulnerable nontreatment seeking drug-using population than healthy controls. (b) Personal motivations for study participation (e.g., compensation) may impact initial comprehension of a study's purpose. (c) Literacy, which would be important for consent comprehension, was not formally assessed; however, all participants had at least a high school education, limiting the concern of this potential confound. (4) The results of a second consent form quiz given at the end of the consent discussion should be examined to determine if study misconceptions remained.

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Women's Views About Rules Governing Reproductive Issues in the Context of Biomedical Clinical Trials

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Keywords
clinical trials, research ethics, maternal health, pregnancy

Background

Rules governing reproductive issues in the context of biomedical clinical trials aim to protect fetuses from potential research-related risks. However, they may constrain women's autonomy and perpetuate evidence gaps on preventing and treating non-obstetrical conditions during pregnancy, including HIV. Women's views on these rules are important and underexplored.

Method

Trained interviewers conducted 140 in-depth interviews exploring experiences and perspectives regarding participating in research during pregnancy with pregnant or recently pregnant women living with or at risk for HIV; 70 were conducted at two sites in the Eastern United States and 70 in Malawi. As part of the interviews, we solicited and explored women's opinions about the following rules and regulations commonly employed in biomedical research trials: (a) the requirement of paternal consent for pregnant women's participation, particularly in trials offering the prospect of direct benefit to the fetus, but not the woman (45 CFR 46.204); (b) birth control (BC) requirements for enrollment (including the requirement for two forms of BC) in trials that exclude pregnant women; and (c) discontinuation of a study drug for women who become pregnant while enrolled. Thematic analysis informed the analytic approach. Interviews were transcribed, translated when necessary, coded, and emergent themes identified.

Findings

Responses reflected two contrasting, overarching themes for all three rules/regulations: (a) respecting women's agency, autonomy, and right to benefit from clinical trials; and (b) respecting fathers' interests and protecting fetuses from potential harms. Rule 1: Those opposed indicated that, as "it's the woman's body," enrollment should be her choice, with some noting that fathers who are uninvolved should not have a say. Supporters felt that because it is "his baby too," the father should share responsibility for the decision. Rule 2: Those opposed viewed two forms of BC as unnecessary, and expressed concern about side effects. Supporters believed the rule protects potential fetuses and it is fair if women can choose which BC they use. Rule 3: Those opposed felt that the participant should be involved in the decision to discontinue study drugs. Supporters cited the need to protect the fetus from unknown effects. High

acceptance of Rules 2 and 3 reflected deference to medical experts.

Discussion

Interviews were intended to identify and explore women's opinions on research rules rather than measure prevalence of views. Our sample is not representative of all women at risk for or living with HIV, and results cannot be generalized to the population of women who might be eligible for research participation. We explored perspectives of a key stakeholder group directly affected by the rules and regulations governing reproductive issues in the context of biomedical clinical trials. Through this cross-national sample, women's diverse perspectives juxtaposed the needs and rights of women who are pregnant or may become pregnant, and those of fathers and fetuses. These findings indicate that the current rules and regulations, which are largely focused on fetal protection, do not fully account for the interests or agency of research participants. More equitable approaches that respect women's ability to make informed decisions for themselves and their potential offspring should be considered.

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Analysis of the Present Recognition Toward a Central IRB (cIRB) System in Japanese Medical Schools

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Keywords

central IRB, reliance agreement, local context

Background

The use of a central institutional review board (cIRB) has been advocated in many countries, including Japan. However, this concept is not completely accepted in the broader Japanese research environment due to a lack of apparent incentives. In this study, we aimed to understand the current recognition status of cIRBs in Japanese medical schools.

Method

One hundred seventy-one IRBs established in 80 medical schools were sent anonymous, self-administered questionnaires. All of these medical schools are members of the Liaison Association of Medical Schools' Ethics Committees, a non-profit organization that exchanges information regarding IRB regulations and operations. The questionnaire survey was comprised of two themes: one regarding their experience in accepting requests from external sources to conduct ethics reviews, and the other regarding their experience in outsourcing such reviews. The survey was conducted over a month long period between mid-February and mid-March 2016.

Findings

The questionnaire was sent to 171 IRBs and 84 responded (response rate of 49.1%). The characteristics of the respondents (based on multiple-choice questions) were IRB staff members (71.4%), IRB chairs (17.9%), research support departments (16.7%), and IRB members (6.0%). There were 36 committees (42.9%) that had accepted reviewing research protocols from external institutes, but only one tenth (11.3%) had experience in reviewing multicenter research in which their own institution was not involved. As to what type of research they would agree to review if an external research institute requested relying review, we found approximately a quarter of the committees (22.6%) felt that all types of clinical research, regardless of its details, could be accepted. On the contrary, there were only seven committees that had relied on their ethics reviews (8.3%).

Discussion

This study involved a limited number of IRBs in 80 medical schools, and there may be a sampling bias in which the subject of the surveys could also be the primary research institute. As the result of this survey, we found that approximately half of the committees have accepted to review the clinical

research from external institutes. On the contrary, it became clear that less than a 10th of the committees have relied on ethical reviews from external institutions. The results thus indicate that the number of relying on IRBs were much fewer than reviewing IRBs. The discrepancy between these numbers may suggest the heterozygous quality of IRB committees in Japan.

Declaration of Conflicting Interests

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The Million Veteran Program: Enhancing and Expanding Recruitment for a Representative Cohort

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Keywords

million veteran program, cohort recruitment, veteran recruitment, veteran outreach

Background

This study analyzes data from the Department of Veterans Affairs' Million Veteran Program (MVP), a national research program involving a genomic cohort of over 610,000 Veteran participants. The program strives to ensure representation of the Veteran population by increasing available enrollment options via specific initiatives.

Method

A number of enhanced recruitment strategies are underway to increase Veteran enrollment in MVP. This abstract focuses on enrollment expansion from 58 VA Hospitals, as main facilities, to an additional 75 satellite locations. We compared demographic data of MVP Veteran participants enrolled at main versus satellite locations, and compared our participant population with the overall VA populations at these location types to determine if our cohort is representative of the VA population.

Findings

The proportion of Black/African American participants who enrolled at main facilities (19.4%) was higher than Black/African American participants who enrolled at satellite locations (16.1%); $p < .01$. Analyses showed some uneven distributions, but no significant differences were found between age (main facilities [61.83 years], satellite locations [61.81 years]), education, service era, and top 5 self-reported illnesses (hypertension, high cholesterol, acid reflux/GERD [gastroesophageal reflux disease], tinnitus, and hearing loss) between participants enrolled in main facilities and satellite locations. Comparisons between the VA population and the MVP participant population did not demonstrate many significant differences, suggesting our results are generalizable to the larger VA population.

Discussion

Demographic data are self-reported, but given modest levels of missing or potentially inaccurate information, the validity of our findings should not be affected. Future efforts will incorporate self-reported data along with information from electronic health records. The expansion of recruitment to satellite locations has allowed us to reach a wider segment of Veterans. Comparison of our participant population between location type and the overall VA population yields few significant differences, suggesting our results are generalizable to the larger VA population. This is important as we want to ensure we are recruiting and enrolling an accurate representation of the larger Veteran population. We will continue to create new opportunities to promote participation for all Veterans, including a web-based and phone/mail-based recruitment and enrollment strategy.

Authors' Note

This research is based on data from the Million Veteran Program, Office of Research and Development, Veterans Health Administration. This publication does not represent the views of the Department of Veterans Affairs or the United States Government.

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Broad Consent for Tissue Banking: Views of Actual Donors at 4 U.S. Medical Centers

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Keywords
broad consent, biobanking, biospecimen donor, informed consent, ethical issues, survey

Background

The donation by surgical cancer patients of their extra tissue via a broad consent model for research biobanking is a key tool in advancing medical progress, but concerns persist that cancer patients may not fully understand or be comfortable with the storage of their tissue and data for broad future research.

Method

At four academic cancer centers, we surveyed 302 surgical patients who had recently provided informed consent for biobanking for broad future research use. Nine multidisciplinary investigators, including experts in biobanking, research participant protections, bioethics, psychometrics, and survey methods, designed a new 28-question survey to assess patient views and concerns regarding the donation of their tissues for indefinite storage in human tissue repositories for future research. Surveys were administered by face-to-face or phone interviews and took on average about 30 min. Respondents were compensated with a US$50 merchandise card for time and effort. The study was approved by institutional review boards (IRBs) at each site. Survey questions included the following:

1. Twenty-four rating scaled (0 to 10) questions about views and concerns related to donating tissue for broad future research
2. Four open-ended questions related to tissue donation motives and concerns
3. Sixteen questions about patient background characteristics

Findings

Cancer patient donors of excess biospecimens from surgery for broad future use in research, on average, (a) believe they were given the right amount of information regarding informed consent for tissue donation; (b) believe it is very important for expert committees to approve studies that will use their biospecimens; (c) are highly accepting of using their donated tissues to conduct most types of research, including mental illness and pregnancy research; (d) are only moderately accepting of for-profit researchers and researchers outside the United States accessing their tissue; (e) are highly accepting of use of donated tissues in genetic research on cancer and other diseases; (f) are highly accepting of use their tissues for research that "changes some cells," "grows a cell line," or "involves adult stem cells"; (g) express low concern that breaches of confidentiality of their data might disclose their genetic data outside research teams; and (h) strongly desire researchers to disclose clinically actionable genetic data. Ninety percent expressed altruistic motives for donating their tissues, and less than 10% expressed any concerns about future use of their tissues in research. Results generalize across the four diverse research sites and both genders of cancer patients. Ninety-three percent of patients donated their tissues when asked.

Discussion

Cancer patients who donate their excess biospecimens for future research generally strongly endorse broad uses of their tissues in medical research. Results generalize across four diverse medical centers in this study and in effect replicate findings, but future research should assess larger samples to determine if patients of certain types may express concerns about use of their donated tissues to guide IRB and expert committee decisions.

The data were derived only from patients who consented to donate tissue, and views of patients who decline to donate might be different.

Declaration of Conflicting Interests

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