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Clinical Researcher™

The Authority in Ethical, Responsible Clinical Research

September 2019 (Volume 33, Issue 8)

Breaking New Ground in Recruitment and Management for Trials

Clinical Researcher™

Association of Clinical Research Professionals

Clinical Researcher—September 2019 (Volume 33, Issue 8)

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Clinical Researcher—September 2019 (Volume 33, Issue 8)

EXECUTIVE DIRECTOR'S MESSAGE

The Heat Goes On

Jim Kremidas

Despite some 90+ degree temperatures of late here in ACRP's Alexandria, Va. stomping grounds, the truth is summer's just about over. Now that we've enjoyed the Labor Day break, which marks the traditional end of summer, it's time to roll up our sleeves and get back to work.

Actually, as an organization we have had a pretty busy—and fun—summer. I wanted to share a few quick updates with you. First, we added a great new member to the Workforce Innovation Steering Committee (WISC): The Medical University of South Carolina (MUSC).

The WISC is a collaborative partnership of private and public stakeholders working to improve clinical trial quality and respond to changes impacting the workforce by providing oversight and alignment around the competencies required to meet the needs of the future. The partnership has led several important initiatives in clinical research, including publication of competency guidelines for clinical trial monitors, coordinators, and investigators.

Workforce planning, development, and assessment are imperative to the existence, quality, and efficiency of clinical research. Yet, these factors have been largely overlooked as industry focuses instead on also-important initiatives to improve quality and efficiency through process and technology innovation.

Last month, we made another exciting announcement about a partnership designed in part to help contract research organizations around the world attract and retain key talent. This partnership is with Austria-based VIARES GmbH.

VIARES provides its growing customer base with on-demand, highly qualified clinical research associates and clinical trial assistants through its proprietary VIARES ACADEMY training programs.

Under this new partnership, ACRP's professional support and development programs—including the industry's most recognized and respected certification programs—are now integrated into the VIARES ACADEMY and immediately available worldwide.

Finally, I hope to see you at our first ACRP Southeast Regional Conference, being held at the Sheraton Imperial at Raleigh-Durham Airport in North Carolina in conjunction with the ACRP Research Triangle Park Chapter on October 3–4. Please check out the webpage devoted to this event, which offers 12 contact hours, for details on our exciting lineup of speakers, techXpo session, and networking opportunities, as well as instructions on how to register.

Jim Kremidas (jkremidas@acrpnet.org) is Executive Director for ACRP.

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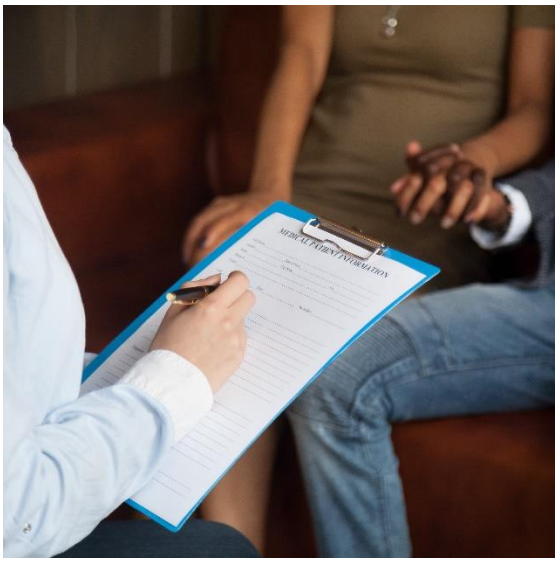
PEER REVIEWED

Perspectives on Successes and Challenges in the Recruitment and Retention of Pregnant Women in a Research Study

Amy Rider, RN; Christine Aubry, RN; Sara Moyer, RN; Patricia Kinser, PhD



Pregnant women have historically been excluded from clinical trial research, given their former "vulnerable population" status and in consideration of potential impacts to the developing fetus. However, the National Institutes of Health (NIH) and the NIH Office of Research on Women's Health have called for more expansive research to address areas of high clinical need and to promote evidence-based clinical practice related to pregnancy.{1}

To promote an inclusive research environment and to enhance the rigor of future studies, it is essential to discuss the multiple challenges that may arise regarding recruitment and retention of pregnant women in clinical trials, and to share perspectives on successes and failures in individual studies.

In this paper, we focus on the importance of consistency, flexibility, and compassion by the research nurse/clinical research coordinator. We present perspectives on challenges and successes regarding recruitment and retention of pregnant women in a longitudinal pilot study designed to evaluate the feasibility, acceptability, and preliminary effects of a self-management intervention for depressive symptoms.{2} We also discuss successes and "lessons learned" within the context of recruitment methods, study design, and retention strategies.

Consistency, Flexibility, and Compassion in Recruitment Methods

To engage in effective recruitment, we found that the process of building trusted relationships{3,4} was at the heart of our study's success. Collaboration with community stakeholders and clinic staff and establishing trusted relationships are steps that take much effort prior to the initiation of the study, but when done well, contribute to success in both recruitment and retention.{3,5}

In our study, we built effective relationships in several ways. First, we capitalized upon contacts within our academic institution (Virginia Commonwealth University), from healthcare providers to registration staff, to provide layers of access as entry points to successful recruitment.{6}

For example, speaking with the local director of CenteringPregnancy® Care (a group prenatal care approach of the Centering Healthcare Institute) led to a meeting with the clinical coordinator of the ambulatory care center; their collegial relationship paved the way for research staff to have access to vacant rooms, print-outs of the daily schedule, and computers. The director also allowed research staff to speak to prenatal care groups as an active recruitment strategy.

As another example, a key contact within the academic institution was the social worker for the high-risk obstetrics clinic, with whom our principal investigator (PI) and head research nurse met at a local café in the community prior to the start of the study. Meeting outside the busy clinic setting meant that the social worker could get to know the study details and staff in an unrushed environment and feel confident about making study referrals.

Second, our study team used both active and passive recruitment methods, with the goal of reducing recruitment bias and facilitating access to a diverse community population.{7} Although passive methods, including flyers, Facebook posts, and e-mails to listservs, were successful for reaching many interested individuals, we found that active recruitment was essential, and the only way to effectively do so was to develop relationships with clinic staff.

For example, active recruitment in busy clinic waiting rooms can be challenging, so orientation to the "ins and outs" of clinic operations was critical. By meeting with clinic nurses at staff meetings, study research nurses gained credibility and learned how to minimize intrusions on

clinic operations; thanks to this credibility, clinic staffers offered use of vacant rooms and computers and referred patients to the study. These informal orientations allowed study research nurses to feel less intrusive while recruiting in the clinic waiting rooms. By cultivating mutual respect between the clinic and research nurses, the two could co-exist working toward equally important missions of the academic institution: research and clinical care.{4,6}

Research suggests that engagement of healthcare providers is a critical component for recruitment. Previous studies have suggested that participants are more likely to sign up for research if it has been recommended by their healthcare provider.{7,8} Similarly, engaging in informal networking with clinicians and having regular presence at key events has been found to be key to the successful recruitment of pregnant women.{9}

In our study, the clinics of midwives, obstetricians, psychologists, and primary care providers were targeted as access points because it was clear to us that it was critical for healthcare providers to have confidence in, and a connection with, the research nurses in order to make referrals. Further, our presence at local clinician conferences, Grand Rounds in the academic health system, and local conferences were important aspects of recruitment.

For example, we secured a booth at a conference of the local Association of Certified Nurse Midwives chapter, during which we were able to communicate with midwives who showed enthusiastic interest and actively referred interested individuals. It was important that we maintained active staffing at this event, rather than simply placing materials at an unstaffed booth; this is consistent with previously mentioned studies{4,9} that found certain techniques to be fruitful (such as attending healthcare provider conferences) and certain techniques to be unfruitful, such as lack of staff presence at events, newspaper advertisements, and recruitment postcards. As another example, the PI talked with the academic health system's chief resident for Obstetrics/Gynecology after Grand Rounds, who acted as a "champion" of the study—providing brochures for fellow obstetricians and who subsequently sent us several participant referrals.{6}

Two additional important recruitment methods were "flyering" and thinking "outside of the box." First, although it is a time-consuming practice, "flyering" involves spreading flyers/ brochures in multiple venues throughout a community, from churches to busy restaurants.{10}

An important aspect of "flyering" is to maintain professionalism while posting flyers: this includes asking permission to post when necessary and following the rules of the bulletin board. In addition, because of our commitment to reaching women of all socioeconomic backgrounds, flyers were delivered to health department resource centers in lower income communities; during this time, study research nurses briefly educated health department staff about the study.

Second, in order to increase recruitment numbers, study research nurses accessed "outside the box" entry points such as car-seat installation sessions at a large retail store, yard-sale events at local low-income housing developments, childbirth education classes and doula sessions at a local library, and "electronic flyering" via social media. Although recruitment was minimally successful at several of these sites, important connections were established with community members in attendance. In addition, fruitful social media sources included individual doulas' Facebook pages, new mom/baby Facebook pages, and university-wide e-mail blasts.

A key lesson learned from the experiences described above is that in-person visits, rather than e-mails or phone calls, to recruitment sites will enhance success in connecting with clinicians about the study. Engaging the "gate-keepers" of offices (typically the receptionist or clinic manager) was essential and is consistent with other research{5}; an effective manner to pique interest is for the research nurse to briefly state how the study goal overlaps with the mission of the practice and that it is run by a reputable academic institution. For future success, we recommend building upon a network of interdisciplinary connections to enable scheduled meetings with office managers and clinicians.

Another lesson learned is that low-income housing developments may be rewarding targets for recruiters of future studies wishing to access a diverse population. Many housing developments have onsite childcare, which may address the common barrier of time and need for childcare.

In our study, we made a successful connection with a social worker at a local low-income housing development who arranged space in the community center for intervention delivery. Unfortunately, the individual was unable to identify pregnant residents. Nonetheless, this setting should be considered as an important option for future studies, given previous researchers' successful experiences with low-income housing community partnerships.{11}

Consistency, Flexibility, and Compassion in Study Design

Striking a balance of consistency, compassion, and flexibility in the study design was important in its implementation.{12} Within a context of respect for the initial pilot study design, our team collaborated with Virginia Commonwealth University's Institutional Review Board (IRB) and our Data and Safety Monitoring Board (DSMB) to implement small changes to the recruitment and retention plan to afford a more compassionate, flexible approach to participants' needs, as supported by previous work.{6}

Creating ease for depressed, pregnant woman study participants became a goal for recruitment and retention. With the creative and flexible thinking of the study PI, we were able to make subtle changes that not only increased recruitment numbers, but also met the needs of the women.{12}

One example of a change to the study design intended to enhance flexibility for participants involved obtaining IRB and DSMB approval to allow participants a choice of in-person or phone-based baseline study visit. This was in response to our realization of the added burdens of potential participants' anxiety/anhedonia and their concerns with parking, directions, and childcare. For anyone who preferred an in-person visit but who lacked childcare at the last minute, study research nurses demonstrated flexibility by allowing the participant to bring her child to that visit.

A second IRB-approved change in study design addressed a need for active recruitment techniques. By seeking a waiver of consent through the IRB, we were able to conduct a basic medical record review prior to approaching potential participants in clinic waiting rooms. With this active recruitment approach, no information was documented about the individual prior to enrollment in the study, but the processes for potential participants who were already deemed potentially eligible were streamlined. Similarly, this prevented any potentially distressing situations for women in the waiting room who were experiencing a fetal loss or other major pregnancy complications.{13}

Consistency, Flexibility, and Compassion in Retention

As a key aspect of the research endeavor, retention of participants required careful planning with efforts to maintain consistency, flexibility, and compassion. Clearly, establishing trust between the research team and participants is important.{3,5,9} Compassionate communication between study staff and participants was essential to keeping study participants engaged and encouraged during the 12-week intervention.

Consistent with other research studies, personalized and non-judgmental communication led to participants stating that they felt cared for and motivated to complete the intervention.{6,11,14} In our study, we conceptualized this in several ways; for example, the first study visit involved a brief, motivational interviewing session during which the research nurse left time for participants to talk about their depressive symptoms. A simple statement to participants (e.g., "I am so sorry that you have been dealing with this") led some to report that no one had ever acknowledged the difficulties of their symptoms and others stated they felt the study environment was a safe space. Similarly, study research nurses checked in frequently with participants (weekly by phone or e-mail) for data collection and to monitor for adverse events, and weekly in-person at the intervention site.

Another aspect of successful retention was the wise and non-judging personality of the intervention instructor. Participant after participant reported through qualitative interviews that much of the success of the study was due to the compassionate personal qualities of this research team member.

A final aspect of retention involved the use of gift cards as IRB-approved compensation to participants at each data collection study visit ($25 per study visit). This financial compensation proved to be important to many participants.

Lessons were learned regarding retention of participants with communication and transportation limitations:

- First, one difficulty during the study was keeping in touch with several participants, all of whom who had a lower socioeconomic status. They encountered problems having enough minutes on their mobile phones and/or lack of reliable wireless access to text or talk and/or with frequent changes to phone numbers. Creativity proved to be key in order to keep these individuals in the study; for example, a particularly complex participant had a social worker who was affiliated with the academic healthcare system. With permission of this participant, the research nurse and social worker coordinated communication and study visit information. As another example, a Google voice account was used to send/receive text messages to and from eligible participants.
- Second, transportation was a common concern for several participants. In response, our research nurse developed a working relationship with the director of a perinatal health community agency; through this collaboration, the agency organized a van to transport interested women to the study visits.

Discussion: Thoughts for Future Studies

In reviewing the literature and following up on our "lessons learned," we propose that future studies could benefit from the following strategies:

- Map the research team's network of academic, public, and private organizations with overlapping goals related to perinatal health early in the project timeline; recognize that the most fruitful partners for recruitment are those with whom the research team has a previously established connection.
- Identify influential individuals within the healthcare community who may serve as "champions" for the study, demonstrating their strong belief in the study goals when communicating with patients and colleagues.
- Chart out a plan for a mix of active (e.g., screening and recruitment in waiting rooms) vs. passive (e.g., flyering, social media) recruitment to help enhance diversity of participants and ensure expeditious recruitment.
- Demonstrate early flexibility in research design to minimize burden to participants, while communicating with appropriate ethical/regulatory bodies.

- Consider methods to meet the needs of individuals for whom issues with technology, childcare, and transportation might limit their ability to participate.
- Convey professionalism and give an empathetic, respectful, and knowledgeable voice to the study when advertising its availability.
- Finally, and most importantly, demonstrate consistency, flexibility, and compassion in all decisions and communications regarding study recruitment and retention processes.

Conclusion

Locating productive recruitment entry points, fostering relationships, and allowing for flexibility in a study's design can help bridge the gap when recruitment is a challenge. Through thoughtful relationships with key academic and community providers, effective recruitment can be achieved.

Understanding the nuances of the clinical setting will help research nurses gain trust from clinic staff and secure access to eligible individuals. Flexibility around study design can prevent additional burdens to the pregnant participant.

At the heart of successful recruitment and retention of pregnant women is consistent and compassionate attention from study research nurses.

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PEER REVIEWED

Established Safety Profiles Allow for a Gene Therapy Boom and Streamlining of Regulatory Oversight

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Once thought of as being pursued only in the realm of science fiction or under highly experimental conditions, the science of gene therapy is now considered to be well understood, and the field is thriving.

Gene therapy research involves delivering engineered genetic material to humans with the goal of compensating for genetic mutations, conferring the capability to produce potentially therapeutic substances, or eliciting immune responses to fight disease.

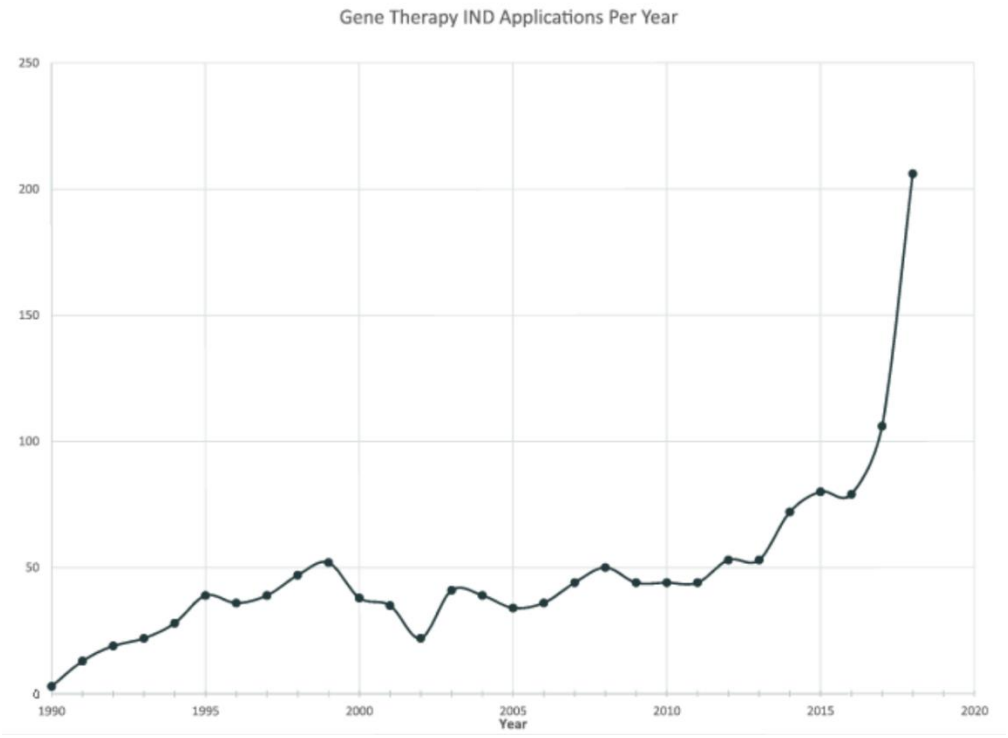
As of the writing of this article, to date, more than 2,900 gene therapy studies have been initiated worldwide.{1} Searching ClinicalTrials.gov for the keywords “gene therapy” results in more than 3,800 studies, with more than 1,000 of them currently recruiting or enrolling research subjects.{2}

The gene therapy field overcame several hurdles to reach its current state. High-profile serious adverse events have been reported over the years, including the tragic death of Jesse Gelsinger in 1999 and leukemia in children with life-threatening immune deficiencies (i.e., severe combined immune deficiency [SCID] and chronic granulomatous disease [CGD]).{3–6} These incidents

occurred at the turn of the century and led to a decade of intensive study, redesign and safety testing of gene therapy technology.{7–10}

During this period, the U.S. Food and Drug Administration (FDA) issued various guidance documents regarding the manufacture of gene therapy products, design of clinical trials, and long-term follow up for certain types of investigational products for gene therapy.{11} As the field focused on reassessing safety, the number of investigational new drug applications (INDs) received by FDA for gene therapy products has grown exponentially from 1995 to 2010 (see Figure 1).{12}

Figure 1: Gene Therapy IND Applications Submitted Per Year



Data adapted with permission from Peter Marks, Director, FDA Center for Biologics Evaluation and Research (CBER).{12}

Since 2011, the field has regained confidence in the safety of gene therapy technology, and the number of gene therapy product INDs received by FDA has been steadily climbing; 2018 marked an all-time high number of IND applications (206), almost doubling the previous all-time high achieved in 2017 (106).

The surge in research has also led to approvals (see Table 1). FDA issued its first approval of a product containing engineered genetic material (i.e., recombinant DNA) in 2015 and has since issued six more approvals, with the most recent dated May 24, 2019. With 291 gene therapy studies currently in Phase III, several more gene therapy products will likely be considered for approval in the coming years.

Table 1: FDA Approvals of Gene Therapy Products

Product Name	**Manufacturer**	**Indication**	**Engineered Genetic Material**	**FDA Approval Date**
IMLYGIC	Amgen	Melanoma	Herpes simplex virus 1 based oncolytic therapy	October 2015
VAXCHORA	PaxVax	Cholera vaccine (serogroup O1)	Live, attenuated, orally administered *V. cholerae* bacteria, cholera toxin A gene (ctxA) deleted	June 2016
KYMRIAH	Novartis	B Cell Acute Lymphoblastic Leukemia	Chimeric Antigen Receptor (CAR) T Cells, engineered with a retrovirus vector	August 2017
YESCARTA	Kite (Gilead)	Non Hodgkins Lymphoma	Chimeric Antigen Receptor (CAR) T Cells, engineered with a retrovirus vector	October 2017

LUXTURNA	Spark Therapeutics	Retinitis Pigmentosa	Adeno associated virus (AAV) vector delivering the RPE65 gene	December 2017
DENGVAXIA	Sanofi Pasteur	Dengue serotypes 1-4	Tetravalent dengue vaccine based on the Yellow fever 17D204 vaccine strain	May 2019
ZOLGENSMA	Novartis	Spinal muscular atrophy	Adeno associated virus (AAV) vector delivering the *SMN1* gene	May 2019

With the increasing number of late-phase gene therapy studies and continued growth of the field, it's important for clinical research professionals to familiarize themselves with the prospects, risks, and regulatory requirements for conducting gene therapy research.

Areas of Gene Therapy Research

Approximately two-thirds of gene therapy studies are in the field of oncology.{1} With the aging Baby Boomer demographic, demand for advancements in oncology and availability of research subjects for clinical trials are likely to increase.

Common areas of oncology gene therapy research include cancer vaccines, engineered immune cells targeting cancer, and oncolytics (the use of viruses that selectively reproduce in and kill cancer cells while sparing normal, healthy cells). High-profile immunotherapies, such as chimeric antigen receptor (CAR) T cells, utilize genetic engineering to reprogram white blood cells (i.e., T cells) to specifically target cancer cells. CAR T cells have been especially successful in treating B cell malignancies in cases of resistant or refractory disease.

The second most common area of gene therapy research (11.5% of reported studies) applies to monogenic diseases.{1} While diseases caused by single gene mutations are rare, they represent low-hanging fruit from a technical perspective, as current technology offers a wealth of techniques for correcting single gene mutations. Examples of such diseases are listed in Table 2.

Table 2: Examples of Monogenic Diseases

Disease	Description
Retinitis pigmentosa	An inherited form of night blindness in children that progresses to complete blindness by adolescence.
Severe Combined Immune Deficiency (SCID)	Famously characterized by the movie *The Boy in The Bubble,* is a disease preventing bone marrow stem cells from developing into white blood cells leaving the host immune compromised.
Chronic Granulomatous Disease (CGD)	Causes impaired antimicrobial activity in phagocytic cells leading to immune deficiency and granuloma formation at sites of infection.
Cystic fibrosis (CF)	A progressive disease leading to persistent lung infections, limiting ability to breathe as well as causing digestive problems.
Hemophilia A and Hemophilia B	A bleeding disorder caused by a lack of blood clotting factor VIII and IX, respectively.
Severe sickle cell disease	Red blood cells contort into a sickle shape and die prematurely causing anemia and blockage of vasculature.

The third most common type of research (6.3% of reported studies) occurs in the field of infectious diseases.{1} Genetic engineering allows new avenues for development and manufacture of vaccines. FDA has already approved vaccines containing engineered genetic material to protect against cholera and dengue virus infections. Genetically engineered Ebola vaccines are undergoing evaluation in the current outbreak in the Democratic Republic of the Congo, with promising early results.{13–14}

Managing Risks Associated with Genetic Engineering and Gene Therapy Research

Most clinical researchers are familiar with the regulatory requirements pertaining to the FDA phases of research, as well as with institutional review board (IRB) review. Gene therapy studies may require additional review to assess the risks associated with the engineered genetic material, especially as the technology frequently utilizes genetically engineered viruses to deliver genetic information into target cells. Viral infection involves the transfer of the virus' genetic material to host cells, making viruses ideal tools for gene transfer—once the viral genes responsible for viral replication and disease are removed. While genetically modified viruses have a greater safety profile than the naturally occurring unmodified variety, they remain infectious and capable of posing risks.

National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) provide the standard for oversight of research involving genetic engineering and gene therapy.{15} NIH Guidelines are promulgated by the NIH Office of Science Policy (OSP) and call for local oversight at the research site by institutional biosafety committees (IBCs) that report to the NIH OSP. IBCs are charged with protecting study personnel, the community, and the environment from exposure to engineered genetic material. An IBC may also advise the IRB to aid in assessing risks to the study subjects.

The requirement for IBC review applies to gene therapy research at sites that are receiving funding from the NIH or that have ever participated in NIH-funded research. Sponsors or sites that have received any NIH funding are obligated to comply with IBC review regardless of whether the funding is associated with the gene therapy study. Studies and sites completely independent of NIH funding may still require IBC review if the research and development that led to the investigational product was funded by NIH. Even if there are truly zero NIH funds involved, IBC review is considered a best practice: NIH Guidelines state that "individuals, corporations, and institutions not otherwise covered by the NIH Guidelines are encouraged to adhere to the standards and procedures set forth" in the Guidelines (Section IV-D-1).

IBCs are composed of at least five members, including at least two unaffiliated community members, who collectively possess the expertise to assess the risks associated with proposed

research projects. IBC review involves assessing the risks associated with the genetically modified investigational product, as well as the adequacy of a facility's safety practices and training intended for use of the investigational product at the site.

The IBC ensures the site has adequate incident reporting and response plans in place to address potential occupational exposures, spills, or environmental releases of the investigational product. The IBC may review informed consents and other research subject training materials to mitigate possible risks to casual or close contacts in the community. Reviewing the site's plans for disposal of the investigational product and associated biomedical waste allows the IBC to ensure environmental protection.

Because they are charged with protecting the local community and environment, IBCs are locally based at the research site and can only oversee research at that location. For the sake of efficiency, however, local IBC meetings can be centrally coordinated and synchronized, with each IBC remaining responsible for local review.

Pharmaceutical companies and contract research organizations conducting multisite clinical trials may benefit from efficiencies provided by centrally administered IBC reviews, utilizing a model similar to central IRB reviews. NIH refers to such review bodies as externally administered IBCs and allows sites to utilize them as long as the IBCs are registered with the NIH OSP as representing the individual sites at the time the review is performed. NIH allows sites to register multiple IBCs, so an academic institution with an existing IBC focused on preclinical research in the laboratory setting may choose to utilize an externally administered IBC for review of clinical trials and industry-sponsored research.

At a single meeting, the centrally administered IBCs can conduct reviews for multiple sites participating in a single study, as long as the required local representatives are present at the meeting and separate minutes are recorded for each site. This approach streamlines the process for submission and review, providing a single point of contact for submissions as well as harmonized forms, policies, and procedures across sites.

IBCs run by institutions may have set monthly or quarterly meeting schedules, and can insert IBC review as a "blocking review" (i.e., the institution's IRB will not accept a protocol for

review until the IBC has issued its approval). Centralized IBCs, in contrast, often convene "on demand," which eliminates the practices of submission deadlines and standing meeting schedules, and results in turnaround times measured in days instead of weeks or months. For example, in 2019 the central IBC service provided by Advarra, a commercial research compliance organization, has averaged turnaround times of 7.1 business days (N = 40 studies) from submission to review for National Cancer Institute–designated cancer centers. These centers previously experienced turnaround times of up to three to four months when working with their locally administered IBCs.

Evolving Federal Oversight for Genetic Engineering and Gene Therapy Research

NIH Guidelines have relied on advisory committees to review emerging research and advise the NIH Director regarding policy matters.{16} The role of this advisory committee has evolved over time.

In the 1980s, the ability to transfer engineered genetic material into humans was completely new to the clinical setting. Review of gene therapy studies was included in the responsibilities of the NIH Recombinant DNA Advisory Committee (RAC), which created the first set of requirements for review of gene therapy research in 1985.

Over time, FDA became increasingly involved with review of gene therapy studies and, in 1991, issued its own guidance document regarding review of gene therapy studies. By 1995, FDA and NIH agreed FDA would assume primary responsibility for review of gene therapy studies, with NIH and FDA jointly determining which studies required RAC review. The NIH Guidelines were revised in 2016 to require the IRB and IBC at the initial site conducting a gene therapy study to determine whether to recommend RAC review. This recommendation was based on the novelty of the science and whether the risks or possible toxicities were difficult to ascertain.

The latest version of the NIH Guidelines (issued on April 25, 2019) removes the requirements for IRB and IBC RAC determination, as well as protocol registration and reporting requirements to the NIH OSP. These requirements were deemed to be duplicative with the level of oversight currently provided by FDA as well as the IRB and IBC. As the RAC no longer reviews

individual clinical trials, the role of the RAC was revised to focus on the "scientific, safety, and ethical issues associated with new and emerging biotechnologies."{17}

To further emphasize this more general role, the RAC has been renamed the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC). The committee's amended charter charges it with advising the NIH Director "on matters related to the conduct and oversight of research involving emerging technologies in biomedical science…."{18}

As the committee no longer reviews large volumes of gene therapy studies, the NExTRAC can now focus on emerging biotechnology requiring the focus of a national panel of experts. Many issues are likely on the horizon for the NExTRAC, such as emerging developments in gene editing technology like CRISPR and zinc finger nucleases, especially as they pertain to clinical research. Other likely matters of future discussion include applying gene editing technology to human reproduction and environmental issues, such as gene drives and environmental release of modified mosquitos incapable of transmitting diseases.

FDA and the Future Oversight of Gene Therapy

As the lead regulatory agency for review of gene therapy studies, FDA has taken a number of steps in recent years to assist in bringing gene therapy from the realm of scientific theory and research to the world of approved and licensed therapeutics for clinical use:

- FDA has issued guidance documents for the manufacture of gene therapy products, design of clinical trials, and long term follow up (see Figure 2).{11}
- The 21st Century Cures Act authorized FDA to create the Regenerative Medicine and Advanced Therapies (RMAT) designation to allow for expedited review of regenerative medicines and advanced therapies. The associated guidance issued by FDA stated the RMAT designation also applies to "…gene therapies, including genetically modified cells, that lead to a durable modification of cells or tissues."{19}
- FDA is expanding its capabilities to review gene therapy studies in order to accommodate the growing field. In a June 2018 interview, then-FDA Commissioner Scott Gottlieb disclosed that he expects the agency to have

approved 40 gene therapies by 2022, a gargantuan number considering only four approvals had been issued at the time.{20} In a statement{21} issued in January 2019, Gottlieb and Center for Biologics Evaluation and Research Director Peter Marks mentioned plans for:

- Hiring 50 additional clinical reviewers for cell and gene therapy
- 200 IND applications for gene therapy products submitted per year by 2020
- 10 to 20 gene therapy approvals per year by 2025

Figure 2: FDA-Issued Gene Therapy Guidance Documents

- Human Gene Therapy for Rare Disease
- Long Term Follow-Up After Administration of Human Gene Therapy Products
- *Disease-specific guidance:*
  - Human Gene Therapy for Retinal Disorders
  - Human Gene Therapy for Hemophilia
- Chemistry Manufacture and Control Information for Human Gene Therapy INDs
- Testing of Retroviral Vector-Based Gene Therapy Products and Patient Follow-up
- Expedited Programs for Regenerative Medicine Therapies for Serious Conditions
- Evaluation of Devices Used with Regenerative Medicine Advanced Therapies

In their joint statement, Gottlieb and Marks write that the growth in gene therapy "…reflects a turning point in the development of these technologies and their application to human health…. It's similar to the period marking an acceleration in the development of antibody drugs in the late 1990s, and the mainstreaming of monoclonal antibodies as the backbone of modern treatment regimens."{21}

Concluding Remarks

Once considered highly experimental and limited to early-phase studies at highly specialized research sites, the field of gene therapy has progressed to mainstream clinical research. With the

current research boom and progression into large multi-site clinical trials, clinical researchers are increasingly likely to be involved in gene therapy studies throughout their careers.

Clinical researchers should be aware of the maturation of this field and consider the opportunities it may provide to their careers and their patients. Understanding the history and fundamental technical principles of this science will allow clinical researchers to understand the capabilities and limitations of this exciting and innovative field. It is also important for clinical researchers to be familiar with the prospects, risks, and regulatory requirements to be able to safely conduct gene therapy research.

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DATA-TECH CONNECT

It's Time for a Change...Again

Paula Smailes, DNP, RN, MSN, CCRP, CCRC

We all see it. Technology moves fast, at what seems like lightning speed.

I bought my daughter a Chromebook last July for school and the salesperson said it would likely be good for a year, two years maximum. Suddenly, the expense of this item doesn't seem like a good investment, despite the educational value. Recently, my old, faithful work laptop died. My new laptop has all the latest features that the old one didn't, and I haven't a clue how to work most of them or the time to learn.

Whether it's a necessity or not, the urge for having the latest technology is a driving motivator for consumers in the 21st century. So much so that the current 2019 predictions for consumer spending on technology is estimated to reach $1.32 trillion.{1}

Technology Upgrade

Technology turnover to the latest system version is big business. This may not occur because new features are appealing; it may be needed to help information systems perform both optimally and efficiently. System updates may be inclusive of new software that protects the system from hackers, malware, and viruses.

From a business perspective, organizational leaders must also consider the likely effects of new technology on the financial bottom line. Within those considerations, one may include a risk/benefit analysis of upgrading vs. not doing so, along with what the potential return on investment may be of that action.

Unintended Results

Waste

As technology is turning over, so are the piles of waste growing. It has been noted that the rise in electronic consumption has two significant adverse ecological impacts:

1. It creates a substantial increase in mining and procurement of materials needed for production and gadgets.
2. Discarded devices produce large quantities of electronic waste.{2}

This issue has become of such importance that the U.S. Environmental Protection Agency supports the government's National Strategy for Electronics Stewardship in an effort to manage electronics throughout the lifecycle of these products.{3} Ten years ago, it was estimated that 438 million electronic products were sold in the United States, and 2.4 million tons were ready for end-of-life management.{4} These numbers have rapidly increased each year due to consumer demand.

Change Fatigue

Beyond the material impact, there can be a psychological impact from constant change, especially in terms of technology. Change fatigue is a phenomenon that impacts each person differently, with past and current experiences contributing to its severity. It manifests in a variety of ways, such as low energy or lack of enthusiasm for change. Employees may feel unfocused or overwhelmed, and they may lose motivation due to a lack of buy-in or readiness for a pending innovation. As employees become disengaged, the impact on business operations can be an unintended consequence.

Researcher Impact

As someone who is responsible for ensuring that clinical researchers know how to use an electronic medical record (EMR), I can attest that keeping them updated on system changes is not an easy task. Whenever we change the system, I can guarantee we will change it yet again in the near future. This commonly happens just as end-users are settling into their new workflows with the system. Therefore, don't get comfortable!

At our organization thus far in 2019, the EMR system alone has had three major changes in six months that have impacted clinical researchers. When I teach classes, I tell those in attendance that when I teach the class again in a few months, the section on EMRs will be different.

Obviously, technology change for clinical research is not limited to EMRs. Clinical trials management systems, electronic case report forms, medical equipment, and much more all inevitably change. Whatever the system, the goal in our industry is succeeding in times of change.

Strategies for Success

The old saying goes, "Those who fail to plan, plan to fail." Since change is inevitable with technology, it's even more important to have adaptive strategies for success that do not impede the workforce when change happens. Here are a few considerations:

- **Downtime**: Change may occur and users won't have access to the new system right away. Is there a back-up plan in place? How will staff continue their work?
- **Training**: When technology change occurs, what is the training plan to make users successful?
- **Communication**: Give plenty of advanced notice to make sure people have time to mentally adjust to the idea of change. Additional communication is necessary on what the change will be and when it will come.
- **Time:** While you may feel like you don't have time to learn about the changes, it's important to educate yourself on what they are and how to operate new software or hardware.

- **Ripple Effect:** Some specific staff members are expected to be impacted by change, but who else will be affected? Have a customer service approach allowing that delays may occur as system transitions are made, and consider what service recovery can be done in cases of serious delays.

From an organizational leadership perspective, consider how much change is too much. Frequent change without time to adjust can lead to stress, anxiety, turnover, burnout, and other negative outcomes. Be mindful of when staff may be reaching their saturation point. Consideration for reducing the discomfort of change includes the frequency and nature of change, along with the level of supportive leadership provided to employees.{5}

Employees should also be empowered to speak up when it all becomes too much. As technology change becomes a way of life, we need to proactively consider the necessity and impact of this inevitable process.

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RECRUITMENT & RETENTION

Ponderings and Perspectives on Recruiting College Students as Research Subjects

Gary W. Cramer

During Phase I studies, a drug is tested for the first time in small numbers (20 to 100) of healthy volunteers—often college students. – Clinical Trials Transformation Initiative's "Learn More About Clinical Trials" webpage

The stereotypical scenario of the cash-strapped college student who is reduced to selling his or her plasma to make a quick buck has perhaps hung on in good economic times and bad because just enough people see it happening for real to fuel the notion that it's happening all the time, everywhere. Slightly less pervasive, but carrying with it the same whiff of a practice that is somehow potentially unseemly, is the scenario of those same poor students enrolling in clinical trials to earn their financial infusions.

If the need (or simply the desire) to earn money is the principal goal of trial participation, does this somehow classify the volunteer as vulnerable? Perhaps not in the same manner that research ethicists usually think of certain other categories of subjects—pregnant women, prisoners, children, the developmentally disabled, etc.—being vulnerable to coercion, but perhaps so if the economically distressed volunteer is a student and the researcher has some real or perceived authority over him or her at the institution hosting the study.

When this issue was raised in the ACRP Online Community earlier this year, some of the comments it generated indicated the respondent's surprise at the idea that students could ever be considered vulnerable. Others, however, pointed to policies in place at their institutions to address the concern and avoid the appearance of coercion.

A Sampling of Student-Focused Recruitment Policies

Although it is not limited to the realm of clinical trials at Johns Hopkins University (JHU), the institution's "Policy Concerning the Recruitment and Enrollment of Students in Research Involving Human Subjects" from 2005 notes the following:

There has been increasing concern in recent years in the academic community about protecting the rights and welfare of potential human subjects, particularly those who may not be well positioned to protect their own interests. …There have been…concerns expressed about students participating in research conducted at the institution in which they are enrolled.

The primary concern with respect to students is the possibility that, under certain circumstances, they may not feel free to refuse to participate…in research that is under the direction of people who have some control over their academic success and academic future. An additional issue is posed by the granting of extra credit or academic credit for participation in research projects.

Later in the policy, the topic of compensation comes up in this manner:

The use of monetary incentives for soliciting JHU student participation in research is permissible but must be guided by the same considerations and constraints as those applicable to all human subjects.

The use of extra credit as an incentive for JHU student research participation is acceptable if such participation offers educational benefits to the students in question, and the students are offered non-research alternatives by which they may earn an equivalent amount of extra credit.

Edward Fuchs, PA-C, MBA, associate director of the Drug Development Unit at Johns Hopkins School of Medicine, says, "My group does Phase I healthy volunteer studies at Johns Hopkins. For recruitment of college students who do not attend JHU, we have no particular restrictions on

recruiting…and they receive the same remuneration as any other healthy volunteer. We do not actively recruit on college campuses."

Policies at other universities also focus on the practice of recruiting students into studies, though not all the examples below refer directly to clinical research as opposed to surveys, observational studies, psychological assessments, or other research designs:

- At the University of Pittsburgh, a policies and procedures resource from the Human Research Protection Office states that "[r]ecruitment of students as research participants must be designed to minimize the possibility of undue influence. In general, potential participants should be solicited from a 'broad base' of individuals meeting the conditions for study, rather than by personal solicitation of specific students. …For research studies in which medical students are being recruited as subjects, including surveys of medical students, the *School of Medicine's Research on Medical Students (ROMS) Review Committee* must review the proposed research plan **before** it can be submitted to the University of Pittsburgh Institutional Review Board (IRB)."
- Syracuse University's Office of Research Integrity and Protections, meanwhile, notes on its "Students as Research Participants" webpage that "[r]esearch with one's own students presents unique considerations with regard to human subjects protections. At the center of the issue is the inherent power difference between student and instructor. Regardless how well a faculty member presents the recruitment and option not to participate, students may feel as though they have to participate or risk having their non-participation impact their grade or relationship with the professor. In addition, the idea of ongoing voluntary participation is a potential issue if a student decides they want to discontinue their participation after initially consenting. Real coercion is rare is research, but the perception of coercion can be just a problematic in obtaining voluntary informed consent."
- The University of Waterloo, on its webpage for "Conducting Research in Classes or With Students as Participants," explains that "[t]he Office of Research Ethics and the two Research Ethics Committees at the University…recognize that participating in research can have educational value for students by exposing them to the methods used in their discipline or engaging them in the analysis of their own data." In cases of researchers

> recruiting their own students, "a third party, who is not connected with the research, nor has any power or authority over the students, must be part of the consent process. …As the instructor and researcher you must wait until the end of the professor-student relationship before accessing the consent forms collected by the third party…[to] mitigate any real, or perceived, influence that you may have toward the student's grades. Identifiable data must be analyzed only after grades have been submitted to the Registrar's Office so that any real, or perceived, influence on the student's grades no longer exists."

Experts Eye the Ethical and Pragmatic Concerns

Various researchers have weighed in on the ethics and logistics of recruiting students into trials through peer-reviewed articles. For example, in a 2007 issue of *The Journal of Chiropractic Education,* Goldenberg, et al. note how "[c]ollege research departments have often recruited students at their schools to participate in research trials. Commonly, students are perfect candidates for these trials because many are young and asymptomatic." However, "[d]isputes have arisen about the appropriateness of financial incentives for study recruits. Most commonly noted is that financial reimbursement could be coercive or serve as an unnecessary stimulus to encourage participation. Conversely, there are those who report that there is justification for reimbursing participants for time and expenses." The overall article describes methods of recruitment of students for one study at Palmer Center for Chiropractic Research, and includes comments from two other schools about how those institutions recruit volunteers.

A 2004 article by Ferguson, et al. in the *International Journal of Qualitative Methods* concludes that "failure to address ethical issues in research projects can result in the impairment of the [faculty-student] trust relationship in both the research relationship and the preexisting fiduciary relationship. Because research involving these vulnerable and dependent participants is essential for the development of disciplinary knowledge, researchers must address issues threatening the trust relationship. In all instances, these dependent participants must be protected by ethically and methodologically sound research. As such, faculty researchers using student participants must attain high standards of ethical actions in their studies. Student participants would expect nothing less of faculty researchers."

The Online Community Has its Say

Respondents in a thread on the ACRP Online Community devoted to considerations about college students as trial subjects touched on some of the same factors as the policies cited above.

"We have done a research where we reached out to healthy volunteers and, being a university, we did have a large response from the student body," wrote Laurie Pearsall, LPN, CCRC, a research coordinator at University of South Florida. "Under our guidelines, students were not to be in any of our [principal investigator's] lectures or classes. …[W]e did have a few that were only interested in the money and not the science behind the work and were unwilling to invest the time. …[W]e did have some compliance issues [in terms of students] not taking the drug, not refraining from alcohol, and not following through with washout once the study was completed for Part 1. Even with continued education at every visit concerning the importance of compliance—especially to wash out the drug—the students had the mentality of nothing will happen to them, as most young people have."

Another concern raised by Janine Bennett, ACRP-CP, a regulatory associate with the University of North Carolina's Lineberger Comprehensive Cancer Center, is that "[f]or research conducted by a peer, [a student] may want to participate to try and benefit the peer if they have a positive relationship, or they may want to participate as a means of sabotaging a peer with whom they have a poor relationship."

In a private response to this author, an ACRP-certified study coordinator with a university-based medical center in Ohio indicated that her institution has "been doing healthy human subject research" in simulation-based medical education. "Our research participants are residents, medical students, nursing students, and [students from] other disciplines…. We have recruited volunteers from the [main campus's] undergraduate population…as well. We follow the guidance from our IRB. They do consider these individuals to be vulnerable…."

Finally, in another piece of private feedback resulting from the Online Community thread, an ACRP-certified research coordinator for a nonprofit healthcare system in Virginia noted she has used college students as participants in her site's industry-sponsored, multisite trials. "There's no 'relationship' to give us any ethical concerns about vulnerability," she wrote. "A plus [is that]

they tend to be more tech-savvy than the elderly participants, making some processes easier to teach…. [On the other hand] if they're from out of town, I don't have good access to their other medical records, and they might be unavailable for summer visits."

Further Reading

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SCIENCE & SOCIETY

#WhyWeDoResearch: An Opportunity for Professional Input

Al O. Pacino

In an effort to maximize their voices, clinical research practitioners are taking to social media to create spaces where they can collaborate on ways to positively impact clinical research.

Many of us understand the importance healthcare and clinical research has for the well-being of communities across the globe. What industry officials sometimes overlook is the significance of professional community within the workplace.

While many decisions are made in boardrooms and at thriving industry conferences, nurses and first responders are finding their seat at the table on social media. Several patient recruitment companies have turned to social media as their central medium for doing business. Twitter, LinkedIn, and Facebook have been platforms for clinical research professionals to streamline problem discussions, solutions, and accomplishments in clinical research using #WhyWeDoResearch.

Overall, as hinted at by the examples below, use of the hashtag has been an efficient method to contribute and track meaningful insight from hundreds of nurses and first responders.

"Really positive patient story @bhamcommunity board today showing the benefits of research & explaining treatment to people more clearly. Great example of how professional (Jonathan) and patient (Perry) have to understand each other & work together to get outcomes #WhyWeDoResearch" – @cleary_susan

"Don't forget, our Research Forum is taking place in September! Our theme this year is the power of digital. If you'd like to attend, find out more information and sign-up here: (link: http://bit.ly/crnem2019researchforum) bit.ly/crnem2019resea… #IAmResearch #WhyWeDoResearch #NHS" – @NIHRCRNMidEastMids

"#Whywedoresearch TWEETCHAT ALERT!!!!! Join @JoannLeeding & I on Wed 21st Aug 8pm BST We'll be talking all things 'principles' around staff, patient & public engagement & would really value your thoughts & opinions #bepartofresearch #proudofthepaget #research #principles" – @ClaireW_UK

"Our research helped write guidelines on how to treat people with acute #bowel #bleeding in the #NHS. Just one of the reasons #WhyWeDoResearch! This blog from @stemlyns discusses the guidelines: http://www.stemlynsblog.org/jc-lower-gi-bleeding-guidance-st-emlyns/" – @BDRF1

Tag, You're It!

The trending hashtag #WhyWeDoResearch offers a lot of value to those interested in the clinical research space. Twitter users who follow the hashtag can tune into clinical research professionals hosting their own online forums, share abstract submission opportunities, communicate in different media outlets (like podcasts) that uplift patient and nurse stories, and share breakthroughs within their own work in research. The consolidated thread of dialogue facilitates teamwork, brainstorming, and connections between patients and beneficial resources.

Building Professional Communities of the Future

We've all become aware of the rapidly changing environment of healthcare and clinical research. Major institutions from site management organizations to research-based nurse associations to patient advocacy groups have an opportunity to listen to perspectives of nurses and first responders by following the #WhyWeDoResearch hashtag.

Person-to-person and business-to-business networking events are currently the standard for many wanting to spur positive developments in the clinical research industry. For a variety of reasons, attendance may not always be a viable option for many professionals, but it is important

to remember that smartphones with internet access have become ubiquitous. When it comes to connectivity, there is potential value to conducting clinical research focused events through an online platform and increased participation as a result. By bringing stakeholders together in a modern way, we can learn about best practices moving forward and give everyone—including patients—a chance for a better clinical experience.

Conclusion

Sharing our personal stories can have a profound impact on someone. I am a head and neck cancer survivor. My life was ultimately saved by the innovation of, and professionals in, clinical research.

We are in an era where we no longer need speculate what research professionals "might" need or "want" to make the system better—we can simply look online and join the conversation. If I am an RN in Ohio and want to know how to get involved in research or want to share my scientific discoveries, I can now be a part of a community of like-minded RNs from across the globe who can point me in the right direction.

Due to social media's rise, breaking down silos and sharing knowledge can be integral to enhancing clinical research as we know it.

Al O. Pacino is President at BlueCloud® by HealthCarePoint Professional Collaborative Networks, based in Cedar Park, Texas, and a former member of the Editorial Advisory Board for ACRP.