Published in final edited form as:

Soc Work Soc Sci Rev. 2016 May ; 18(2): 67–78. doi:10.1921/swssr.v18i2.904.

A Social Work Perspective on Paediatric and Adolescent Research Vulnerability

Kyle A. McGregor, Ph.D. [Postdoctoral Fellow in Informatics],

Yale Center for Medical Informatics, Yale University, Phone: 1-203-737-6029

James A. Hall, Ph.D. [Professor of Pediatrics and Social Work]

Indiana University School of Medicine—Section of Adolescent Medicine

Indiana University School of Social Work

David A. Wilkerson, Ph.D. [Assistant Professor of Social Work], Larry W. Bennett, Ph.D.

[Professor of Social Work]

Indiana University School of Social Work

Mary A. Ott, MD, MA [Professor of Pediatrics]

Indiana University School of Medicine—Section of Adolescent Medicine

Introduction

Jane Addams wrote, “Action is indeed the sole medium of expression for ethics (1902).” These words, written over 110 years ago, still ring true today, and are a mainstay within the growing 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 labelled as “vulnerable populations” (Frohlich and Potvin 2008). Thus, research on/with 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 (Gelberg et al. 2000; Aday 1994). Due to these factors, social workers are uniquely positioned to understand the complex nature of vulnerability and the multidimensional ways in which it can manifest with minors across all research types, not just social, behavioural, or service use studies. Using this enhanced understanding of individuals and their environments to focus on potential vulnerabilities, opposed to blanket approaches to assessing vulnerability which largely restrict research access, has the potential to ethically expand the scope of research involvement. This article will examine one possible framework for understanding research vulnerability and how social workers can better understand the complex interplay between vulnerability and capacity to consent.

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. Although numerous methods are used in social work to address vulnerability *in practice*, the same amount of attention has not been paid to *research* and presents real opportunities for growth within the field. For instance, the potential impacts of the utilization of the strengths perspective on the pharmaceutical research recruitment process have not been closely examined. Specifically, how interactions in the recruitment process can yield opportunities for service connection and referral to community resources. 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 & autonomy, and upholding justice by looking at research participation as a right (John 2007; Elks 1993). While there have been efforts across the world to include multiple perspectives in research (participatory action research, community based participatory research, and service user-research) these efforts do not go far enough to understand the widely varying nature of adolescent and paediatric research vulnerability in the types of studies that have the higher than minimal levels of risk (for example: biomedical, pharmaceutical, and sexual health). Removing the issue of legality of consent which varies from country to country, the core issue of vulnerability in research and what impact that will have on capacity is of global concern. As we begin to consider the ethics of research participation and how to best show respect for and uphold: self-determination, autonomy, justice, nonmaleficence and beneficence, we can thoughtfully design research recruitment efforts that open access to research participation while reducing risk of exploiting a vulnerability in the populations we wish to work with.

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 and 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 not only clinically but also within research settings.

The present review explores the concepts of “vulnerability” and “capacity” within research participation, with a specific focus on paediatric and adolescent participation in research studies. Specific attention is paid to ways in which social work may enhance the ethical recruitment of subjects into a variety of different types of research studies (social,

biomedical, pharmaceutical) as well as increasing inclusiveness, building stronger community relationships, and enhancing the overall quality of research. As social work continues to build bridges between practice and research, and even between different forms of human subjects research, it is crucial 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). Once we are able to more directly involve these perspectives throughout all types of research we can continue conducting research with an enhanced and evidenced confidence that all participants are free from *any* form of coercion and all potential sources of harm to participant have been fully considered and mitigated (Economic and Social Research Council 2015).

Vulnerability and Capacity

Capacity has been identified as the most important issue in paediatric 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 and 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 while limiting use of unjustifiable pressure and manipulation, specific attention must be paid to *how* researchers interact with potential adolescent research participants (Department of Health 1979). A focus on the rights of participants while closely monitoring for issues around capacity may enhance ethical recruitment, and plays into the natural skillset of social workers. With an enhanced focus on capacity comes the need for greater understanding how capacity and vulnerability interact.

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 review: “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 (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 (Partridge 2013; Levine 1995; Santelli et al. 1995). This propensity in the US 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 (Levine et al. 2004). This approach 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 deeper and more contextualized understanding of capacity, or an individual's ability to make informed decisions, is needed in the US. 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 all human subjects' research with children and adolescents. In the UK, the General Medical Council has enacted progressive consent policies based on available research that individuals age 16 and older are presumed to have capacity to consent (General Medical Council 2013). This policy seems to fall closely in line with the available research and would greatly improve one piece of the research ethics puzzle; however, researchers must take into account the various forms of vulnerability present within their potential subjects/participants. Failure to account for the various forms of vulnerability will diminish any research teams' ability to accurately assess capacity to consent.

Discerning vulnerability can be even more complicated in paediatric and adolescent 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). In the UK, there are no specific laws regulating the consenting process for research. Legal decisions have impacted the consent process clinically (Gillick Competence is used in assessing capacity broadly and the Fraser Guidelines for provision of birth control) but these standards have been mostly rejected within the research context (Hunter & Pierscionek 2007) and do not provide clear unbiased ways in which to functionally/empirically test capacity. When it is suspected that the child lacks capacity to consent, in the US 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. Given that capacity was already found to be insignificant with the research participant themselves the issue of how valid/important/meaningful this assent actually is questionable. In the UK, each country has their own set of guidelines for the inclusion of children lacking capacity, with England, Wales and Northern Ireland having specific provisions allowing parents to consent in place of the child (General Medical Council, 2013). In both countries, this idea of

including parents while respecting minors abilities to make decisions has the potential to create power differentials within family systems and is an area where research and treatment participation may differ.

Potential power differentials are important for social workers and other professionals that work with children & adolescents to be aware of as they can play a large role in decision making. 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 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 research, and plays a crucial role in ethical recruitment regardless of legal requirements for capacity. One approach to shielding vulnerable populations would be designating every individual as having some form of vulnerability (Handmer 2003) and therefore requiring unique tailored protections. However, this might not be a reasonable definition because it is too cumbersome and time consuming to measure vulnerability and track the effectiveness of any effort to counterbalance that vulnerability. Another approach is to identify specific vulnerable groups. However, this approach has the potential for stereotyping, thereby ultimately acting as a form of oppression, not adequately accounting for individual differences (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, making note of both ways to assess vulnerability and ways to safeguard against exploiting them. Kipnis (2003) developed a framework of vulnerability to identify and categorize its differing manifestations in paediatric 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 individuals 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 individuals ability to make his or her own decisions; allocational, wherein factors such as education and poverty may impact an individuals 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).

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 possible claims of 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 may feel a baseline level of compulsory participation. Social workers are ideally positioned to screen for deferential behavior that shows misalignment between the implicit or explicit preferences of the adolescent and what they feel may be 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, 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. 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 difficulty 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.

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, as in adult research capacity is assumed and only in the light of clear and pressing evidence is their capacity challenged. 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.

Summary of Vulnerability

Capacity emerges as a key concept in understanding and contextualizing the different forms of vulnerability. Utilizing the Kipnis (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 the 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

Ethical enrolment of children and adolescent populations is fundamental to furthering scientific understanding. From better understanding disease trajectories from childhood through adulthood, to finding cures for childhood disorders, to better understanding the way in which social and environmental factors impact development. All of these questions have roles for social workers. Social workers interested in research should first seek to become better informed and involved in all aspects of research, taking note of the methods used in biomedical, genomic, and bench research. Having even a basic level of understanding of the methods and outcomes of these study types has the potential to expedite the process being undertaken by translational sciences, trying to bridge the gap between bench science discoveries to successful community implementation.

Fortunately, the interdisciplinary nature of social work practice and education provides those interested in accessing research with the necessary skillset to manoeuvre the complexities of these various research settings. A change in mind-set 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—where you can only really do one or the other. 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 have to 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 upon entering the job market—or even worse, never knowing of the ways in which they could impact these other systems. 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 while also giving students an opportunity to forge their own path towards transdisciplinary understanding of concepts and their application. Further, the social work profession needs to expand its scope of involvement in research endeavours beyond the bounds currently

utilized. The field of research only stands to benefit by inclusion of researchers well versed in multiple ways of thinking, approaching problems, finding solutions, and developing ways to effectively implement those solutions.

References

- Aday LA (1994). Health status of vulnerable populations. *Annual review of public health*, 15(1), 487–509.
- Addams J (1902). *Democracy and social ethics*. New York: Macmillan.
- Berman RE, & Field MJ (2004). *The ethical conduct of clinical research involving children*: National Academies Press.
- Boonstra H, & Nash E (2000). Minors and the right to consent to health care. *The Guttmacher Report on Public Policy*, 3(4), 4–8.
- Brody JL, & Waldron HB (2000). Ethical issues in research on the treatment of adolescent substance abuse disorders. *Addictive behaviors*, 25(2), 217–228. [PubMed: 10795946]
- Bronstein LR (2003). A model for interdisciplinary collaboration. *Social Work*, 48(3), 297–306. [PubMed: 12899277]
- Commission NBA (2001). *Ethical and policy issues in research involving human participants*.
- Department of Health, E., and Welfare, (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. Washington, DC: OPRR Reports.
- Economic and Social Research Council (2015). *Framework for research ethics*.
- Elks ML (1993). The right to participate in research studies. *The Journal Of Laboratory And Clinical Medicine*, 122(2), 130–136. [PubMed: 8340698]
- Frohlich KL, & Potvin L (2008). Transcending the known in public health practice: the inequality paradox: the population approach and vulnerable populations. *American Journal of Public Health*, 98(2), 216. [PubMed: 18172133]
- Gelberg L, Andersen RM, & Leake BD (2000). The Behavioral Model for Vulnerable Populations: application to medical care use and outcomes for homeless people. *Health services research*, 34(6), 1273. [PubMed: 10654830]
- General Medical Council (2013). *Good Medical Practice*. London, General Medical Council.
- Guttmacher Institute (2014). *An overview of Minors' Consent Law State Policies in Brief* (09/01/2014 ed., pp. 2). New York, NY: Guttmacher Institute.
- Handmer J (2003). *We are all vulnerable*.
- Hill BJ (2011). Whose Body? Whose Soul? Medical Decision-Making on Behalf of Children and the Free Exercise Clause Before and After *Employment Division v. Smith*. *Cardozo Law Review*, 32, 1857.
- Hunter D, & Pierscionek BK (2007). Children, Gillick Competency and Consent for Involvement in Research. *Journal of Medical Ethics*, 33(11), 659–662. [PubMed: 17971470]
- Hurst SA (2008). Vulnerability in research and health care; describing the elephant in the room? *Bioethics*, 22(4), 191–202. [PubMed: 18405317]
- John JE (2007). Children and research. The child's right to participate in research: myth or misconception? *British Journal of Nursing*, 16(3), 157–160. [PubMed: 17363882]
- Kipnis K (2003). Seven Vulnerabilities in the Pediatric Research Subject. *Theoretical Medicine and Bioethics*, 24(2), 107–120, doi:10.1023/a:1024646912928. [PubMed: 12943266]
- Largent EA, Grady C, Miller FG, & Wertheimer A (2012). Money, coercion, and undue inducement: a survey of attitudes about payments to research participants. *IRB*, 34(1), 1.
- Levine C, Faden R, Grady C, Hammerschmidt D, Eckenwiler L, & Sugarman J (2004). The Limitations of “Vulnerability” as a Protection for Human Research Participants. *The American Journal of Bioethics*, 4(3), 44–49, doi:10.1080/15265160490497083.
- Levine RJ (1995). Adolescents as research subjects without permission of their parents or guardians: Ethical considerations. *Journal of Adolescent Health*, 17(5), 287–297. [PubMed: 8924433]

- Maramaldi P, Sobran A, Scheck L, Cusato N, Lee I, White E, et al. (2014). Interdisciplinary Medical Social Work: A Working Taxonomy. *Social Work in Health Care*, 53(6), 532–551, doi: 10.1080/00981389.2014.905817. [PubMed: 25050659]
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1977). Report and Recommendations on Research Including Children. U.S. Department of Health (Ed.), (Vol. 05). Bethesda, Maryland: DHEW publication.
- Oakes JM (2002). Risks and Wrongs in Social Science Research An Evaluator's Guide to the IRB. *Evaluation Review*, 26(5), 443–479. [PubMed: 12243104]
- Partridge BC (2013). The Decisional Capacity of the Adolescent: An Introduction to a Critical Reconsideration of the Doctrine of the Mature Minor. [Article]. *Journal of Medicine & Philosophy*, 38(3), 249–255.
- Rothman AA, & Wagner EH (2003). Chronic illness management: what is the role of primary care? *Annals of Internal Medicine*, 138(3), 256–261. [PubMed: 12558376]
- Santelli JS, Rosenfeld WD, DuRant RH, Dubler N, Morreale M, English A, et al. (1995). Guidelines for adolescent health research: a position paper of the Society for Adolescent Medicine. *Journal of Adolescent Health*, 17(5), 270–276. [PubMed: 8924431]
- US Department of Health and Human Services (2009). Protection of human subjects. 45
- World Medical Association (1964). Declaration of Helsinki, ethical principles for medical research involving human subjects 52 nd WMA General Assembly, Edinburgh, Scotland.

Figure 1.
Conceptualization of Kipnis' (2003) vulnerability framework combined with the functional areas thought to be required for consent.