NEW APPROACHES TO RESEARCH WITH VULNERABLE POPULATIONS - INTERDISCIPLINARY APPLICATION OF A FRAMEWORK FOR VULNERABILITY AND ADOLESCENT CAPACITY TO CONSENT

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Children's and adolescents' capacity to provide valid informed consent is one of the key ethical concerns in pediatric research, and the focus of this project. The original contribution to knowledge is the advancement of both conceptual and empirical bioethical approaches to research with vulnerable populations. First, a review of adolescent vulnerability is presented to highlight the complex interplay between capacity and other forms of vulnerability. This review is offered as an interdisciplinary analysis to better understand why the study of vulnerable populations is critical to the ethical advancement of clinical research. Results from this analysis suggest the need for enhanced screening techniques as well as the utilization of specialized staff to identify and reduce the impact of different forms of vulnerability.

The primary tasks of the empirical portion of the dissertation were to: (1) Adapt a validated adult competency assessment tool for clinical research, the MacArthur Competency Assessment Tool for Clinical Research, to assess the capacity of children and adolescents to consent to clinical research; (2) Identify predictors that impact children and adolescents' capacity to provide consent to clinical research; and (3) assess differences and similarities in capacity between healthy and chronically ill children and adolescents.

Overall results suggest adolescent capacity to consent to research was similar to adults, and most strongly associated with their family's socioeconomic status as well as

their level of health literacy. These findings contrast starkly with the age-based criterion for providing consent currently utilized in assent and consent determinations. These findings also provide insights into ways to ethically involve youth in complex biomedical research.

James A. Hall, PhD

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V. Introduction

Jane Addams wrote, "Action is indeed the sole medium of expression for ethics (1902, p. 273)." These words, written over 110 years ago, still ring true today, and are a mainstay within the field of social work ethics. This reflection largely concerns the vulnerable populations social workers encounter on a daily basis coupled with the field's aim of making a difference in the community. However, it is not enough for social workers to consider the implications of action or inaction—both practitioners and researchers are part of a multi-generational reiterative process of implementing new and innovative ways of making the world a better place for oppressed and disenfranchised populations who find themselves broadly labeled as "vulnerable populations" (Frohlich & Potvin, 2008). For this reason, the study of vulnerable populations is central to the efficacious practice and development of applicable social work theories for better advocating for, treating, and understanding those in the greatest need and considered at-risk (Aday, 1994; Gelberg, Andersen, & Leake, 2000). Studying such populations highlights the ways in which social workers are uniquely positioned to understand the complex nature of vulnerability and the multidimensional ways in which it can manifest.

Within social work practice, considerable time is spent discussing how to best work with different vulnerable populations, respect their self-determination, and navigate the complex systems necessary to advocate for clients. This advocating for vulnerable populations is a hallmark of the social work profession, and is one of the primary goals of the field. Although numerous methods are used in social work to address vulnerability *in practice*, the same attention has not been paid to *research*. For instance, the potential impact of the utilization of the strengths perspective on the research recruitment process

have not been examined. Additionally, within the realm of research, a scant amount of data exist demonstrating how social workers are intervening within the research process to advocate for the rights of research participants, respect participants' self-determination and autonomy, and do justice by looking at research participation as a right (Elks, 1993; John, 2007).

The present dissertation explored the concepts of vulnerability and capacity within the context of research participation, with a specific focus on adolescents' participation. A variety of factors influencing research participation were examined to deepen current understanding of the ways in which social work can improve ethical recruitment of subjects to studies as well as increase research inclusiveness, build stronger community relationships among participants, and enhance the overall quality of research.

Outline

The purpose of the following literature review is to outline the ways in which different types of vulnerability inform our understanding and application of capacity with adolescents. The overarching hope is to clarify the classification of vulnerability in human subjects research in the context of adolescent capacity to consent to research. Although the intended focus is on capacity as it applies to adolescents, it is important to note that many of the issues raised also apply to other vulnerable populations (e.g., the mentally ill, the elderly). This review begins by providing functional definitions for the terms that will be used throughout, including placing the concepts of vulnerability and capacity into a social work context and explaining how and why this topic is of specific concern to social work practitioners and researchers. The concept of vulnerability is

broad in its application; therefore, a number of conceptual areas will be covered to contextualize vulnerability and better understand how capacity is addressed in practice. The review concludes with a discussion of the implications of this research for the field of social work, with special attention being paid to both practice and theory.

Definitions

To be able to discuss adolescent vulnerability and capacity in research, key terms must be defined. Due to the multidisciplinary nature of the topic, these terms can have various definitions depending on the context; thus, the following section offers the definitions of terms and concepts as to how they apply in the present work, namely, *capacity, vulnerability, adolescence, informed consent, and assent*.

Capacity generally refers to an individual's ability to make an informed decision (Clausen, 1991; Weithorn & Campbell, 1982). In the present work, capacity was operationalized through four criteria governing an individual's ability to give or withhold consent. These criteria are based on Applebaum and Roth's (1982) framework and include (1) understanding, which is defined as utilization of relevant information to make a decision, (2) appreciation, being able to comprehend the significance of the decision (e.g., that the decision *truly* is one's own), (3) reasoning, having the ability to manipulate information rationally, and (4) making a decision having the ability to communicate one's intended decision.

Vulnerability in terms of individuals and populations can be difficult to define. Vulnerable populations and how to identify them been defined in numerous ways in previous studies (Hurst, 2008). The Declaration of Helsinki (1964) defined vulnerability as "…an increased likelihood of being wronged or of incurring additional harm." (p. 4)

Similarly, the National Bioethics Advisory Commission (2001) defined vulnerability according to participation: Those who are not fully capable of resisting the request to become participants—such as prisoners or other institutionalized/vulnerable persons—should not be enrolled in studies merely because they are easily accessible or convenient. This work used the following definition of vulnerability, based on Iltis (2009): "The ability to give or withhold informed consent and the likelihood of being misled, mistreated, or otherwise taken advantage of in research." (p.7)

Vulnerability has been partially addressed at the federal level by the Department of Health and Human Services (2009), which offers a non-exhaustive list of potentially vulnerable groups, including pregnant women, human fetuses, neonates, prisoners, and children. From a regulatory perspective, adolescents comprise both children and adults. The Protection of Human Subjects statute (2009) of the US Department of Health and Human Services defines a child as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" (46.402 subpart A). The legal age is generally 18 years of age, although underage adolescents can consent to some medical treatments (e.g., STD testing). Thus, not all adolescents are considered "children" and therefore "vulnerable" according to US research regulations.

Adolescence refers to the transitional period from childhood to adulthood, beginning at the onset of puberty and ending with taking up of adult social roles (e.g., work, marriage) and responsibilities (Lerner & Steinberg, 2004). The operationalized definition of this term for the present work was that of the United Nations, wherein adolescence spans from ages 12–24 years (United Nations, 2012). Note that this range is

but one of many utilized in research; it was utilized in the present dissertation because I wanted to compare early and late adolescence without regard for the legal status of minor/adults. Adolescence was categorized as follows: early (12–14 years), middle (15–17 years), and late (18–24 years).

Informed consent is a process potential research subjects undergo and is intended to promote and honor autonomy during enrollment into a research protocol (Faden, Beauchamp, & King, 1986). This process is a legal requirement ensuring that participants are given information about the risks and benefits of participation, how to withdraw, what the procedures are, and who they can contact to get more information and assistance pertaining to study involvement (Appelbaum, Lidz, & Meisel, 1987). In a research setting, the informed consent process is where potential participants exercise their decision-making capacity.

Assent is discussed directly in the federal regulations guiding research and is defined as "…a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent" (Protection of Human Subjects, 2009, 46.402 subpart B). Within the research enrollment process, attaining assent follows the informed consent process; however, concerns have been raised about the voluntariness of the assent obtained via this process (Kipnis, 2003). Specifically, researchers of child and adolescent assent believe that the process of attaining assent might in fact mask adolescents' true desire to participate or abstain from research (Kumpunen, Shipway, Taylor, Aldiss, & Gibson, 2012; Scherer et al., 2013).

A social work perspective

Both the professional and academic aspects of social work are inherently interdisciplinary and attempt to address a diverse array of topics and vulnerable populations using a variety of philosophies and methods. As the social work profession continues to grow and diversify to address the needs of the ever-changing social landscape, social workers are increasingly being tapped as direct members or consultants for interdisciplinary treatment and research teams (Maramaldi et al., 2014). Collaborative interdisciplinary care is becoming increasingly common in both acute and chronic care cases, as many cases must address a host of tangential issues connected to the illness, such as the mental health of the patient or the shifting family dynamics that illness can cause (Rothman & Wagner, 2003). Collaborative interdisciplinary teams utilizing social workers have been particularly effective within the medical model, and, in addition to benefitting patients, have provided social workers with a diversified view of health care and treatment (Bronstein, 2003). Academically, these collaborative teams allow social workers to participate in and have a direct impact on all facets of research and practice. As social workers often provide counsel and advocacy for highly vulnerable populations, they are in a unique position to fully understand and respond to a multitude of vulnerabilities both clinically and within a research setting.

Pediatric and adolescent research is of vital importance to advancing our understanding of the diseases and behaviors that influence young people, while the recruitment of young participants is of similarly vital importance for the advancement of such research (Llewellyn-Thomas, McGreal, Thiel, Fine, & Erlichman, 1991). Human subjects research is a multifaceted process, with various different contributing variables

at play in each stage. A variety of factors affect the decision-making process of whether an adolescent will participate in research, and there are key differences between adult and adolescent in terms of motivation for participation. An essential factor for social work practitioners and researchers to consider is as follows: if we consider vulnerability a blanket assignation for all minors, why do we believe that assent (gained after parental consent) is necessary? Accordingly, social workers may be poised to better understand *true* vulnerability and its use in research, including how and when it is applied and the protections that can be offered to alleviate it.

As research with hidden and hard to reach populations becomes more accessible through the use of technology and enhanced recruiting techniques, the use of highly skilled individuals' with experience in comprehensive assessments will be necessary to facilitate ethical research. With additional training and experience, social workers will be perfectly poised to step into this role across all types of research and can act as a conduit to bridge the perceived gap between assessment, treatment, and research. This dissertation presents both a review of a conceptual framework for social workers to utilize when working in research recruitment as well as beginning evidence for an objective measure of capacity to consent to research which can be used in participation decisions as well as a screening measure to identify different needs and vulnerabilities one might present in a research recruitment setting. Conceptually, this work seeks to add a framework for understanding adolescent vulnerability in research recruitment as well as evidence for use of formalized capacity assessment measures in research recruitment.

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VI. Literature Review

This chapter provides an overview of the literature on capacity using a framework of vulnerability that highlights the different ways in which adolescents might be considered systematically unable to provide consent. To understand capacity and how it can be utilized to enhance clinical trial recruitment, a comprehensive understanding of vulnerability is necessary. I first discuss the concept of vulnerability within adolescent research as a means to understand the ways in which adolescent populations are considered vulnerable.

Vulnerability and capacity

Per US federal regulations, vulnerability is currently a blanket term assigned to large groups of individuals without recognition of their individual characteristics (C. Levine et al., 2004). For instance, merely by not having attained the legal age of consent, anyone in the US under the age of 18 is viewed as vulnerable despite the considerable literature base suggesting that older adolescents may have similar levels of capacity to make decisions as adults (R. J. Levine, 1995; Partridge, 2013; Santelli et al., 1995). This propensity to ignore individual characteristics has led to both overuse and misuse of the term, systematically eliminating potential participants according to group membership rather than their individualized level of actual vulnerability (C. Levine et al., 2004). This policy poses problems not only because it excludes potential participants from research, but also because it potentially masks people who require meaningful protections despite being able to participate. Given the biased and systematic exclusion resulting from this use of vulnerability, it is clear that a better understand of capacity, or an individual's ability to make informed decisions, is needed. Improving policies regarding capacity to

consent can be considered a primary means of expanding the scope of adolescent clinical trial involvement and increasing the safety of health research.

Discerning vulnerability is further complicated in pediatric research because of the circumstances surrounding the decision to participate in research. When making decisions about research participation, a number of processes must be evaluated. First, the research team must recruit the parents of the child into the study and get them to provide *parental permission*. The requirements for parental permission and assent in the context of human subjects research are outlined in the Protection of Human Subjects statute, Title 45, Part 46 (2009) and involve multiple disclosures to the subject, including the purpose and duration of the research, the procedures involved and if they are considered experimental, the risks, a contact for any questions, the fact that participation is entirely voluntary, and the fact that declining to participate will not render loss of other benefits or treatment (US Department of Health and Human Services, 2009). Second, the child must provide his or her *assent* to participate. This process of acquiring both consent and assent is a safeguard to ensure that both parents and children are properly informed and willing to participate in the research project. However, this process can cause problems when there is a disagreement between parent and child or when parental permission is not a meaningful protection for the child (e.g., research on sensitive issues). Current regulations primarily give decision-making power to parents based solely on the vulnerability assigned to their children. Circumstances wherein minors may be able to provide consent without parental permission include research on treatments or situations for which the adolescent typically provides consent for themselves, such as the diagnosis or treatment of sexually transmitted diseases (STDs), contraceptive services, prenatal

care, substance abuse treatment, and mental health treatment (Boonstra & Nash, 2000; Guttmacher Institute, 2014). These minor consent laws vary by state. For example, screening and treatment for STDs is permissible in all 50 states without parental notification or permission, but only 34 states have explicit laws related to consent to contraceptive services (Guttmacher Institute, 2014).

These power differentials between parent and adolescent as well as researcher and adolescent are of importance to social workers and other professionals that work with adolescents. For instance, depending on how adolescents and their parents are approached in the recruitment process, shared decision-making can be reduced by researchers automatically deferring to the parent. Although generally accepted practice, this poses risks to adolescents' emerging sense of autonomy, self-determination, and justice and can ultimately reduce their involvement in the decision making process. Furthermore, it may pose specific problems for clinicians and researchers in ethically and effectively interacting with adolescent participants. During later adolescence, emphasis needs to be placed on supporting growing autonomy and responsibility. This concept is respected and given full weight when making treatment decisions, especially for sensitive topics (e.g., STD screening and treatment, pregnancy, mental health treatment, substance abuse treatment) (Hill, 2011). The explicit distinction between when parental consent is needed and when it can be waived is a sign that even within such a complex regulatory system it is unclear why and when every person under the age of 18 is considered vulnerable. Understanding this complex system and its impacts on clinical care and research recruitment can help social workers better navigate the systems as well as advocate for their adolescent clients.

A framework of vulnerability

As noted above, vulnerability can be challenging to operationalize. One approach is to suggest that every individual has some form of vulnerability and therefore requires specialized protection in certain situations. However, such an approach may not be reasonable, being too cumbersome and time consuming. Another approach is to identify specific vulnerable groups. However, this approach has the potential to stereotype said groups, ultimately acting as a form of oppression that does not adequately account for individual differences (C. Levine et al., 2004). A third alternative is to examine the characteristics and situations that may lead to vulnerability, such as Kipnis's (2003) framework, which proposed to identify and categorize differing manifestations of vulnerability in pediatric research participants. This framework allows investigators to examine the types of vulnerability and their relevance to research. Within this framework, seven main types of vulnerability can influence adolescent informed consent:

- Incapacitational, or an individual's ability to make decisions using the information at hand;
- Deferential, wherein decisions are deferred to other professions or others in power;
- Juridic, wherein someone has legal authority over an individual's ability to make his or her own decisions;
- Allocational, wherein factors such as education and poverty may impact an individual's decision;
- Medical, which refers to when a person feels obligated to participate in research due to a health condition for which there are few or unsatisfactory cures;
- Situational, which refers to when someone has an illness that prevents necessary deliberation needed to make an informed decision to participate; and
- Social, which involves being the member of a group with a history of being socially devalued.

(Kipnis, 2003)

This list represents the range of possible characteristics that may make an individual vulnerable. It is important to note that at any one point in time any number of these types of vulnerability can affect an individual and may be highly dependent on the situation. For this reason, it is crucial that social workers more closely examine how vulnerability is formulated, evaluated, and addressed within research settings (Kipnis, 2003). The most important form of vulnerability for making decisions about informed consent is incapacitational vulnerability. For adolescents, the ability to give informed consent rests mainly on the idea of capacity to make that decision, and is an aspect of research participation decision making unique to adolescents.

Capacity and incapacitational vulnerability

Capacity has been identified as the most important issue in pediatric research ethics (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1977) as well as a critical issue in research with adolescents (Berman & Field, 2004). The issue of capacity is of specific concern in the recruiting and consenting process represents a major barrier to recruitment of adolescent participants (Kipnis, 2003). Because ethical standards require an individual to be free of undue influence and coercion and limit use of unjustifiable pressure and manipulation, specific attention must be paid to how researchers interact with potential adolescent research participants (Department of Health, 1979). However, the inclusion of social workers and social work perspectives in pharmaceutical or clinical trial research may bring up issues that directly conflict with the NASW Code of Ethics. Within the Code of Ethics (2008), one section outlines that the social worker's duty is to obtain informed consent that does

not violate the terms and laws specified in both the Code and the Belmont Report (1979), where the concept of informed consent is thoroughly discussed.

A variety of factors contribute to the decision making process of whether an individual will participate in a research study or not (McGregor, Ott, Lally, & Zimet, 2014). Two factors that ultimately coexist in a research participant are willingness to participate (WTP) and capacity to consent to research (Broome, 1999). These two ideas are similar and directly related, but cover different facets of this decision making process (Spigarelli, 2008). WTP is associated with the general outcome of the deliberations of a potential subject. A person will either indicate that they want to participate or will indicate that they do not want to. This dichotomous decision (which can be revised as the study goes on) is merely an outcome and does not include any information about the process that an individual goes through to reach this decision. Therefore, to more fully assess the decision making process of the individual, we utilize the concept of capacity as a measure to ensure that an individual has not only the WTP, but also the ability to weigh the tangible pros and cons of participation (or not participating) along with the more intangible risks and benefits. Viewed in this light, WTP would be the simple outcome of the complex interplay of decision making processes that form the capacity to consent to research. Whereas a monetary incentive could instill a high WTP, it could lead to an ethical grey area of exploitation and coercion in terms of consent (Dempsey, Back, Waldrop, Jenkins, & Brady, 2008; Klitzman, 2013).

The literature on research recruitment has increasingly focused on the ethical concerns of providing incentives, whether incentives have any impact on study recruitment, and the determinants of research participation (Singer, 2003; Singer &

Couper, 2008; Verheggen, Nieman, & Jonkers, 1998). With such an increased focus on the methods used to improve recruitment and retention, information is lacking on the effects of systematic exclusion and reasons as to why individuals decline to participate.

Within clinical research, ethical standards backed by institutional review boards (IRBs) can directly affect researchers' limits on what they can and cannot do to recruit participants (Grant & Sugarman, 2004; Holden, Rosenberg, Tuhrim, & Brenner, 1993). Although this oversight provided by IRBs is intended to protect research participants, certain circumstances might arise wherein IRB protections do not specifically protect a population, but indirectly act to hinder research of populations that are at risk and therefore in great need of clinical research (Morris, 2012). Due to concerns of coercion and posing a greater than minimal risk to participants, many within the research community are concerned about what populations can be directly studied and what methods researchers can use to increase participation rates (Grant & Sugarman, 2004; Singer & Couper, 2008).

Deferential and juridic vulnerability

The deferential and juridic types of vulnerability span all ages, but are particularly likely among adolescents because of their power differentials with parents, researchers, and other adults (Kipnis, 2003). Specifically, parents' role in the decision making process coupled with adolescents' lack of legal standing to provide their own assent make it especially difficult to separate parental motivations from adolescent motivations, and even harder to know if adolescent assent is given freely (Brody, Turner, Annett, Scherer, & Dalen, 2012). Furthermore, within clinical research trials with adolescents, a number of factors affecting participation decisions do not apply when parents must make the

decision for their child compared to when they make it themselves (Berman & Field, 2004). An increased focus on the capacity of adolescents independent of parental consent could provide not only validation of adolescents' assent, but also further pinpoint what motivators are at play and how adolescents view any potential risks involved in the research.

Research in this area has examined the decision-making of both parents and their children together as well as how adolescents make decisions independently, and has shown that parents have higher levels of risk aversion and that all groups cite some form of altruism as a main reason for participating (Brody, Annett, Scherer, Perryman, & Cofrin, 2005; Llewellyn-Thomas et al., 1991; Pasternak, Geller, Parrish, & Cheng, 2006). Recent research (specifically that within the field of adolescent asthma treatment) has focused on the differences in motivations between parents and adolescents that choose to participate in research. Brody and colleagues (2012) found that adolescents were much more likely to participate in research if they felt a strong connection with the research team. Furthermore, adolescents who did feel such a connection were more likely to perceive financial compensation as a motivating factor. This finding is divergent from the adult findings, which indicate that parents are much more concerned about safety, how much time participation will take, and being used as a "guinea pig" (Brody et al., 2012; Epstein, 2007; Swanson & Ward, 1995). Additionally, Morris (2012) found a strong indication that adolescents place less emphasis on risk than do their parents (Morris, 2012). As previously posited, this points to a higher prevalence of protection concerns within parental decision making overall instead of a modified risk/benefit calculation when adolescents are involved.

Within newly emerging research on adolescent and parent decision making in clinical research, it is notable that researchers who place greater emphasis on the development of rapport with pediatric participants will not only do better in securing parental consent, but will do significantly better in securing meaningful adolescent assent with those effects lasting throughout the study, thereby increasing retention in longitudinal studies. A tool for measuring adolescent capacity paired with good rapport could act as an additional indicator of the individual's ability to not only provide assent, but also fathom the necessary commitment to participation in a longitudinal study. Additionally, when designing a research protocol, it is of increasing importance to know the intended audience. Studies focusing on adults as individual actors will have different recruitment protocol needs than will studies focusing on adolescents or parent–adolescent dyads. An increased focus on adolescent capacity and the decision-making logic of different target populations in participating or declining to participate will help research teams recruit more effectively, increase subject retention, and hopefully help reduce the likelihood of deferential and juridic vulnerability influencing study participation.

Allocational vulnerability

Substantial concerns have been raised about the ethics of providing monetary incentives for research participation, and these incentives are a major conversation topic in the context of allocational vulnerability (Kipnis, 2003). When using a monetary incentive for research participation, a gauge of capacity is critical. Researchers tow an ethical line when paying participants, making the understanding of what drives the decision to participate of great importance to ethical research practice. A number of authors have challenged the use of monetary incentives as an ethical research practice,

claiming incentives can act as a form of coercion in human subject recruitment (Holden et al., 1993; Singer & Couper, 2008; Verheggen et al., 1998; Yancey, Ortega, & Kumanyika, 2006). Despite this sharp division on the use of monetary incentives, numerous attempts have been made to develop guidelines for determining how much and in what form monetary incentives should be utilized. One generally accepted guide developed by Fry, Hall, Ritter, and Jenkinson (2006) states that research payments are ethically permissible in most circumstances, but need to be closely monitored to ensure that the payment is not functioning as an inducement that exacerbates harm or creates additional risks for the participant.

The notions of coercion and undue influence have been widely discussed within the research ethics literature (Grady, 2001; Wertheimer & Miller, 2008). Concerns over the coercive effect of payments have persisted in the adult research ethics literature, particularly regarding how payment undermines autonomy and the requirement for voluntariness (Macklin, 1989), discourages people to freely opt out due to the financial necessity of participation (Emanuel & Miller, 2007), and reflects a general sense of paternalism (Miller & Wertheimer, 2007). Incentives are intended to act as a means of compensating people for their time and reimbursing them for any expenses they might incur during the study period (Klitzman, 2013). An argument follows that if the utilization of monetary incentives is seen as necessary it is important that researchers can analyze the decision making process and participants' capacity. The potential risk for an individual to participate out of financial desperation despite not being comfortable with the risk or without properly considering the risk due to the incentive is high. This point when an incentive crosses the line from reimbursement to coercion or an undue influence

is crucial to identify (London, Borasky, Bhan, & Ethics Working Group of the HIV Prevention Trials Network, 2012; Wertheimer & Miller, 2014).

Using financial incentives to recruit adolescents and their parents can be an effective strategy as long as the incentives do not induce behavior that the participant would not have engaged in otherwise (Singer & Couper, 2008). However, as previously mentioned, these practices should be closely monitored for ethical concerns. Indeed, families with chronically ill children may greatly benefit from any form of monetary incentive. Furthermore, approximately 40% of families of children with special healthcare needs experience financial burden due to the child's condition (Kuhlthau, Hill, Yucel, & Perrin, 2005). Although this statistic provides ample support for a monetary incentive for this particular population, researchers should always be careful to ensure that the incentive is not exploited and that increased risk is not accepted by the subject in exchange for financial incentive. A tool for assessing capacity while simultaneously engaging in the current methods of continually monitoring the ethical use of incentives—namely, evaluating protocols for favorable risk-benefit ratios, using enhanced consent methods, and ensuring that highly vulnerable populations are not systematically enrolled in high-risk/low-benefit research—would be beneficial (Emanuel, 2005).

Medical and situational vulnerability

Medical vulnerability is defined as participants' feeling of obligation to participate in research due to a health condition for which there are few or unsatisfactory cures (Kipnis, 2003). This type of vulnerability is especially important to consider in clinical research due to its reliance on sick individuals to participate in clinical protocols. Similarly, situational vulnerability refers to when an individual has an illness that

prevents them from engaging in the necessary deliberation for making an informed decision to participate. These types of vulnerability often coincide in pediatric and adolescent research because of the necessity to quickly enroll patients in clinical protocols after diagnosis to enhance the likelihood of a positive outcome from treatment.

Adolescents and families dealing with chronic illness or special health needs tend to be treated by not only medical professionals, but also social workers. Medical vulnerability is at its highest in research on experimental therapies for adolescents with life-threatening conditions that have no approved satisfactory remedies (Kipnis, 2003). This type of vulnerability is of particular concern to studies on adolescents and their families, because both groups could feel as though they have no choice but to enroll in potentially risky trials. Similarly, with situational vulnerability, the adolescent and his parent may be pressured into a clinical research study without having the time to truly consider the risks and benefits of participation. For these types of vulnerability, social workers can be utilized to provide a professional opinion on capacity, quality of consent, and assent. Social workers can also maintain an ongoing professional relationship with the subject and/or family to monitor for any possible coercion by external motivators such as financial compensation or other ethical compromises. Additionally, the strain of chronic illness increases the risk for depression, and families may require additional counseling to assist in coping and stress management (Katon, 2011; Pinquart & Shen, 2011).

Chronically ill populations receive a great deal of attention within the medical ethics literature (Beresford & Sloper, 2003; Broome, Richards, & Hall, 2001), and this is especially true with regard to chronically ill adolescents' participation in clinical trials.

Less research is available on adolescents' experiences in chronic illness research; however, within the court of public perception, researchers may be thought of as exploitive by conducting studies with this population, especially when results are not quickly and directly shared with participants (Fernandez et al., 2007). In Kipnis's (2003) discussion of medical vulnerability and coercion, he is very clear that chronically ill individuals are not inherently being exploited or taken advantage of. Although disagreement exists as to how and what specifically constitutes exploitation in this sense, feedback from research participants suggests that they feel like they are able to give back, to provide assistance to the medical community in hopes of one day finding a cure for their disease, and that they do hold out hope that enrollment in a new research protocol might cure them of the disease (Brody et al., 2005; Pasternak et al., 2006). In this sense, research staff should work with subjects to ensure they are completely informed of the risks as well as the realistic benefits that the subject may experience, including the fact that participation may not yield a change in medical condition (Rice & Broome, 2004). A more comprehensive capacity measurement and consenting process coupled with continued social work involvement with participants would hopefully lead researchers to redesign their clinical trials to extend treatments for individuals showing positive results for experimental therapies. This change in approach would drastically reduce the prevalence and likelihood of medical and situational vulnerability for adolescent research participants. As a first step, the present research project examined the role of chronic illness in decision making.

Social vulnerability

Although there are few data on adolescent ethnic minority trial participation, larger patterns of adolescent discrimination have been reported across all ethnic groups specifically within educational settings (C. B. Fisher, Wallace, & Fenton, 2000). These larger patterns of feeling discriminated against by those in power have been discussed primarily in research on adults; however, they have been brought up within adolescent research as well (C. B. Fisher et al., 2002; McLoyd, 1998).

Adult research shows higher minority group enrollment in Phase I clinical trials than in Phase III trials by a considerable margin, suggesting that minorities may be bearing more risk and reaping less benefit (Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999; J. A. Fisher & Kalbaugh, 2011; Schmotzer, 2012; Swanson & Ward, 1995). Although a prima facie evaluation of high minority involvement in Phase I studies may seem to run contrary to the notion of a bias in clinical research, deeper analysis of the risks and benefits of Phase I versus Phase III clinical trials provide more insight into the depth and nature of institutional bias. Comparing study types shows that minorities are typically targeted for Phase I studies and that the differences in their participation rates between Phase I and Phase III trials underscores an inherent problem within the research community (J. A. Fisher & Kalbaugh, 2011, 2012). Utilizing lower socioeconomic status (SES) and minority participants for high-risk studies, yet not offering them the opportunities to participate in the Phase III trials that could potentially improve their health, illuminates a major research ethics issue (J. A. Fisher & Kalbaugh, 2012).

These multiple vulnerabilities are an area in which social workers can substantially contribute to participant protections, particularly those populations, such as

adolescents, who have been identified as "vulnerable." Social workers can evaluate not only the potential for coercion, but also for the overlapping social and societal considerations that might influence an adolescent and his/her parent/guardian's ability to make an informed decision. There are myriad ways in which potential subjects in a research protocol could be greatly affected by a legacy of social devaluation; for instance, African American parents of minors may experience considerable distrust because of a long history of abuse by researchers (Shavers-Hornaday & Lynch, 1997). This legacy can in turn cause conflict during the consent and assent process, ultimately limiting the number of viable candidates available for research. Additionally, when evaluating minors' capability to provide informed consent, their opinions and rights may be squelched by overprotective IRBs that are unaware of the protections available for minors, researchers who shy away from "hot topics" and sensitive subject research with vulnerable populations, or funding mechanisms ill-equipped to accurately assess the value and merit of research with minors (Risjord & Creenberg, 2002).

Responding to vulnerability occurring as a result of being socially devalued, for both adolescents and adolescent–parent pairs, seems uniquely suited to social workers with training in family systems or adolescent development. A grounded understanding of how oppression and vulnerability can affect decision making enables a social worker to work with a family to help dispel inaccurate information or misunderstanding and provide greater detail on the topic at hand in a vernacular appropriate for the situation. Concerns have been raised that spending an excessive amount of time discussing a study with a family may burgeon into coercion. In other words, researchers, in an attempt to enroll an individual into a study, may provide a one-sided view of the study that

erroneously convinces a parent to provide consent. However, available evidence on the subject provides initial evidence that such lower levels of transparent information may actually lead to a decrease in parents' willingness to participate (Lally et al., 2014). Additional efforts to assess capacity may help to not only provide candidate participants with better information about the study (i.e., both more comprehensive and more clearly delivered), including the risks and benefits of participation, but also provide researchers with more information about why candidates may be unwilling to participate (Condon, 1986; Conroy & Harcourt, 2009). This is where social workers and a social work perspective could be helpful by utilizing a comprehensive evaluation framework including a capacity assessment, social workers may be poised to provide information while assessing potential participants fit for studies, toeing a fine line between educating and coercing. Furthermore, it could improve the recruitment process overall by providing more information on the potential problems of recruitment, thereby helping recruit participants to a project where they may be able to provide significant and meaningful contributions.

Summary of vulnerability

Capacity emerges as a key concept for understanding and contextualizing the different forms vulnerability. Utilizing the Kipnis (2003) framework (Figure 2 provides a foundation for understanding the potential problems of recruitment. Indeed, it is not until these factors are considered in relation to each other that a hierarchical model with capacity functioning as the dominant concept emerges. Although the other six forms of vulnerability are important to assess and monitor, capacity is ultimately what will determine the impact those other factors have on an individual's decision-making

process. For this reason, the primary focus of this research was the role of capacity in adolescent decision making. By better understanding how capacity functions within the research recruitment process, social workers and researchers will be better able to assess the effects of the various other forms of vulnerability.

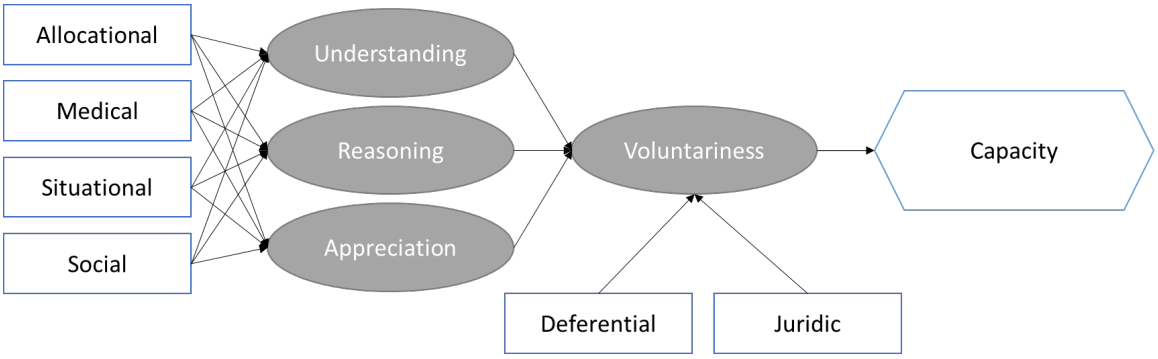

Figure 1. Conceptualization of Kipnis's (2003) vulnerability framework and requirements for consent

VII. Methods

Purpose and aims

The overall objective of this research project was to evaluate adolescents' capacity to consent to participate in research. The purpose of the present study was to adapt an adult capacity assessment instrument for 12- to 24-year-olds with chronic illness to assess their decision-making capacity to consent to research. More specifically, the aims of this study were to:

1. Identify the predictors of capacity, including (a) chronic illness, (b) health literacy, (c) developmental and demographic factors, and (d) previous research participation;
2. Compare the key predictors of capacity between chronically ill adolescents and healthy adolescents; and
3. Compare the predictors of capacity between minors (<18) and young adults with chronic illness.

Participants

Participants were adolescents aged 12–24 years. Primary inclusion criteria were being within this age range and the ability to read and speak English. Exclusion criteria included individuals who were obviously intoxicated or under the influence of a substance as well as individuals obviously lacking the capacity to understand the study procedures due to severe medical illness or significant cognitive impairment. Such status was assessed by the parent (if the participants were minors) or the interviewer according to the participants' ability to understand and give informed consent for the study. Individuals were recruited into the study without consideration of their chronic illness

status, which was only discovered after completion of the initial study demographic survey.

Recruitment and enrollment

Adolescents and young adults ages 12-24 were recruited from primary care clinics, schools, and the community. Research staff contacted teachers and school administrators, program directors, youth workers, physicians, and clinic administrators to ask permission to recruit youth from the relevant institutions. This approach allowed recruitment of adolescents across a range of sociodemographic characteristics and life experiences. Furthermore, this recruitment approach was similar to that used for clinical and behavioral research with healthy adolescents. The IRB approved the research protocol. Adolescents provided consent, and parents/guardians provided permission for those under 18 years of age.

Adolescent consent and parental permission. Prospective participants who were minors (including those recruited from schools, clinics, or who were self-referred) were given a copy of the study consent form, either in person or via email, for their parents to sign. Parents were provided with the researcher's phone number and e-mail address so that they could ask questions. Adolescents who returned to their school, clinic, or other study site with a signed consent form then met with the researcher, who reviewed the study information and consent form with the prospective participants in a private room. Interested participants were then given a consent form to sign themselves and were provided with a copy of the form. Parents were encouraged to visit the study site and participate in this consent process if able.

Protection against risk. Protection against risk was accomplished by thorough training of the research staff; careful orientation of potential subjects regarding the nature, risks, and benefits of the study; strict adherence to study protocols; and regular surveillance for adverse events. The procedures utilized had no more risk than did normal daily activities an adolescent might experience.

Participants' confidentiality was protected by omission of individual identifiers associated with their study responses. Data were stored in a password-protected database containing only study numbers. Separate password-protected files containing individual names and contact information (e.g., cell phone numbers) were maintained for administrative purposes to re-establish contact with participants who were recruited from sites participating in the test-retest reliability portion of the study. These computer files were maintained within the offices of the principal investigator. Access to any files was limited to research personnel.

Procedure

A 60- to 90-minute interview, involving both interviewer-administered and self-administered questionnaires, was used to assess participants' capacity to understand and consent to research and related factors.

Capacity for consent was assessed using the MacCAT-CR, a standardized measure of capacity, in a semi-structured interview format, along with three consent forms for various types of research study: a randomized controlled trial of a new headache medication, a biobanking study, and a sexual behavior and surveillance study. These three studies were chosen because they represent the range of study types in which adolescents are typically enrolled. The order of consent form presentation was

randomized for each participant to minimize possible exposure bias; this was done upon enrollment by randomly assigning participants to one of three groups with differing presentation orders of the three consent procedures. Participants were asked to read the consent form on their own, and then go through the typical consent procedure with the researcher for that individual form.

The interviews were conducted in a private location of the participant's choosing, and participants were reminded that they could refuse to answer any question for any reason. Following assessment of eligibility, enrollment, and informed consent, participants' recruitment site was noted and they were given the self-administered survey collecting demographic (age, ethnicity), developmental (education), and medical information (diagnoses, medications, treatments, hospitalization); 12- to 13-year-old participants were given a different questionnaire that did not include items about sexual activity. Next, the Rapid Estimate of Adult Literacy in Medicine (REALM), MacCAT-CR, Adapted University of California, San Diego Brief Assessment of Capacity to Consent (UBACC), and Evaluation to Sign Consent Form (ESC) were administered by the researcher; audio recordings were made of the MacCAT-CR, UBACC, and ESC administrations.

Main measurement instruments

MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR). The MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) is a comprehensive assessment tool for adult capacity assessments (Appelbaum & Grisso, 2001). There are emerging data supporting its use with adolescents (Hein, Troost, & Lindeboom, 2014; Hein et al., 2012; Koelch, Prestel, Singer, Schulze, & Fegert, 2010).

The effectiveness of the tool stems from its focus on the four criteria thought to be required for consent: evidence of choice, factual understanding of the issues, rational manipulation of information, and appreciation of the nature of the situation (Appelbaum & Roth, 1982; Kim, 2010; Turrell, Peterson-Badali, & Katzman, 2011). Use of the MacCAT-CR with chronically ill adults has been shown to be a reliable and effective way to assess patient capacity for clinical trials (Karlawish, Casarett, & James, 2002). This project sought to evaluate the effectiveness of the MacCAT-CR on chronically ill children and adolescents, as these are the pediatric populations most likely to participate in clinical trials research (Koelch et al., 2009). The research available on the MacCAT-CR's effectiveness in adult populations with waning cognitive capacity suggest that the measure should be sensitive enough to capture evolving capacity (Karlawish, et al., 2008; Kim & Caine, 2014; Palmer et al., 2005).

Specifically when assessing adolescent capacity to consent we were interested in how social/behavioral factors played into an adolescents ability to consent, and if there was a difference in those relationships between healthy and chronically ill participants. There is emerging information on the association between health literacy, family affluence, and age on capacity, and we we're interested to see how these factors would impact capacity assessment scores on the two different adolescent populations.

REALM

Health literacy has been identified as one of the most important emerging constructs in health care communication (Dumenci, Matsuyama, Kuhn, Perera, & Siminoff, 2013), and is currently viewed as a key factor in determinates of health care utilization and outcomes (Sentell, Baker, Onaka, & Braun, 2011). The REALM is one of

the highest utilized assessments to assess health literacy (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011).The REALM consists of 66-items and is currently the most utilized test of health literacy in research settings (Dumenci et al., 2013). The 66-items administered take less than 5-minutes to administer and produce a raw score than can be quickly converted into five different reading grade equivalencies. The REALM has been found to correlate well with the WISC Verbal IQ score.

FASII

The family affluence scale II is a self-reported measure that has been validated for use in adolescents and is considered to be a more accurate measure of adolescents perceptions of SES than traditional self-report measures (Boudreau & Poulin, 2009; Boyce, Torsheim, Currie, & Zambon, 2006; Currie, Elton, Todd, & Platt, 1997; Currie et al., 2008). Traditional SES scales administered to adults were found to be inaccurate when utilized with adolescents due to differences in adolescents' perceptions of SES and lack of knowledge of common measures of SES, such as family income, parent education, or enrollment in federal anti-poverty and benefit programs for lower income families (e.g. Medicaid). Development of the FASII attempted to identify related questions that would be easy to know and articulate while also corresponding directly to actual SES of the larger family unit. The FASII is a quickly administered tool that focuses on objective statues that exist within households; does the respondent have their own bedroom, how many cars does the family have, how many vacations a year does the family go on, and how many computers does the family own. These four items form a scale that ranges from 0-9 with 0-2 corresponding with low affluence, 3-5 with middle affluence, and 6-9 indicating high affluence (Boyce et al., 2006).

Statistical analysis

Analysis of data pertinent to the specific aims of the study began with a description of the sample and its overall capacity in terms of the MacCAT-CR and other measures. Then, using cross-tabulations and regression models, we identified the age-related and other correlates of research decision-making capacity in adolescents. The MacCAT-CR scores were compared across the different consent procedures.

The psychometric properties of the MacCAT-CR were assessed as well. Criterion and convergent validity were evaluated through comparison to clinical interviews and other commonly used capacity assessment tools (UBACC and ESC). Inter-rater reliability was assessed to ensure homogeneity in scores across all items. Regression analyses were utilized to evaluate the predictors of overall MacCAT-CR scores. Correlations and ANOVA will also be utilized assess association to compare groups.

Statistical analyses were performed with SPSS version 23. Demographic characteristics and initial bivariate correlations between the main study measures were analyzed utilizing Pearson χ^2, Pearson correlations, ANOVA, and *t* tests. Receiver operating characteristic (ROC) curves were utilized to evaluate the performance of the capacity assessment tools to determine cutoff scoring for assigning capacity to determine the predictors of a binary classification of capacity (i.e., capacity/no capacity).

A Framework for Understanding Vulnerability in Research with Adolescents

As evidenced from above, vulnerability can be remarkably challenging to operationalize in related research. One approach would be designating every individual as having some form of vulnerability (Handmer, 2003) and therefore requiring tailored protection in certain situations. However, this might not be a reasonable definition because it is too cumbersome and time consuming to measure. Another approach is to identify specific vulnerable groups. However, this approach has the potential for stereotyping, thereby ultimately acting as a form of oppression term not adequately accounting for individual differences (C. Levine et al., 2004). A third alternative, which is perhaps the most suitable to date, is to examine the characteristics and situations that may lead to vulnerability for each specific study. Kipnis (2003) developed a framework (Figure 1) of vulnerability to identify and categorize its differing manifestations in pediatric research participants. This framework gives researchers the ability to clarify what types of vulnerability might influence recruitment for their research projects. Kipnis suggests that vulnerability has seven main forms, as follows: (1) incapacitational, or an individual's ability to make decisions using the information at hand (i.e., their capacity); (2) deferential, or when decisions are deferred to other professions or others in power; juridic, when someone has legal authority over an individual's ability to make his or her own decisions; allocational, wherein factors such as education and poverty may impact an individual's decision; medical, which refers to how an individual feels obligated to participate due to a health condition for which there are few or unsatisfactory cures; situational, or when someone has an illness that prevents them from engaging in the

necessary deliberation for an informed decision to participate; and social, or being a member of group with a history of being socially devalued (Kipnis, 2003).

It is important to note that at any one point in time, any number of these types of vulnerability could affect an individual and may be highly dependent on the situation. For this reason, it is crucial that social workers more closely examine how vulnerability is formulated, evaluated, and addressed. In assessing vulnerability, capacity, and informed consent, social workers have a unique training and perspective that could allow them to play a useful role in protecting research participants (Kipnis, 2003). The most important form of vulnerability for social workers to consider in making determinations about informed consent is arguably incapacitational vulnerability. For adolescents, providing informed consent relies mainly on the idea of a capacity to make that decision, which is an aspect of decision making for research participation unique to adolescents. For this reason, a social work perspective of the seven types of vulnerability should seek to conceptualize incapacitational vulnerability, or capacity, as the overarching variable from which all other forms of vulnerability manifest.

Illustrating the Types of Vulnerability in Practice

As noted in the previous section, multiple types of vulnerability may be at play at one time and simple group membership should not be an identifying factor. Social workers can play a role by identifying the type of vulnerability and take a strengths based perspective in supporting that vulnerability. Starting with the overarching concept, attempting to gain greater insight into adolescent capacity would provide social workers in a research setting with a better idea of how well the potential research participant

understands the information being presented and how he/she has integrated that new knowledge into the existing frameworks of understanding that he/she already possesses.

In a research setting, adolescents who lack capacity may not be able to tell research staff what the risks and benefits of their participation are. Specifically, they might be unable to recall or understand what is expected of them if they choose to participate in the study; beyond this, they might be unaware that they have a choice to participate or be unable to make that choice based on the information provided. In these circumstances, it is ethically justifiable to exclude these adolescents from the study on the basis that they do not have adequate understanding of the relevant information needed to participate. Conversely, this may be the opportunity to provide enhanced information on the study procedures and help the potential participant to come to a decision. Deciding whether to eliminate or provide further information requires careful balance between overprotectiveness and coercion. It would help to identify specific procedures for such situations early on in protocol development.

After decisions have been made about whether an adolescent has capacity, additional steps can be taken to identify other types of vulnerability that might affect the potential participant's experience in the research setting. Adolescents with deferential and juridic vulnerability may feel compelled to participate based on relationships and perceived expectations from the research staff, parents, doctors, etc. Addressing these two types of vulnerability would require finding ways to reduce or eliminate the perceived pressure on the potential participant to help him/her feel as though he/she has a voice in the decision making process. Such methods of reducing deferential and juridic vulnerability might include common language explanations that let adolescents know that

no one expects anything of them; that it is completely their decision on if they want to participate; and that if they decide that they do not want to participate or change their mind about participating in the future, it is completely permissible and will have no impact on their relationship with the medical team, research staff, etc. The most important issue to be aware of with such types of vulnerability is that due to their status as minors, their parents' presence, and the perceived power differential inherent between research staff and participants, adolescents will always feel a baseline level of compulsory participation. Social workers are ideally positioned to screen for deferential behavior that shows misalignment between the preferences of the adolescent and what is expected of them. Throughout the informed consent process, social workders skills in building a rapport with the potential participant can help better assess for the presence of deferential or juridic vulnerability.

Concerns of coercion are common in all types of human subject research (Largent, Grady, Franklin, Miller, & Wertheimer, 2012; Oakes, 2002), and this fear is compounded when considering adolescent participation in research (Brody & Waldron, 2000). Kipnis's (2003) framework allows for social work researchers to examine the issues of perceived power differentials and possible financial inducement more deeply, to truly consider the division of benefits received as well as the fairness of the situation as a whole. Issues of allocational vulnerability go far deeper than remuneration for research participation, and defining, identifying, and correcting this type of vulnerability provides one of the greatest challenges to researchers looking to design ethically defensible research protocols with adolescents. However, it is this difficultly that plays into social work's natural strength to quickly assess and remedy issues with power imbalance,

resource allocation, justice, and fairness. Within the realm of allocational vulnerability, concerns over payments functioning as an inducement should be considered; however, a broader focus on the just recruitment of adolescent subjects should consider access to research, fair compensation for time and expertise, and ensuring that the target group of study is characteristically similar to the group that would benefit from the research. Ways of controlling for this type of vulnerability include conscious research design as well as enhanced interactions between research staff, parents, and adolescent participants.

The medical and situational types of vulnerability are of concern in adolescent research because they present a potential lack of time and available options to make an informed decision (Kipnis, 2003). This is particularly true with adolescent cancer diagnoses, where the only option for treatment might be a therapeutic trial that needs to begin immediately on diagnosis. In this case, both the medical and situational conditions may cause adolescent and their parents to feel forced into a decision because of such a lack of time or options. However, this exigency coupled with the overwhelming nature of such a sudden or traumatic situation fits well into medical social work's natural role as communication facilitators and enhancers. When medical and situational vulnerabilities are of concern, social workers are a necessary force to ensure that all parties are given as much helpful information as possible in a caring and empathic manner. It is social work's specific focus on the role of the individual within a large series of connected systems that can help to alleviate these tensions.

Summary of Vulnerability

Capacity emerges as a key concept in understanding and contextualizing the different forms vulnerability. Utilizing Kipnis's (2003) framework (Figure 1) provides a

foundation to understanding the variety of potential problems with recruitment; indeed, it is not until these factors are considered in relation to each other that a hierarchical model with capacity functioning as the dominant concept emerges. Although the other six forms of vulnerability are important to assess and monitor, capacity ultimately informs what impact those other factors have on an individual's decision-making process. By better understanding how capacity functions within the research recruitment process, social workers would be better able to assess the impact and effect of the various other forms of vulnerability.

Next Steps for Social Workers

Social workers interested in research with vulnerable populations should first seek to become better informed and involved in all aspects of research. Fortunately, the interdisciplinary nature of social work practice and education provides those interested in accessing research with the necessary skillset to maneuver the complexities of biomedical research settings. A change in mindset to see research as an extension of practice as opposed to a completely separate field would be a good first step. Far too often in BSW and MSW education, it is implied that research and practice is a dichotomous choice. It might be helpful to begin teaching research *as* practice (and vice versa), which could partially increase the number of social workers involved in research. However, this educational change must occur from the top down; social work programs should provide more opportunities for social work students to interact professionally with other medical professions, statisticians, and bench scientists. In other words, students must be exposed to interdisciplinary collaboration as the norm from day one instead of being expected to navigate such collaboration merely upon entering the job market. Allowing students from

a wide set of disciplines to interact would help enhance the interdisciplinary approach that many health education programs are starting to enact. Furthermore, this change would provide students with a wider variety of research/practice outlets, thereby allowing them to naturally develop insights into how they might become more involved in health care research and practice settings.

IV. A Social Work Perspective on Vulnerability

Introduction

Jane Addams wrote, "Action is indeed the sole medium of expression for ethics (1902, p. 273)." These words, written over 110 years ago, still ring true today, and are a mainstay within the field of social work ethics. This reflection largely concerns the vulnerable populations' social workers encounter on a daily basis coupled with the field's aim of making a difference in the community. However, it is not enough for social workers to consider the implications of action or inaction—both practitioners and researchers are part of a multi-generational reiterative process of implementing new and innovative ways of making the world a better place for oppressed and disenfranchised populations who find themselves broadly labeled as "vulnerable populations" (Frohlich & Potvin, 2008). Thus, the study of vulnerable populations is central to the efficacious practice and development of applicable social work theories for better advocating for, treating, and understanding those in the greatest need and considered at-risk (Aday, 1994; Gelberg et al., 2000). This intentional motivation highlights the ways in which social workers are uniquely positioned to understand the complex nature of vulnerability and the multidimensional ways in which it can manifest.

Within social work practice, considerable time is spent discussing how to best work with different vulnerable populations, respect their self-determination, and navigate the complex systems necessary to advocate for clients. This advocating for vulnerable populations is a hallmark of the social work profession, and is one of the primary successes of the field. Although numerous methods are used in social work to address vulnerability *in practice*, the same attention has not been paid to *research*. For instance, the potential impacts of the utilization of the strengths perspective on the research

recruitment process have not been examined. Additionally, within the realm of research, a scant amount of data exist demonstrating how social workers are intervening within the research process to advocate for the rights of research participants, respect participants' self-determination and autonomy, and do justice by looking at research participation as a right (Elks, 1993; John, 2007).

The clinical practice of social work with pediatric and adolescent populations includes skills that are potentially of value in research with dually vulnerable populations. The professional and academic nature of social work is inherently interdisciplinary and addresses a diverse array of topics and vulnerable populations using a variety of philosophies and methods. As the social work profession continues to grow and diversify to address the needs of the ever-evolving social landscape, social workers are increasingly being tapped as direct members or consultants for interdisciplinary treatment and research teams (Maramaldi et al., 2014). Collaborative interdisciplinary care is becoming increasingly common in both acute and chronic care, as many cases must address a host of tangential issues connected to the illness, such as the mental health of the patient or the shifting family dynamics that illness can cause (Rothman & Wagner, 2003). Collaborative interdisciplinary teams utilizing social workers have been particularly effective in the context of the medical model, and in addition to benefitting the patient, have provided social workers with a diversified view of healthcare and treatment (Bronstein, 2003). Academically, these collaborative teams allow social workers to participate in and have a direct impact on all facets of research and practice. Because social workers often provide counsel and advocacy for highly vulnerable

populations, they are in a unique position to fully understand and respond to a multitude of vulnerabilities both clinically and within a research setting.

Pediatric and adolescent research is of vital importance for advancing our understanding of diseases and behaviors that affect young people, while recruitment of young participants is similarly vital for the advancement of human subjects research (Llewellyn-Thomas et al., 1991). Human subjects research is a highly multifaceted process with numerous different contributing variables at play in each stage. A key factor for social work practitioners and researchers to consider is: if we consider vulnerability a blanket term assigned to all minors, why do we believe that assent (gained after parental consent) is necessary? Accordingly, social workers may be poised to understand the complexity and nuance of vulnerability, and its use in research, including how and when it is applied as well as the protections that can be offered to alleviate it.

The present review explores the concepts of "vulnerability" and "capacity" within research participation, with a specific focus on adolescents' participation in research studies. A variety of factors influencing research participation are examined to deepen current understanding of the ways in which social work may enhance the ethical recruitment of subjects into research studies as well as increase inclusiveness, build stronger community relationships, and enhance the overall quality of research. As social work continues to build bridges between practice and research, it is crucial for such bridging to directly incorporate the values and traditions of the social work profession, by focusing on human relationships and human dignity, promoting responsible self-determination, and challenging social injustice (National Association of Social Workers, 2008).

Vulnerability and Capacity

Capacity has been identified as the most important issue in pediatric research ethics (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1977) as well as a critical issue in research with adolescents (Berman & Field, 2004). The issue of capacity is of specific concern in the recruiting and consenting process and represents a major barrier to recruitment of adolescent participants (Kipnis, 2003). Because ethical standards require an individual to be free of undue influence and coercion and limit use of unjustifiable pressure and manipulation, specific attention must be paid to how researchers interact with potential adolescent research participants (Department of Health, 1979). However, the inclusion of social workers and social work perspectives in pharmaceutical or clinical trial research may bring up issues that directly conflict with the NASW Code of Ethics. Within the Code of Ethics (2008), one section outlines that the social worker's duty is to obtain informed consent that does not violate the terms and laws specified in both the Code and the Belmont Report (1979), where the concept of informed consent is thoroughly discussed.

Closely related to the concept of capacity is "vulnerability." Numerous definitions of "vulnerable populations" have been utilized that include criteria for how to know when a person/group is vulnerable (Hurst, 2008). The Declaration of Helsinki (1964) defined vulnerability as "…an increased likelihood of being wronged or of incurring additional harm." Similarly, the National Bioethics Advisory Commission (2001) defined vulnerability according to participation: namely, those who are not fully capable of resisting the request to become participants (e.g., prisoners or institutionalized individuals) should not be enrolled in studies merely because they are easily accessible or

convenient. I adopted the following definition of vulnerability for this study: “The ability to give or withhold informed consent and the likelihood of being misled, mistreated, or otherwise taken advantage of in research” (Iltis, 2009) as it most concisely and directly relates to the concept of vulnerability in research settings.

US federal regulations assign vulnerability as a blanket term to large groups of individuals without acknowledging their individual characteristics (C. Levine et al., 2004). For instance, merely by not having attained the legal age to consent, anyone under the age of 18 years is considered vulnerable in the U.S., despite considerable evidence indicating that older adolescents have similar levels of capacity to make decisions as adults do (R. J. Levine, 1995; Partridge, 2013; Santelli et al., 1995). This propensity to ignore individual characteristics has led to both overuse and misuse of the term, thereby systematically eliminating potential participants according to group membership rather than actual vulnerability (C. Levine et al., 2004). This policy poses problems not only because it excludes potential participants from research, but also because it potentially masks people who require meaningful protection despite being legally eligible to participate. Given the biased and systematic exclusion resulting from this use of vulnerability, it is clear that a better understanding of capacity, or an individual’s ability to make informed decisions, is needed. Indeed, improving policies regarding capacity to consent can be considered a primary means of expanding the scope of adolescent clinical trial involvement and increasing the safety of health research.

Discerning vulnerability can be even more complicated in pediatric research because of the circumstances surrounding the decision to participate in such research. When making decisions about adolescents’ research participation, a number of factors

must be evaluated. First, when recruiting minors, the research staff must recruit children's parents and obtain their *parental permission*. The requirements for parental permission and assent in the context of human subjects research are outlined in the Department of Health and Human Services Code of Federal Regulations Title 45 Part 46 and involve multiple disclosures to the subject and her/his parent, including the purpose and duration of the research, the procedures involved and if they are considered experimental, the risks, a contact for any questions, the fact that participation is entirely voluntary, and the fact that declining to participate will not render loss of other benefits or treatment (US Department of Health and Human Services, 2009). Second, the child must provide his or her *assent*, defined as "…a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent" (US DHHS, Protection of Human Subjects, 2009, 46.402 subpart B). This need to acquire both consent and assent was implemented as a safeguard to ensure that both parents and children are properly informed and willing to participate in the research project.

However, this requirement can cause problems when there is conflict between parent and child regarding participation or when parental permission is not a meaningful protection for the child (e.g., research on sensitive issues where parental involvement could prevent adolescent from participating or giving truthful responses). Current regulations award primary decision-making power to parents based solely on their children's group-level vulnerability. There are, however, circumstances wherein minors are given the opportunity to provide consent without parental permission, including research on treatments or conditions in which the adolescent typically provides consent

for themselves, such as the diagnosis or treatment for sexually transmitted diseases (STDs), contraceptive services, prenatal care, substance abuse treatment, and mental health treatment (Boonstra & Nash, 2000; Guttmacher Institute, 2015). These minor consent laws vary by state; for example, screening and treatment for STDs is permissible in all 50 states without parental knowledge or permission, but only 34 states have explicit laws relating to consent for contraceptive services (Guttmacher Institute, 2015).

These power differentials are important for social workers and other professionals that work with adolescents. For instance, depending on how adolescents and their parents are approached in the recruitment process, shared decision-making can be reduced when the social worker primarily engages the parent. Although generally accepted practice, this poses risks to adolescents' emerging sense of autonomy, self-determination, and justice and can ultimately reduce their involvement in the decision making process. Furthermore, it may pose specific problems for clinicians and researchers in ethically and effectively interacting with adolescent participants. During mid to late adolescence, emphasis needs to be placed on supporting growing autonomy and responsibility. This concept is respected and given full weight when making treatment decisions, especially for sensitive topics (e.g., STD screening and treatment, pregnancy, mental health treatment, substance abuse treatment) (Hill, 2011). The explicit distinction between when parental consent is needed and when it can be waived is a sign that even within such a complex regulatory system it is unclear why and when every person under the age of 18 is considered vulnerable. Understanding this complex system and its impacts on clinical care and research recruitment can help social workers better navigate the systems as well as advocate for their adolescent clients.

A Framework for Understanding Vulnerability in Research with Adolescents

As evidenced from above, vulnerability can be remarkably challenging to operationalize in related research. One approach would be designating every individual as having some form of vulnerability (Handmer, 2003) and therefore requiring tailored protection in certain situations. However, this might not be a reasonable definition because it is too cumbersome and time consuming to measure. Another approach is to identify specific vulnerable groups. However, this approach has the potential for stereotyping, thereby ultimately acting as a form of oppression term not adequately accounting for individual differences (C. Levine et al., 2004). A third alternative, which is perhaps the most suitable to date, is to examine the characteristics and situations that may lead to vulnerability for each specific study. Kipnis (2003) developed a framework of vulnerability to identify and categorize its differing manifestations in pediatric research participants. This framework gives researchers the ability to clarify what types of vulnerability might influence recruitment for their research projects. Kipnis suggests that vulnerability has seven main forms, as follows: (1) incapacitational, or an individual's ability to make decisions using the information at hand (i.e., their capacity); (2) deferential, or when decisions are deferred to other professions or others in power; juridic, when someone has legal authority over an individual's ability to make his or her own decisions; allocational, wherein factors such as education and poverty may impact an individual's decision; medical, which refers to how an individual feels obligated to participate due to a health condition for which there are few or unsatisfactory cures; situational, or when someone has an illness that prevents them from engaging in the

necessary deliberation for an informed decision to participate; and social, or being a member of group with a history of being socially devalued (Kipnis, 2003).

It is important to note that at any one point in time, any number of these types of vulnerability could affect an individual and may be highly dependent on the situation. For this reason, it is crucial that social workers more closely examine how vulnerability is formulated, evaluated, and addressed. In assessing vulnerability, capacity, and informed consent, social workers have a unique training and perspective that could allow them to play a useful role in protecting research participants (Kipnis, 2003). The most important form of vulnerability for social workers to consider in making determinations about informed consent is arguably incapacitational vulnerability. For adolescents, providing informed consent relies mainly on the idea of a capacity to make that decision, which is an aspect of decision making for research participation unique to adolescents. For this reason, a social work perspective of the seven types of vulnerability should seek to conceptualize incapacitational vulnerability, or capacity, as the overarching variable from which all other forms of vulnerability manifest.

Illustrating the Types of Vulnerability in Practice

As noted in the previous section, multiple types of vulnerability may be at play at one time and simple group membership should not be an identifying factor. Social workers can play a role by identifying the type of vulnerability and take a strengths based perspective in supporting that vulnerability. Starting with the overarching concept, attempting to gain greater insight into adolescent capacity would provide social workers in a research setting with a better idea of how well the potential research participant

understands the information being presented and how he/she has integrated that new knowledge into the existing frameworks of understanding that he/she already possesses.

In a research setting, adolescents who lack capacity may not be able to tell research staff what the risks and benefits of their participation are. Specifically, they might be unable to recall or understand what is expected of them if they choose to participate in the study; beyond this, they might be unaware that they have a choice to participate or be unable to make that choice based on the information provided. In these circumstances, it is ethically justifiable to exclude these adolescents from the study on the basis that they do not have adequate understanding of the relevant information needed to participate. Conversely, this may be the opportunity to provide enhanced information on the study procedures and help the potential participant to come to a decision. Deciding whether to eliminate or provide further information requires careful balance between overprotectiveness and coercion. It would help to identify specific procedures for such situations early on in protocol development.

After decisions have been made about whether an adolescent has capacity, additional steps can be taken to identify other types of vulnerability that might affect the potential participant's experience in the research setting. Adolescents with deferential and juridic vulnerability may feel compelled to participate based on relationships and perceived expectations from the research staff, parents, doctors, etc. Addressing these two types of vulnerability would require finding ways to reduce or eliminate the perceived pressure on the potential participant to help him/her feel as though he/she has a voice in the decision making process. Such methods of reducing deferential and juridic vulnerability might include common language explanations that let adolescents know that

no one expects anything of them; that it is completely their decision on if they want to participate; and that if they decide that they do not want to participate or change their mind about participating in the future, it is completely permissible and will have no impact on their relationship with the medical team, research staff, etc. The most important issue to be aware of with such types of vulnerability is that due to their status as minors, their parents' presence, and the perceived power differential inherent between research staff and participants, adolescents will always feel a baseline level of compulsory participation. Social workers are ideally positioned to screen for deferential behavior that shows misalignment between the preferences of the adolescent and what is expected of them. Throughout the informed consent process, social workers skills in building a rapport with the potential participant can help better assess for the presence of deferential or juridic vulnerability.

Concerns of coercion are common in all types of human subject research(Largent, Grady, Miller, & Wertheimer, 2012; Oakes, 2002), and this fear is compounded when considering adolescent participation in research (Brody & Waldron, 2000). Kipnis's (2003) framework allows for social work researchers to examine the issues of perceived power differentials and possible financial inducement more deeply, to truly consider the division of benefits received as well as the fairness of the situation as a whole. Issues of allocational vulnerability go far deeper than remuneration for research participation, and defining, identifying, and correcting this type of vulnerability provides one of the greatest challenges to researchers looking to design ethically defensible research protocols with adolescents. However, it is this difficultly that plays into social work's natural strength to quickly assess and remedy issues with power imbalance, resource allocation, justice, and

fairness. Within the realm of allocational vulnerability, concerns over payments functioning as an inducement should be considered; however, a broader focus on the just recruitment of adolescent subjects should consider access to research, fair compensation for time and expertise, and ensuring that the target group of study is characteristically similar to the group that would benefit from the research. Ways of controlling for this type of vulnerability include conscious research design as well as enhanced interactions between research staff, parents, and adolescent participants.

The medical and situational types of vulnerability are of concern in adolescent research because they present a potential lack of time and available options to make an informed decision (Kipnis, 2003). This is particularly true with adolescent cancer diagnoses, where the only option for treatment might be a therapeutic trial that needs to begin immediately on diagnosis. In this case, both the medical and situational conditions may cause adolescent and their parents to feel forced into a decision because of such a lack of time or options. However, this exigency coupled with the overwhelming nature of such a sudden or traumatic situation fits well into medical social work's natural role as communication facilitators and enhancers. When medical and situational vulnerabilities are of concern, social workers are a necessary force to ensure that all parties are given as much helpful information as possible in a caring and empathic manner. It is social work's specific focus on the role of the individual within a large series of connected systems that can help to alleviate these tensions.

Summary of vulnerability

Capacity emerges as a key concept in understanding and contextualizing the different forms vulnerability. Utilizing Kipnis's (2003) framework (Figure 1) provides a

foundation to understanding the variety of potential problems with recruitment; indeed, it is not until these factors are considered in relation to each other that a hierarchical model with capacity functioning as the dominant concept emerges. Although the other six forms of vulnerability are important to assess and monitor, capacity ultimately informs what impact those other factors have on an individual's decision-making process. By better understanding how capacity functions within the research recruitment process, social workers would be better able to assess the impact and effect of the various other forms of vulnerability.

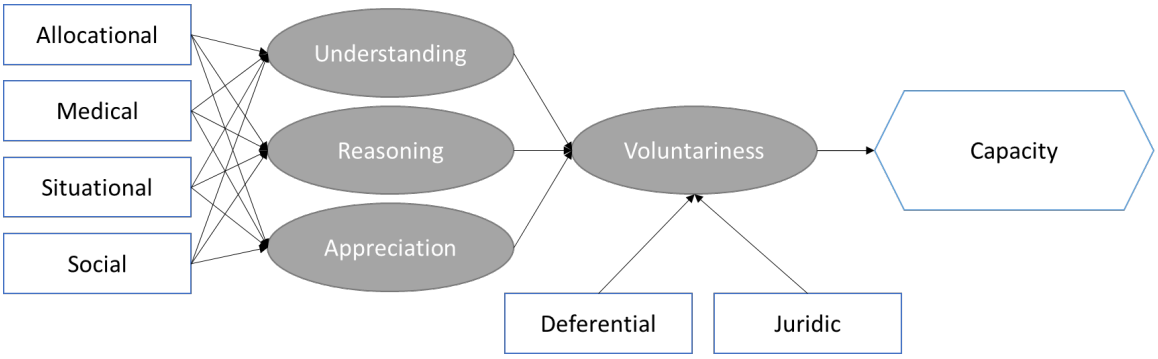

Figure 1. Conceptualization of Kipnis's (2003) vulnerability framework and requirements for consent.

Next Steps for Social Workers

Social workers interested in research with vulnerable populations should first seek to become better informed and involved in all aspects of research. Fortunately, the interdisciplinary nature of social work practice and education provides those interested in accessing research with the necessary skillset to maneuver the complexities of biomedical research settings. A change in mindset to see research as an extension of practice as opposed to a completely separate field would be a good first step. Far too often in BSW and MSW education, it is implied that research and practice is a dichotomous choice. It

might be helpful to begin teaching research *as* practice (and vice versa), which could partially increase the number of social workers involved in research. However, this educational change must occur from the top down; social work programs should provide more opportunities for social work students to interact professionally with other medical professions, statisticians, and bench scientists. In other words, students must be exposed to interdisciplinary collaboration as the norm from day one instead of being expected to navigate such collaboration merely upon entering the job market. Allowing students from a wide set of disciplines to interact would help enhance the interdisciplinary approach that many health education programs are starting to enact. Furthermore, this change would provide students with a wider variety of research/practice outlets, thereby allowing them to naturally develop insights into how they might become more involved in health care research and practice settings.

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V. Banking the future: Adolescent capacity to consent to biobank research

Introduction

Pediatric biobanks are important to understanding the long-term consequences of pediatric disease as well as discovering methods to prevent adult diseases during childhood. Additional reasons for looking more closely at adolescent consent in biobanking research are direct results of the nature of indefinitely storing samples from minors that will age into adults. This simple reality highlights an overarching need for adolescents to be directly involved in the consent process from the very beginning of enrollment. Beyond this, there is a direct need to support developing autonomy in minors that shows a respect for them as individual's who can have a direct say in their participation in research. Biobanking includes the long-term storage of samples from individuals with linkages between the biological sample and personal health information. Samples in these facilities can include any type of biological material: blood, feces, urine, cell cultures, saliva, etc. (Spriggs & Fry, 2015)

The main difference between biobanking studies and general clinical research is the collection and indefinite storage of biological information linked to various aspects of an individuals personal health record as opposed to an individual agreeing to provide information and or samples for a clearly defined research purpose. In biobanking there is no defined research question the subject is agreeing to participate in, they are instead agreeing to provide a sample that can be utilized for any purpose. This difference in intent and purpose of sample collection poses specific challenges for consent for all potential participants, minor or not. This challenge is compounded when considering developmental trajectories as well as samples can be collected from minors and then

finally used in a research study after they have reached the age majority. While this idea of consent is considered a risk in biobanking studies it should also be noted that the potential for benefit could be high. This paper will discuss ways in which we may be able to go about reconciling concerns about consent with adolescent participation in biobanking research in hopes of tipping the scale of risk/benefit to show that the potential gains in collecting adolescent and pediatric samples (personalized medicine, better understanding the life-course of adult diseases, and potential use of genetic material in cures for diseases to name a few) far outweigh the risks associated with sample collection.

Similarly to adult biobanking studies, consent is of great concern in pediatric biobanking. Current assent procedures do not take into account pediatric capacity to provide consent and does not take into account the developmental differences between younger pediatric populations and older adolescents. Self-consent from older pediatric populations may be important in showing respect for growing autonomy as well as allowing adolescents' to have a direct say in the long-term banking of their biological material as well as linkages with personal health information. For instance, while a 15 year old may understand why they are giving a biobank a sample of their blood, they will have no way of knowing what happens to their blood and how the information is used later on down the line. Specifically of concern in pediatric biobanking is how samples are utilized over time and the evolving nature of capacity to provide informed consent.

Ethical concerns around voluntariness and the consent process have been described for adult biobanks (Anderson & DuBois, 2012; Brothers & Clayton, 2009). These concerns are even more important in pediatric populations due to the evolving

nature of capacity and the longitudinal banking of samples collected while the donor was a minor and potentially being used after they have reached the age of majority. This also brings up concerns about how/when/if participants should be contacted when their samples are used in different study types (Brothers & Clayton, 2009).

Due to the majority of issues with pediatric biobanking centering on the consent process it is important to first evaluate the components that make up informed consent. Capacity to consent is a concept that generally refers to an individual's ability to make an informed decision about participation in research or treatment (Clausen, 1991; Weithorn & Campbell, 1982). In this research, the idea of capacity will be operationalized through four criteria that can be thought to influence an individual's capacity to give or withhold consent. The criteria for capacity are based on Applebaum & Roth's (1982) framework and include 1) utilizing understanding of the information relevant to make a decision, 2) appreciation of the significance of the decision (e.g., that the decision truly is one's own), 3) the ability to manipulate the information rationally and engage in reasoning, and 4) the ability to communicate the intended decision by making a choice.

While adult research has validated a number of tools for individuals with dementia and severe mental illness to capture waning capacity, there are no adolescent specific tools to capture evolving capacity. For this reason, developing adolescent and pediatric capacity assessment tools that seek to systematically assess capacity are of fundamental importance to ensuring research ethics. Development and successful implementation of such tools will provide researchers with contextualized information on participants' capacity to consent relative to the specific study they are attempting to enroll in. This study adapted the MacCAT-CR for use with adolescents' because of the

emerging data to support the success of the MacCAT-CR with a wide variety of adults. Additionally, the MacCAT-CR provides much more information to researchers and clinicians compared to other capacity assessments, which do not cover all four functional areas thought to be necessary to provide a valid informed consent.

Methods

Study instruments

MacCAT-CR. The MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) is a comprehensive assessment tool for adult capacity assessments (Appelbaum & Grisso, 2001). There are emerging data supporting its use with adolescents (Hein et al., 2012; Hein et al., 2014; Koelch, Prestel, Singer, Schulze, & Fegert, 2010). The effectiveness of the tool stems from its focus on the four criteria thought to be required for consent: factual understanding of the issues, appreciation of the nature of the situation, rational manipulation of information, and evidence of choice (Appelbaum & Roth, 1982; Kim, 2010; Turrell, Peterson-Badali, & Katzman, 2011). Use of the MacCAT-CR with chronically ill adults has been shown to be a reliable and effective way to assess patient capacity for clinical trials (Karlawish, Casarett, & James, 2002). This project sought to evaluate the effectiveness of the MacCAT-CR on a mixed sample of healthy and chronically ill children and adolescents. Effectiveness with chronically ill participants was important to assess as these are the pediatric populations most likely to participate in clinical trials research (Koelch et al., 2009). The MacCAT-CR was developed for use in participants with waning capacity, but emerging data has applied the tool to child populations to evaluate emerging capacity (Karlawish, 2008; Kim & Caine, 2002; Palmer et al., 2005). This presents a unique opportunity for those

wishing to start biobanking with adolescent populations as (to date) no adolescent specific biobanking studies have been done.

The tool utilizes semi-structured, open-ended questions to assess a potential participants ability to comprehend study specific information based on the four criteria thought to be necessary for consent. Each question is scored on a 0-2 scale where 0 indicates that the respondent did not correctly answer any portion of the question, 1 indicating that they were able to identify some portion of the correct answer, and 2 indicating that they were able to provide a response that captured all ideal aspects of a response. Since each version of the MacCAT-CR needs to be study specific in order to assess capacity, multiple individuals with topic expertise were consulted in developing the scoring rubric.

Comprehensive breakdown of the modified MacCAT-CR

Understanding
What is the purpose of the research project I described to you?
How long will the research project last?
What sorts of things will be done with people who agree to be in the study?
What sorts of things will people have to do if they agree to be in the study?
Do you believe this study is primarily for research or primarily for treatment?
What might doctors learn about diseases if people decide to be in this research project?
In what way might people who volunteer be better off by being in this research project?
Is it possible that being in this study will not have any benefit to you?
What unpleasant side effects might people experience in this study?
What uncomfortable things are done to people in the study?
Who will pay for your medical care if you are injured as a direct result of participating in this study?
What will happen if a person refuses to be in the research project?
If you withdraw from this study, will you still be able to receive regular treatment?
Appreciation
Do you believe that you have been asked to be in this study primarily for your personal benefit?
What makes you believe that this was/wasn't the reason you were asked?
What do you believe would happen if you were to decide not to be in this study?
What makes you believe that this would happen?
Reasoning
What makes you want to consider participating in this study?
How might [risk or benefit] affect your daily life?
Expressing a choice
Now that we've discussed everything, do you think you want to participate?

Figure 2. MacCAT-CR items

Specifically when assessing adolescent capacity to consent we were interested in how social/behavioral factors played into an adolescents ability to consent, and if there was a difference in those relationships between healthy and chronically ill participants. There is emerging information on the association between health literacy, family affluence, and age on capacity, and we we're interested to see how these factors would impact capacity assessment scores on the two different adolescent populations.

REALM. Health literacy has been identified as one of the most important emerging constructs in health care communication (Dumenci, Matsuyama, Kuhn, Perera, & Siminoff, 2013), and is currently viewed as a key factor in determinates of health care utilization and outcomes (Sentell, Baker, Onaka, & Braun, 2011). The REALM is one of

the highest utilized assessments to assess health literacy (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011).The REALM consists of 66-items and is currently the most utilized test of health literacy in research settings (Dumenci et al., 2013). The 66-items administered take less than 5-minutes to administer and produce a raw score than can be quickly converted into five different reading grade equivalencies. The REALM is administered by having participants read down a list of common medical terms, when a word is pronounced correctly the participant receives one point. If a word is not attempted, mispronounced, or altered in anyway the participant does not receive a point for that word. The test relies heavily on an individual's ability to read and sound out words that range from common to higher complexity medical terminology. An example of words on the REALM are: fat, flu, pill, colitis, osteoporosis, jaundice, anemia, and constipation.

FASII. The family affluence scale II is a self-reported measure that has been validated for use in adolescents and is considered to be a more accurate measure of adolescents perceptions of SES than traditional self-report measures (Boudreau & Poulin, 2009; Boyce, Torsheim, Currie, & Zambon, 2006; Currie, Elton, Todd, & Platt, 1997; Currie et al., 2008). Traditional SES scales administered to adults were found to be inaccurate when utilized with adolescents due to differences in adolescents' perceptions of SES and their parents' true status. Development of the FASII attempted to identify related questions that would be easy to know and articulate while also corresponding directly to actual SES of the larger family unit. The FASII is a quickly administered tool that focuses on objective statues that exist within households; does the respondent have their own bedroom, how many cars does the family have, how many vacations a year

does the family go on, and how many computers does the family own. These four items form a scale that ranges from 0-9 with 0-2 corresponding with low affluence, 3-5 with middle affluence, and 6-9 indicating high affluence when compared to the global population (Boyce et al., 2006).

Chronic illness

Because adolescents with chronic illness may differ from healthy adolescents in ways relevant to capacity to consent (e.g., different developmental course, experience with clinical procedures), it is necessary to separately assess their capacity and evaluate it in comparison to otherwise healthy participants. Due to concerns of coercion and other types of medical, situational, and developmental vulnerabilities thought to be present in pediatric and adolescent research (Kipnis, 2003), we sought to examine the impact of chronic illness on potential research participants capacity to consent to research participation. Chronic illness in this study was measured using three self-report items that asked participants' if they (1) had a chronic illness, (2) if they took daily medicine, and (3) if they had ever spent the night in the hospital. Questions of chronic illness and experience with the medical system served as an easy way to evaluate relationships between the lived experiences of adolescents and what (if any) impact this has on decision making.

Participants

This study included adolescent aged children from ages 12-24. Primary inclusion criteria were age and ability to read and speak English. Exclusion criteria included individuals who were obviously intoxicated, high, or altered as well as individuals obviously lacking the capacity to understand study procedures due to severe medical

illness or significant cognitive impairment, as assessed by the parent, if the participants were minors, or the interviewer based upon the participants' ability to understand and give informed consent for the study. This study included a broad community-based recruitment strategy pulling in adolescents from universities and community clinics. The institutional review board approved the research protocol, adolescents provided consent, and parents/guardians provided permission for those under 18 years of age.

Recruitment

The study sample is comprised of a broad sample of individuals recruited primarily in adolescent health clinics and throughout the community. Multiple methods of recruitment were used, including clinic recruitment, convenience sampling, and snowball sampling, This approach allowed us to recruit adolescents across a range of socio-demographic characteristics and life experiences. This recruitment approach was employed to be similar to those used for clinical and behavioral research with healthy adolescents.

Procedures

A structured instrument collected information on demographic, developmental, medical history and health literacy from participants. Interviews were conducted in a private location of the participant's choosing, and participants were reminded that they could refuse to answer any question for any reason. Then the interviewer went through three separate informed consent processes for different types of clinical studies that were presented as if the participant were planning on participating in each study. After each informed consent process, the interviewer administered study-specific measures of capacity to consent. Participants were given a $20 gift card for their participation.

Statistical analysis

Statistical analyses were performed with SPSS version 23. Demographic characteristics and initial bivariate analyses of main study measures were compared utilizing correlation. A receiver Operating Characteristic (ROC) curve was produced to evaluate the performance of the MacCAT-CR as a binary classifier of capacity or no capacity based on variables found to be significantly related in bivariate analysis. Use of the ROC curve was a deliberate attempt to use a mathematical approach in developing an objective cutoff score for ease of use in clinical settings. In this analysis, the scores of the MacCAT-CR were dichotomized based on numerical threshold value arrived at through content experts evaluations of the various dimensions. Regression analysis was utilized to evaluate predictors that impact overall MacCAT-CR score. Criterion and convergent validity were evaluated to assess how well the MacCAT-CR was able to measure capacity in the sample through comparison to clinical interviews. Group consensus was utilized to ensure homogeneity amongst scores across all items where each interview was coded twice, when differences in raters scoring of items occurred the group listened to the transcript together to determine a consensus score.

Results

Participants

We enrolled and interviewed 78 adolescents' ages 12-24 (Mean=17.00, *SD*=2.84) who were mostly female (62.5%) in a 70-90 minute scored semi-structured interview. For the overall sample, participants had a mean score of 61 on the Rapid Estimate of Adult Learning in Medicine (REALM), or approximately 8th-9th grade reading level, which represents a similar or higher than average score than reported adult scores (Davis et al.,

1994; Kaphingst, Ali, Taylor, & Kass, 2010). When looking at participants' socioeconomic status the mean score was 6.53 (*SD*=1.79) corresponding to upper middle class, with a wide amount of distribution of scores across all possible values of the scale. 23.6% of the sample responded as having some type of chronic illness, as well as 31.9% reporting that they had stayed overnight in the hospital due to being sick, and 44.4% reporting taking daily medicine other than vitamins or supplements.

Summary of outcome and predictor variables

Variable	range	mean score (SD)
MacCAT-CR Summary score	0-34	30.6 (4.7)
understanding subscore	0-20	16.4 (3.0)
appreciation subscore	0-6	5.3 (1.1)
reasoning subscore	0-8	6.8 (1.5)
REALM	0-66	61 (6)
FAS	0-9	6.5 (1.8)
AGE	12-24	17.0 (2.8)

Table 1. Summary of outcome variables

Capacity to consent

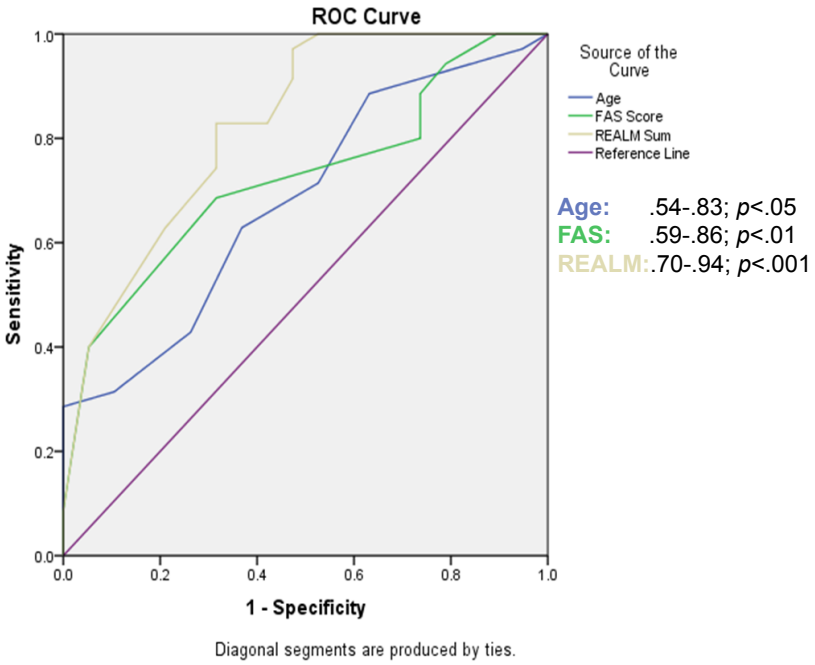
For the MacCAT-CR the overall raw score across the sample was 30.6 (*SD*=4.7) out of a total of 36 possible points. This value reflects that within our sample overall decision-making capacity was high. When looking at the sub-scores of the MacCAT-CR based on the four different components of capacity, participants had a mean score of 16.4 (*SD*=3.0) on the understanding section of a possible 20 points, 5.3 (*SD*=1.1) on the appreciation section with a highest possible score of 6, and 6.8 (*SD*=1.5) on the reasoning

section of a possible 8 points. One hundred percent answered affirmatively to the question, “Do you have a choice to participate in the study?”

Age, health literacy and family affluence

Correlation analysis also supported a relationship between FAS, age, and REALM scores and the different dimensions of the MacCAT-CR, which were all positively correlated. The one exception was for FAS score and the understanding portion of the MacCAT-CR, which approached statistical significance.

We also wanted to examine the MacCAT-CR not only as a tool that could give researchers a better insight into potential participants’ capacity, but also as an objective tool to discern capacity. For this we relied on individuals with expertise in capacity to determine a cutoff scoring value that would force a dichotomy of “has capacity” and “lacks capacity.” Utilizing concurrent criterion validity as well as construct validity we developed a receiver operating characteristic (ROC) curve to help illustrate how the predictor variables found to have significant correlations helped predict whether an individual would have capacity or not. Values for FAS and age were classified as “fair” tests for separating individuals into the dichotomous capacity outcome, and helped to arrive at a score of 28 for differentiating between those who have capacity and those who are lacking capacity. The score of the REALM emerged as a “good” test for correctly classifying adolescents’ level of capacity. Overall this test indicates that the modified MacCAT-CR is sensitive and specific enough to adequately classify individual levels of capacity.



Graph 1. ROC curve results

Based on our results from correlation analysis we utilized SPSS to do a stepwise linear regression. The second model consisted of REALM and FAS scores as predictive variables and had an R^2 of 56.4%, other predictor variables were removed as they failed to reach the level of significance required. Beta values for both variables were .68 for the REALM and .263 for FAS. Age was removed from the final model as it failed to remain significant in the presence of the FAS and REALM scores.

Multiple Linear Regression for MacCAT-CR Biobanking Scores

Predictor Variable	B (SE)	β	*t*
REALM	.57 (.07)	0.68**	7.81
FAS	.70 (.23)	0.26*	3.02
R^2		0.56	
F		37.45	

* *p*<.01 . ***p*<.001.

Table 2. Linear regression results

Interpretation

Adolescent capacity to consent to biobanks was similar to scores similar range as normal adults in similar studies using the MacCAT-CR (Appelbaum & Grisso, 2001; Hein et al., 2012; McDermott, Gerbasi, Quanbeck, & Scott, 2005), and most strongly associated with family affluence and health literacy. This contrasts with the current federal regulations, which use only age as their criteria for providing consent, and provides insights into ways to ethically involve minors in consent for biobanking and similar research. This initial finding is suggests that using standardized measures of family affluence and health literacy may provide greater insights on capacity.

Chronic illness was not found to be a significant factor in capacity to consent and went against our initial hypothesis that the differing level of exposure to health care settings and familiarity with health care professionals would positively impact adolescents' ability to provide consent. However, this may have been an issue of power due to only having 23.6% of the sample of 78 having a chronic illness. Future studies should focus on recruiting higher numbers of chronically ill and healthy participants as well as more participants with a greater severity of chronic illness. Our sample consisted mainly of participants' with asthma and diabetes, two diagnoses with a range of severity and illness experiences.

Conclusion

The benefits of adolescent and pediatric biobanking far outweigh the potential risks associated with informed consent, potential losses of confidentiality, and concerns centered on the longitudinal nature of pediatric biobanking. Specific benefits include the ability to gain information about diseases specifically related to adolescent populations, safer inclusion of adolescents in research protocols, and showing respect for emerging adolescent autonomy. Although the potential benefits may outweigh the potential risks, research protocols including informed consenting processes need to be systematically developed so that the potential participant's ability to provide informed consent can be effectively assessed. Our efforts to find a minimally acceptable level of capacity to consent for adolescents provided insights for future consideration including the need to develop study specific measures of capacity, deeper insight into the interactions between the four criteria considered necessary for capacity are needed, and developing a cutoff score for capacity determinations may be more complicated than a simple additive formula.

For those lacking capacity, enhanced informed consenting processes should provide adequate protections and education. Tough decisions need to be made when considering adolescent participation especially with individuals who lack capacity to provide informed consent. Should research be closed off to these individuals? Or is the research team obligated to provide additional information and education to these individuals in a way that will functionally raise their level of capacity to consent? Although formalized assessment of an adolescent's is only the first step in this process, this information should benefit researchers by better understanding the participants who

come into their studies as well as quelling anxieties centered on vulnerable population research participation.

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VI. Conclusion

The field of social work is built upon the idea and spirit of making a difference, changing things for the better, and giving voice to those who otherwise may not have an outlet to share their experience. Far too often in this field we force artificial divisions or choices upon our students and practitioners; research, clinical, or practice. I have heard these three categories mentioned before in countless conversations amongst students at all levels of education, and I could not possibly disagree more with the presentation that these are mutually exclusive categories. As I have come to understand social work, thankfully through a great amount of exposure to other countries views on what social work is and does (thanks mostly to the Korean cohort in my program), I take personal issue with limiting a field so expansive, so interdisciplinary by design, and so focused on achieving outcomes that transcend the very categories ascribed to it. This project represents a culmination of those ideas put into practice.

The first article presented was a review of a bioethical framework for understanding pediatric and adolescent vulnerability in research. This article was the basis for developing the second article that focused on testing adolescent capacity to consent to research. To understand the different types of vulnerability one might experience in research settings it is important to have a multidimensional understanding of the ways in which researchers and others in the medical professions have come to understand capacity. The two concepts are fundamentally linked in a reflexive and constantly evolving state responsive to a wide variety of interpersonal and environmental factors. Whereas the first article walked through the different types of vulnerabilities and ways social work could act to identify/reduce their impact on individuals, the second

article focused on evaluating the ways in which perceived vulnerabilities impacted individuals enrolling in a more complex biobanking study. In this study the data showed that family affluence (a measure of socioeconomic status) and adolescents' level of health literacy were two of the most important factors in whether or not an adolescent would have capacity to consent. This finding begins to call into question the age-based criterion currently utilized in research participation regulations. This is of importance to illustrate that our current age-based definitions of child and adult may be a forced artificial dichotomy that is not representative of the ideas and values our research regulations and ethical codes are seeking to establish.

Both the conceptual and data-driven articles reflect the current social climate—across numerous domains we are seeking to give voice to individuals who have previously been excluded. In a time where we are seeking to develop and embrace more inclusive categories that better explain individual characteristics is not time to revisit our reliance on age as a criteria for decision-making? The work presented hopefully (at the very least) begins to call into question the foundation upon which those policies are built.

Shifting to think of capacity as a moving target is of special importance for those interested in research ethics, particularly research with populations identified as vulnerable, at risk, or hard to reach. Developing new ways to enroll individuals in a way that provides greater privacy, respect for diverse opinions, enhanced value to the individual, and opportunities to share unique experiences is by far my greatest interest when considering my future research trajectory. I have been very fortunate to get opportunities to work in spaces that are truly interested in making research more reflective and helpful to the populations they involve. My dissertation project was

graciously funded through a competitive grant from the Clinical and Translational Sciences Institute that focuses on conducting scientific research in a way that makes the results applicable and understandable to the population being studied. A key component to this type of research is interdisciplinary communication and collaboration, which are components I hope to integrate into my future research. Interdisciplinary work is a hallmark of social work and one that has helped me move from interdisciplinary understanding of issues to transdisciplinary.

Using a wide lens perspective to evaluate methodological issues in the research process for vulnerable and stigmatized populations is my greatest interest. Luckily for me, this interest easily integrates into a wide variety of fields and types of research and would not have been possible without my exposure to medicine, psychology, sociology, public health, and education research methods. This dissertation process has provided me with the opportunity to learn how to navigate complex and overlapping systems to design and implement translational research directly focused on enhancing the overall research experience for a wider variety of research participants.

My future research will focus heavily on the methods we use to examine hidden and hard to reach populations. This feels like the next most logical extension of my work and interests, and I will seek to illuminate new ways to reach and effectively study highly vulnerable populations. My post-doctoral position will allow me to do just that. While I have worked solely with adolescents for the past five years, my next role will give me an opportunity to expand what I have learned to other vulnerable populations.

Appendix A—Measures

Children with Special Health Care Needs (CSHCN) Screener

1. Do you currently need or use **medicine prescribed by a doctor** (other than vitamins)?
   Yes □ Go to Question 1a
   No □ Go to Question 2

   1a. Is this because of ANY medical, behavioral or other health problem?
      Yes □ Go to Question 1b
      No □ Go to Question 2

      1b. Is this a problem that has lasted or is expected to last for *at least* 1 year?
         Yes □
         No □

2. Do you get extra help in school, work with a therapist or counselor, or spend more time at the doctor's office than other kids your age?
   Yes □ Go to Question 2a
   No □ Go to Question 3

   2a. Is this because of ANY medical, behavioral or other health problem?
      Yes □ Go to Question 2b
      No □ Go to Question 3

      2b. Is this a condition that has lasted or is expected to last for *at least* 1 year?
         Yes □
         No □

3. Are you **limited or prevented** in any way in your ability to do the things other kids your age can do?
   Yes □ Go to Question 3a
   No □ Go to Question 4

   3a. Is this because of ANY medical, behavioral or other health problem?
      Yes □ Go to Question 3b
      No □ Go to Question 4

      3b. Is this a condition that has lasted or is expected to last for *at least* 1 year?
         Yes □
         No □

4. Do you need or get any kind of **special therapy**, such as physical, occupational or speech therapy?
   Yes □ Go to Question 4a
   No □ Go to Question 5

   4a. Is this because of ANY medical, behavioral or other health problem?
      Yes □ Go to Question 4b
      No □ Go to Question 5

      4b. Is this a condition that has lasted or is expected to last for *at least* 1 year?

Yes □
No □

5. While in school or at home, do you often get into trouble, have a hard time keeping your grades up, or feel unhappy or depressed for which you need or get **medicine or counseling**?

Yes Go to Question 5a
No □

5a. Has this problem lasted or is it expected to last for *at least* 12 months?

Yes □
No □

Have you ever been told that you have any of the following conditions?

____ Anemia
____ Bleeding
____ gynecological-menstrual problems
____ PCOS/Hormonal problems
____ Back problems
____ Rheumatologic problem/arthritis
____ Musculoskeletal problems
____ Headaches/Migraines

____ Chronic fatigue
____ Chronic pain
____ Diabetes
____ Cancer/tumor

____ Bowel/Stomach problems

____ Epilepsy or seizures
____ Eye problems
____ Hearing problems
____ Fever
____ Asthma
____ Heart problems
____ Kidney/Bladder trouble
____ Lung disease
____ Liver disease/hepatitis
____ Skin disorders
____ Substance abuse
____ Anxiety
____ Depression
____ ADHD

____ Any other type of disease/condition not listed:_____

Note to interviewer—clarify any condition above, if minor, then (-)

For any of the above conditions, what treatment do/did you need (medicine, therapy, etc.)?

_____
_____

How much did the above condition impact your daily functioning? (list scale of 1-5 for each condition—1 being not at all—5 being prevented from engaging in school, family, play, etc. list number next to condition)

PHQ-9

Over the last 2 weeks, how often have you been bothered by any of the following problems? (Please circle a number to indicate your answer)

PHQ-9	Not at all	Several days	More than half the days	Nearly everyday
1. Little Interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself down	0	1	2	3
7. Trouble concentrating on things, such as reading or watching TV	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3
For Office Use				
10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at homes, or get along with other people?	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult

Demographics

Please put an "X" in the box to select your answer.

Correct: **Incorrect: ☑**

(12-13 year olds)

1. Age: _____ years

2. Ethnicity:
   - White
   - African American
   - Latino
   - Asian or Pacific Islander
   - Other

3. Gender
   - Male
   - Female
   - Transgender or other

4. Grade
   - 6th
   - 7th
   - 8th
   - 9th
   - 10th
   - 11th
   - 12th
   - Graduated High School
   - Received a GED
   - Not in school but haven't graduated or received GED
   - College or technical training
   - College Degree (Bachelor's, Associate's)

5. Have you ever had to stay overnight in the hospital because you were sick?
   - Yes
   - No

6. Do you have any chronic illnesses (diabetes, asthma, cancer, etc.)?
   - Yes
   - No

7. Do you take any daily medicines (other than vitamins or supplements)?
   - Yes
   - No

8. During the past 30 days, on how many days did you smoke cigarettes?

0 days

1 or 2 days

3 to 5 days

6 to 9 days

10 to 19 days

20 to 29 days

All 30 days

9. During the past 30 days, what is the largest number of alcoholic drinks you had in a row, that is, within a couple of hours?

I did not drink alcohol during the past 30 days

1 or 2 drinks

3 drinks

4 drinks

5 drinks

6 or 7 drinks

8 or 9 drinks

10 or more drinks

10. During the past 30 days, how many times did you use marijuana?

0 times

1 or 2 times

3 to 9 times

10 to 19 times

20 to 39 times

40 or more times

11. Skip

12. Skip

13. During the past 12 months, how many times did someone you were dating or going out with physically hurt you on purpose? *(Count such things as being hit, slammed into something, or injured with an object or weapon.)*

I did not date or go out with anyone during the past 12 months

0 times

1 time

2 or 3 times

4 or 5 times

6 or more times

14. During the past 7 days, how many times did you eat fruit? (Do **not** count fruit juice.)
    I did not eat fruit during the past 7 days

    1 to 3 times during the past 7 days

    4 to 6 times during the past 7 days

    1 time per day

2 times per day

3 times per day

4 or more times per day

15. On an average school night, how many hours of sleep do you get?
    4 or less hours

    5 hours

    6 hours

    7 hours

    8 hours

    9 hours

    10 or more hoursDoes your family own a car, van, or truck?

    Yes, one No

    Yes, two or more

16. Do you have a bedroom for yourself?
    Yes No

17. During the past 12 months, how many times did you travel away on holiday with your family?
    Not at all One

    Once Two

    Twice More than two

    More than two

18. How many computers does your family own?

    None

REALM

Instructions:

1. Examiner should say to the subject:

   > "This survey is to help us figure out the best type of patient education materials for you. The survey only takes 2 to 3 minutes to do."
2. Give the subject a laminated copy of the "REALM" Patient Word List.
3. Examiner should hold an unlaminated "REALM" Score Sheet on a clipboard at an angle so that the subject is not distracted by the scoring procedure.
4. Examiner should say:

   > "I want to hear you read as many words as you can from this list. Begin with the first word on List 1 and read aloud. When you come to a word you cannot read, do the best you can or say "blank" and go on to the next word."
5. If the subject takes more than five seconds on a word, say "blank" and point to the next work, if necessary, to move the subject along. If the subject begins to miss every word, have him/her pronounce only known words.
6. Count as an error any word not attempted or mispronounced.
7. Count the number of correct words for each list. Total the numbers.

List 1	List 2	List 3
Fat	Fatigue	Allergic
Flu	Pelvic	Menstrual
Pill	Jaundice	Testicle
Dose	Infection	Colitis
Eye	Exercise	Emergency
Stress	Behavior	Medication
Smear	Prescription	Occupation
Nerves	Notify	Sexually
Germs	Gallbladder	Alcoholism
Meals	Calories	Irritation
Disease	Depression	Constipation
Cancer	Miscarriage	Gonorrhea
Caffeine	Pregnancy	Inflammatory
Attack	Arthritis	Diabetes
Kidney	Nutrition	Hepatitis
Hormones	Menopause	Antibiotics
Herpes	Appendix	Diagnosis
Seizure	Abnormal	Potassium
Bowel	Syphilis	Anemia
Asthma	Hemorrhoids	Obesity
Rectal	Nausea	Osteoporosis

Incest	Directed	Impetigo

Semi-structured MacCAT-CR Interview Guide

Pharmaceutical consent:

A migraine headache is a type of headache that may come with symptoms like feeling sick to your stomach, throwing up, or sensitivity to lights. For this consent, I'd like you to imagine that you have migraine headaches, and your doctor has told you about this research project for a migraine medicine.

Take a few minutes and read this consent form. Afterwards, we will go over it and I will ask you some questions to check your understanding.

Understanding

The purpose of this study is to test the safety of MigrainaGon and how well it works in adolescents and young adults. This study will last for 12 weeks. Subjects will have an initial study visit where they will have a physical exam and a blood draw. They will take the first dose of medicine in the clinic. When they go home, they will take the medicine when they have a headache and write down how much pain they feel after 30 minutes, 1 hour, and 2 hours.

Do you have any questions about what we read?

a) What is the purpose of the research project I described to you?
b) How long will the research project last?
c) What sorts of things will be done with people who agree to be in the study?
d) What sorts of things will people have to do if they agree to be in the study?

It is important for you to understand that the project in which you have been asked to participate in a research project. That means its main purpose is to help the doctors figure out whether the new medication can help some people with migraine headaches. The main purpose is not to find out whether it works for people in the study, as it would be if this were ordinary treatment.

Do you have any questions?

e) Do you believe this study is primarily for research or primarily for treatment?

Because this is a research project, not ordinary treatment, the doctors will be doing things that they would not do in ordinary hospitals/clinics, like those where you may have been treated before. For example, some people who are in this project will get the new medication, but others will get a sugar pill instead – a pill with no medicine in it (called a placebo). Whether they get the new medication of the sugar pill will be decided by chance. The doctors will know if the subject is getting the new medication or the placebo. The subjects will not know. All these things are done to see whether the new medication is better than no medication at all.

Do you have any questions?

f) Will all people in the project get the study medication?
g) How will it be determined what kind of pills each of the people in the project receive?
h) Who will know what kind of pill each person in the study is taking?

There are a few benefits of participating in this study. Doctors will learn more about how this migraine medicine works in young adults and people under the age of 18. You may have pain relief while taking the drug, but that is not guaranteed.

Do you have any questions?

i) What might doctors learn about the treatment of migraines if people decide to be in this research project?
j) In what way might people who volunteer be better off by being in this research project?
    a. Is it possible that being in this study will not have any benefit to you?

There are also risks associated with participating in this study. Subjects experienced physical side effects, like tingling sensation, weakness, nausea, and dizziness. Some people might have a life-threatening reaction called serotonin syndrome if they are taking anti-depressant medicine at the same time.

Subjects will also have their blood drawn at the initial visit.

Do you have any questions?

k) What unpleasant side effects can the medication cause in some people?
l) What uncomfortable things are done to people in the study?

No one has to be in this study. People who agree to be in this research can change their minds at any time. If they don't agree to be in this study or if they decide to stop, they will be referred to their doctor for the usual treatment for migraines.

m) What will happen if a person refuses to be in the research project, or decides to stop once they have started?
    a. If you withdraw from this study, will you still be able to receive regular treatment?

<u>Appreciation</u>

n) Do you believe that you have been asked to be in this study primarily for your personal benefit?
    a. What makes you believe that this was/wasn't the reason you were asked?
o) Do you believe you could get the sugar pill?
    a. What makes you believe this could/couldn't happen to you?
p) What do you believe would happen if you were to decide not to be in this study?
    a. What makes you believe that this would happen?

<u>Expressing a Choice</u>

As you know, you have been invited to participate in a research project testing a medication for the treatment of migraine headaches. Do you think you are more likely to want to participate or more likely to not want to participate?

You think that you are more likely to want to/not want to participate. Tell me what it is that makes that option better than the other option.

q) What makes you want to consider participating in this study?

We've talked about some of the risks of the study, like [mention risks they said], and some of the benefits, like [mention risks they said]. What are some ways that these could affect your everyday activities if you participate in the research project?

r) How might [risk or benefit] affect your daily life?

A few moments ago you told me that you were/were not likely to want to participate in the research project. What do you think know that we have discussed everything?

Biobank consent:

For this consent, I'd like you to imagine that you are at the doctor's office for a routine visit. Your doctor approaches you with a research study called "The Indiana Biobank" and asks if you would be interested in participating.

The purpose of this study is to collect a biological sample, like blood, from healthy and sick people to use in future research. We will collect a small amount of blood from a vein in your arm. This sample will be stored indefinitely in our facility. We will also collect personal health information from you, like your date of birth, race, and medical record number.

a) What is the purpose of the research project I described to you?
b) How long will the research project last?
c) What sorts of things will be done with people who agree to be in the study?
d) What sorts of things will people have to do if they agree to be in the study?

It is important for you to understand that this project is a research project. That means its main purpose is to help the doctors collect biological samples for future research.

e) Do you believe this study is primarily for research or primarily for treatment?

There are no direct benefits to you for participating in the study. The primary benefit is to learn information from your sample about illnesses (like cancer or diabetes) that can help with preventing or treating these illnesses in the future.

f) What might doctors learn about diseases if people decide to be in this research project?
g) In what way might people who volunteer be better off by being in this research project?
    a. Is it possible that being in this study will not have any benefit to you?

There are some risks involved with participating in this research study. You may experience pain or bruising when they draw blood from your arm. There is a risk of loss of confidentiality, which means someone can identify you and see your results. Your DNA is unique to you, and if other people see this information, it could affect your ability to have a certain job or get health insurance in the future.

h) What unpleasant side effects might people experience in this study?
i) What uncomfortable things are done to people in the study?
j) Who will pay for your medical care if you are injured as a direct result of participating in this study?

No one has to be in this study. People who agree to be in this research project can change their minds at any time. If they don't agree to be in this study or if they decide to stop, they will receive their normal care in their doctor's office or hospital.

k) What will happen if a person refuses to be in the research project?
    a. If you withdraw from this study, will you still be able to receive regular treatment?

Appreciation

l) Do you believe that you have been asked to be in this study primarily for your personal benefit?
    a. What makes you believe that this was/wasn't the reason you were asked?
m) What do you believe would happen if you were to decide not to be in this study?
    b. What makes you believe that this would happen?

Expressing a Choice

As you know, you have been invited to participate in a research project for banking a biological sample, in this case blood. Do you think you are more likely to want to participate or more likely to not want to participate?

You think that you are more likely to want to/not want to participate. Tell me what it is that makes that option better than the other option.

n) What makes you want to consider participating in this study?

We've talked about some of the risks of the study, like [mention risks they said], and some of the benefits, like [mention risks they said]. What are some ways that these could affect your everyday activities if you participate in the research project?

o) How might [risk or benefit] affect your daily life?

A few moments ago you told me that you were/were not likely to want to participate in the research project. What do you think know that we have discussed everything?

STD consent:

For this consent, I'd like you to imagine that you are a teenager who has been approached (after school, at the skating rink, basketball court?) to participate in a research project about STDs in Indianapolis youth.

The purpose of this study is to look at how common certain STDs are in the Indianapolis area. We will collect urine samples from approximately 1200 young people and test for gonorrhea, chlamydia, and trichomonas. Once the testing is done, we will call participants and tell them their results.

a) What is the purpose of the research project I described to you?
b) How long will the research project last?
c) What sorts of things will be done with people who agree to be in the study?
d) What sorts of things will people have to do if they agree to be in the study?

It is important for you to understand that the project in which you have been asked to participate in a research project. That means its main purpose is to look at how many people have STDs. The main purpose is not treat STDs, as it would be if this were ordinary treatment.

e) Do you believe this study is primarily for research or primarily for screening and treatment?

There are some benefits to you for participating in this study. The primary benefit is that you will get a free STD test. If you test positive for an STD, we can help you get treatment. That can mean sending you to a doctor or writing you a prescription for antibiotics.

f) What might doctors learn about STDs if people decide to be in this research project?
g) In what way might people who volunteer be better off by being in this research project?
    a. Is it possible that being in this study will not have any benefit to you?

There are some risks involved with participating in this research study. You may feel uncomfortable with some of the questions we ask you. There is a risk of loss of confidentiality, which means someone can identify you and see your STD test results.

h) What uncomfortable thing do people in the study have to do?
i) What can happen in a case of loss of confidentiality?

No one has to be in this study. People who agree to be in this research project can change their minds at any time, and they can stop at any time.

j) What will happen if a person refuses to be in the research project, or decides to stop once they have started?
    a. If you withdraw from this study, will you still be able to receive regular treatment?

Appreciation

k) Do you believe that you have been asked to be in this study primarily for your personal benefit?
    a. What makes you believe that this was/wasn't the reason you were asked?

l) What do you believe would happen if you were to decide not to be in this study?
    a. What makes you believe that this would happen?

Expressing a Choice

As you know, you have been invited to participate in a research project testing Indianapolis youth for STDs and asking them questions about their sexual behavior. Do you think you are more likely to want to participate or more likely to not want to participate?

You think that you are more likely to want to/not want to participate. Tell me what it is that makes that option better than the other option.

m) What makes you want to consider participating in this study?

We've talked about some of the risks of the study, like [mention risks they said], and some of the benefits, like [mention risks they said]. What are some ways that these could affect your everyday activities if you participate in the research project?

n) How might [risk or benefit] affect your daily life?

A few moments ago you told me that you were/were not likely to want to participate in the research project. What do you think now that we have discussed everything?

MacCAT-CR Interview Cards (to be read by subject)

Pharmaceutical consent:

The purpose of this study is to test the safety of MigrainaGon and how well it works in adolescents and young adults. This study will last for 12 weeks. Subjects will have an initial study visit where they will have a physical exam and a blood draw. They will take the first dose of medicine in the clinic. When they go home, they will take the medicine when they have a headache and write down how much pain they feel after 30 minutes, 1 hour, and 2 hours.

It is important for you to understand that the project in which you have been asked to participate in a research project. That means its main purpose is to help the doctors figure out whether the new medication can help some people with migraine headaches. The main purpose is not to find out whether it works for people in the study, as it would be if this were ordinary treatment.

Because this is a research project, not ordinary treatment, the doctors will be doing things that they would not do in ordinary hospitals/clinics, like those where you may have been treated before. For example, some people who are in this project will get the new medication, but others will get a sugar pill instead – a pill with no medicine in it (called a placebo). Whether they get the new medication of the sugar pill will be decided by chance. The doctors will know if the subject is getting the new medication or the placebo. The subjects will not know. All these things are done to see whether the new medication is better than no medication at all.

There are a few benefits of participating in this study. Doctors will learn more about how this migraine medicine works in young adults and people under the age of 18. You may have pain relief while taking the drug, but that is not guaranteed.

There are also risks associated with participating in this study. Subjects experienced physical side effects, like tingling sensation, weakness, nausea, and dizziness. Some people might have a life-threatening reaction called serotonin syndrome if they are taking anti-depressant medicine at the same time.

Subjects will also have their blood drawn at the initial visit.

No one has to be in this study. People who agree to be in this research can change their minds at any time. If they don't agree to be in this study or if they decide to stop, they will be referred to their doctor for the usual treatment for migraines.

Biobank consent:

The purpose of this study is to collect a biological sample, like blood, from healthy and sick people to use in future research. We will collect a small amount of blood from a vein in your arm. This sample will be stored indefinitely in our facility. We will also collect personal health information from you, like your date of birth, race, and medical record number.

It is important for you to understand that this project is a research project. That means its main purpose is to help the doctors collect biological samples for future research.

There are no direct benefits to you for participating in the study. The primary benefit is to learn information from your sample about illnesses (like cancer or diabetes) that can help with preventing or treating these illnesses in the future.

There are some risks involved with participating in this research study. You may experience pain or bruising when they draw blood from your arm. There is a risk of loss of confidentiality, which means someone can identify you and see your results. Your DNA is unique to you, and if other people see this information, it could affect your ability to have a certain job or get health insurance in the future.

No one has to be in this study. People who agree to be in this research project can change their minds at any time. If they don't agree to be in this study or if they decide to stop, they will receive their normal care in their doctor's office or hospital.

STD consent:

The purpose of this study is to look at how common certain STDs are in the Indianapolis area. We will collect urine samples from approximately 1200 young people and test for gonorrhea, chlamydia, and trichomonas. Once the testing is done, we will call participants and tell them their results.

It is important for you to understand that the project in which you have been asked to participate in a research project. That means its main purpose is to look at how many people have STDs. The main purpose is not treat STDs, as it would be if this were ordinary treatment.

There are some benefits to you for participating in this study. The primary benefit is that you will get a free STD test. If you test positive for an STD, we can help you get treatment. That can mean sending you to a doctor or writing you a prescription for antibiotics.

There are some risks involved with participating in this research study. You may feel uncomfortable with some of the questions we ask you. There is a risk of loss of confidentiality, which means someone can identify you and see your STD test results.

No one has to be in this study. People who agree to be in this research project can change their minds at any time, and they can stop at any tim

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Yancey, A. K., Ortega, A. N., & Kumanyika, S. K. (2006). Effective recruitment and retention of minority research participants. *Annual Review of Public Health, 27*(1), 1–28. doi:10.1146/annurev.publhealth.27.021405.102113

Curriculum Vitae

Kyle A. McGregor

Education

PhD in Social Work
Minor concentration*: advanced research methods*
Indiana University
Completed: December 2015
Achievements:
-Social Work Fellow, Leadership Education in Adolescent Health (LEAH) Fellowship through Indiana University School of Medicine, Section of Adolescent Medicine (HRSA/MCHB) (2012-2013)
-LEAH Fellowship Coordinator, Indiana University School of Medicine, Section of Adolescent Medicine (2013-2014)
-Clinical Ethics Fellow, Charles Warren Fairbanks Center for Medical Ethics (2014-2015)
-TL1 Fellow, the National Institutes of Health, National Center for Advancing Translational Sciences & Clinical and Translational Sciences Award (2014-2016)
-Visiting Scholar, Yale Interdisciplinary Center for Bioethics (2014, 2015)

Master of Social Work
Concentration: *interpersonal practice with children and youth in families and society*
University of Michigan Ann Arbor
Completed: April 2011
Achievements:
-Assistant Editor of *The Michigan Journal of Social Work and Social Welfare*

Master of Public Policy
Concentration: *Social service and economic policy*
Loyola University Chicago
Completed: December 2009
Achievements:
-Loyola Arts and Sciences Grant (2008-2009)

Bachelor of Science in Political Science
Grand Valley State University
Completed: April 2008
Achievements:
-Senior thesis: *Arts Funding as a First Amendment Issue: Solutions for a Broken System* (2008)
-Michigan Merit Scholarship (2004-2006)

Teaching
Global Health Ethics—Yale University, summer 2015
Interdisciplinary Approaches to Clinical Ethics—Yale University, summer 2015
School of Medicine—behavioral health rotation, IUSM Med-Peds, spring 2015
Social Work Research—Indiana University, undergraduate, spring 2015

Organizational Theory and Practice—Indiana University, undergraduate, fall 2014
Social Work Research Methods I (online)—Indiana University, graduate, summer 2014
Social Work Practicum I—Indiana University, graduate, spring 2014
Human Behavior in the Social Environment I—Indiana University, graduate, fall 2013
Organizational Theory and Practice—Indiana University, undergraduate, fall 2013
Social Work Research Methods II—Indiana University, graduate, summer 2013

Awards

Excellence in Teaching Award—Indiana University, 2014
Indy's Best and Brightest (Health & Life Sciences), 2014 & 2015
Inspire Award (for outstanding mentorship in education & nonprofit sector), 2015
Top Student in the School of Social Work—Indiana University Graduate and Professional Student Government, 2015
Indiana University Graduate School Elite 50 (award for top 50 students in the IU graduate school), 2015

Selected Refereed Presentations

McGregor, KA, Ott, MA. (2015). An assessment of adolescent capacity to consent to biobanking research. National Translational Science Meeting, Washington DC.

Warus, JD, **McGregor, KA**, Ott, MA. (2015). Social and developmental influences on sexual risk behavior and STI rates in college-aged males. Journal of Adolescent Health, 56(2), S75. Society for Adolescent Health and Medicine Annual Meeting, Los Angeles, CA.

McGregor, KA, Aalsma, MC, Ott, MA. (2015). Adolescent perceptions of importance, discomfort and interest with sexual behavior research. Oral presentation at the Society for Social Work and Research Annual Meeting, New Orleans, Louisiana.

Harris, EM, **McGregor, KA**. (2015). A comparison of transgender and cisgender experiences in primary care. Oral presentation at the Society for Social Work and Research Annual Meeting, New Orleans, Louisiana.

McGregor, KA, Hensel, DJ, Ott, MA. (2014). A structural equation model of IRB risk categorization and approvability in adolescent eating disorder research. Presented at Indiana University School of Medicine Research Symposium, Indianapolis, Indiana.

McGregor, KA. (2014). Assessing adolescent capacity to participate in research. Oral presentation at the Association of Maternal Child Health Bureau Programs Annual Meeting, Washington DC.

McGregor, KA, Hensel, DJ, Molnar EA, Ott, MA. (2014). Predictors of IRB risk categorization and approvability in adolescent sexual behavior research. Journal of Adolescent Health, 54(2), S22-23. Oral presentation at the Society for Adolescent Health and Medicine Annual Meeting, Austin, Texas.

McGregor, KA, Hall, JA. (2014). Brief electronic screening of adolescents in primary health care. Journal of Adolescent Health, 54(2), S92-93. Oral presentation at the Society for Adolescent Health and Medicine Annual Meeting, Austin, Texas.

McGregor, KA, Ott, MA, Zimet, GD, Adolescent Trials Network. (2014). Predictors of adolescent decision-making regarding HIV vaccine trial participation. Oral

presentation at the Society for Social Work and Research Annual Meeting, San Antonio, Texas.

McGregor, KA, Ott, MA, Zimet, GD. (2013). Gender differences in HIV vaccination clinical trial participation amongst at risk females and males who have sex with males. Presented at Indiana University School of Medicine Research Symposium, Indiana.

McGregor, KA, Hall, JA. (2013). Why do adolescents and their parents participate in substance abuse treatment research? Journal of Adolescent Health, 52(2), S94. Presented at the Society of Adolescent Health and Medicine's Annual Conference, Atlanta, Georgia.

Invited Presentations

McGregor, KA. (2015). Interprofessional ethics in action. Oral presentation at the NASW Northwest Indiana Social Work Conference, Merrillville, Indiana.

McGregor, KA. (2015). From multidisciplinary to interdisciplinary: Ethics education as a conduit for enhanced communication. Oral presentation at the NASW Indiana Conference, South Bend, Indiana.

McGregor, KA. (2014). Development of a capacity instrument for adolescent clinical trial participation. Oral presentation at the Charles Warren Fairbanks Center for Medical Ethics.

McGregor, KA. (2014). Truly informed consent & research: Bridging a historical legacy of distrust. Oral presentation at Yale University Center for Bioethics, New Haven, Connecticut.

McGregor, KA. (2014). Translational ethics: Putting bioethics education into translational research. Oral presentation at Yale University Center for Bioethics, New Haven, Connecticut.

McGregor, KA. (2014). Interdisciplinary ethics education for social work students. Oral presentation at the Indiana University Social Work Symposium, Indianapolis, Indiana.

McGregor, KA. (2014). Real world approaches to clinical ethics education. Oral presentation at the Northwest Indiana Social Work Conference, Merrillville, Indiana.

Technical Reports

Caring for Indiana Adolescents: Best Practices in Reproductive Health, Contraception, Confidentiality and LGBT Youth (2014). American Academy of Pediatrics, Section of Adolescent Health: Reproductive Training Grant.

Articles in Preparation

Pfeiffer, EJ, **McGregor, KA**, Ott, MA. Predictors of disclosure of sexually transmitted infections (STIs) to sexual partners among male college students. In press.

McGregor, KA, Hensel, DJ, Ott, MA. IRB risk categorization and approvability in adolescent sexual behavior research.

McGregor, KA, Hensel, DJ, Ott, MA, Zimet, GD, Adolescent Trials Network. Predictors of adolescent decision-making regarding HIV vaccine trial participation.

Warus, JD, **McGregor, KA**, Ott, MA. Social and developmental influences on sexual risk behavior and STI rates in college-aged males.

McGregor, KA, Hall, JA, Ott, MA. Development of a social work framework for research ethics.

McGregor, KA, Hall, JA, Zimet, GD, Ott, MA. Development of a standardized measure of adolescent capacity to consent to biobanking research.

McGregor, KA, Hall, JA, Wilkerson, DA, Bennett, LW, Zimet, GD, Ott, MA. A comparison of three capacity assessment tools adapted for use with adolescents wishing to participate in clinical research.

McGregor, KA, Anderson, JJ, Ott, MA. Teaching social work practice ethics in an interprofessional environment.

Grants Awarded

Trainee/Dissertation Grant, *Teens Having Capacity to Consent to Research-Chronic Illness (THiNCCR-CI)*. TL1-TR001107 & UL1 TR001108 (A. Shekhar, PI) from the National Institutes of Health, National Center for Advancing Translational Sciences & Clinical and Translational Sciences Award.

Co-Investigator, *Adolescent Electronic Preventative Screening in Primary Health Care Settings.* (J. Hall, PI) Funding: $50,000. 2012-2014.

Co-Investigator, *Integrating Family therapy into Substance Abuse Treatment for Youth.* (J. Hall, PI) Funding: $100,000 (Internal). 2012-2013.

Professional Experience

Indiana University School of Medicine Department of Adolescent Medicine, Indianapolis, IN—*Social Work Fellow*

July 2012—Current

-Clinical work in Adolescent Medicine clinics at Riley Hospital and Riley Specialty clinics.

-Conducted advanced data analyses and generated reports for multiple research projects.

-Participate in collecting data for projects centered on adolescent health.

-Work collaboratively with physicians, nutritionists, psychologists, and nursing staff to provide comprehensive clinical and research services.

Youth Contact, Hillsboro OR—*Youth and Family Therapist*

May 2011—July 2012

-Provide family and individual therapy to a diverse group of clientele (active caseload of 25-30 families).

-Maintain accurate and up-to-date case files on clients served.

-Implement therapeutic interventions with a high degree of treatment model fidelity.

-Work collaboratively with other staff members to help conceptualize and manage problems.

University of Michigan School of Social Work, Ann Arbor MI —*Research Assistant*

September 2010—May 2011

-Worked on projects relating to mental health, substance abuse treatment, community organizing, and course design.
-Worked on National Institute of Health Grant for community based implementation study.
-Collaborated to provide comprehensive editing and technical writing support.
-Developed educational resources for clinical social workers in Southeast Michigan.

Holy Cross Children's Services, Clinton MI—*Residential Counselor*
September 2010—May 2011
-Provide individual and group therapy to adolescent male sex offenders in a residential facility using TF-CBT and MST-PSB.
-Conduct research on clinical practices and human services policies, and develop plans to implement best practices.
-Worked on program development and training to increase program effectiveness.
-Maintained accurate and up to date records and case notes.

Service

University Service
Indiana University Health, Clinical Ethics Consultant, 2014-2015
Indiana University Graduate & Professional Student Government, Student Representative 2014-2015
Indiana University PhD Curriculum Committee, Student Representative 2013-2015
Michigan Journal of Social Work and Social Welfare, Assistant Editor 2010-2011