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Informed Consent to Research in Long-Term Care Settings

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Abstract

Informed consent to nursing home research is a two-tiered process that begins with obtaining the consent of a long-term care community at the institutional level and progresses to the engagement of individuals in the consent process. Drawing on a review of the literature and the authors' research experiences and institutional review board service, this paper describes the practical implications of nurse investigators' obligation to ensure informed consent among participants in long-term care research. Recommendations focus on applying a community consent model to long-term care research, promoting an evidence-based approach to the protection of residents with decisional impairment, and increasing investigators' attention to ethical issues involving long-term care staff.

Keywords

informed consent; long-term care; research ethics; community consent

High-quality, methodologically rigorous research is essential to improving the quality of care delivered in nursing homes, personal care homes, and assisted living facilities (Quadagno & Stahl, 2003). Yet, investigators who conduct research in these long-term care (LTC) settings face a broad array of challenges regarding the protection of human subjects (Maas, Kelley, Park, and Specht, 2002). The authors of this article wish to introduce and stimulate discussion of emerging issues concerning informed consent to research in LTC.

Our perspective is that informed consent to LTC research is a two-tiered process that begins with obtaining the consent of a LTC community at the institutional level, and progresses to the engagement of individuals (staff and/or residents) in the consent process. There are three major stakeholders in LTC settings – the institution, its staff, and its residents - each with unique but

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overlapping informed consent issues. Using our collective research experience we review key concepts in research ethics and discuss consent challenges specific to each of these stakeholders. We begin with the institutional level issues of gaining entrée and facilitating informed, voluntary and appropriately authorized community participation decisions. We then discuss resident-specific issues of decisional capacity, competence and identification of decisional proxies. Finally, we address the unique set of ethical issues that arise when involving LTC staff members in the research process.

Part One: Informed Consent at the Community Level

Gaining Entrée and Community Consent

Before approaching individual LTC residents or staff members for consent, researchers must first obtain permission to conduct a planned investigation at a given facility. Investigators typically refer to this process as *gaining entrée (*Mitchell et al., 2006), but it can also be viewed as a preliminary aspect of the informed consent process occurring at the institutional or community level. Dickert and Sugarman (2005) defined *community consent* as the process by which an investigator solicits approval to conduct a study within a community and recruit individual community members for research participation.

The literature on informed consent to nursing home research has traditionally focused on individual-level consent issues (Ouslander and Schnelle, 1993; Cohen-Mansfield, Kerin, Pawlson, Lipson, & Holdridge, 1988; Sachs, Rhymes, Cassell, 1993), but there are compelling reasons to consider adopting a community consent model in LTC settings. First, those who live in long-term care facilities are members of a residential *community* and their involvement in research can have both pragmatic and ethical implications for other members of that community. Conventional, individual-level models of informed consent are rooted in the assumption that the risks and burdens associated with clinical research are incurred solely by those individuals who make (or whose proxies make) voluntary, informed decisions to become involved in a study. With the exception of genetics investigations (Botkin, 2001; Parker, 2002), individual-level processes of informed consent focus on the primary participants of the research with little or no attention to third parties who may be directly or indirectly affected by another individual's participation in a research study (Lingler, Parker, DeKosky, & Schulz, 2006).

In LTC settings, supplementing individual consent procedures with a preliminary process of community consent represents a novel opportunity for giving information and voice to individuals whose daily routine, and possibly care delivery, may be affected by an onsite investigation to which they have not explicitly consented. Further, many prospective research participants in LTC settings are likely to be vulnerable. Providing an advanced, community-wide mechanism to participate in group discussions about the acceptability of a research project would afford this population an additional layer of human subjects protection. By moving beyond conventional notions of gaining entrée and adopting a model of community consent, researchers can dialogue with a fuller representation of the long-term residential and care community than is typically possible. Engaging in such discussions will allow investigators to give earlier and more serious attention to the desires, values, and interests of those who comprise the LTC community.

Information and Voluntariness at the Community Level

Applying the requirements for informed and voluntary consent at the community level—The goal of community consent should be to ensure that community decisional bodies are adequately informed and free of undue influence when considering whether to serve as a research site. In the specific context of LTC research, we interpret the informational component of community consent to require that investigators disclose to the

LTC community the nature, purpose, risks and potential benefits of the proposed research. Such disclosures should incorporate a discussion of the extent to which the research study will disrupt the daily routines of, or otherwise inconvenience, residents who will not directly participate in the research study. This is of particular importance given that such residents will not usually have the benefit of future opportunities to engage in meaningful discussion with the research team, nor will they provide informed consent at the individual level. The voluntary component of community consent can be interpreted to require that facilities are not unreasonably influenced by such factors as the investigators' relationship with the facility (e.g., as in the case of a medical director who is conducting research), the promise of treatment or other services, and/or payment for participation.

Setting-specific considerations—Given that LTC facilities are home to cognitively impaired and otherwise vulnerable populations, the process of community consent may be especially useful for disclosing or negotiating, in advance, the research team's plan to responding to discoveries of resident neglect or maltreatment. A "ripple effect" of conducting research in LTC settings is that research personnel may note problematic care practices affecting not only study participants, but other members of the residential community, such as a participant's roommate. When such practices pose a direct harm to vulnerable persons, the research team may be justified in reporting their observations, even if it means breaching a resident's confidentiality.

Mentes and Tripp-Reimer (2002) stated that initial discussions with potential sites should include a disclosure of what, if any, burden the research process may pose to staff members of the facility. Our experience confirms that need for early interactions with LTC communities to address questions related to staffing. For example, will staff members be asked to collect data? If so, what is the frequency and duration of such data collection? Members of the broader residential community or their family members may have specific concerns regarding the possibility that research-related activities will detract from the care resources of those who are not participating in the study.

Decisional bodies in LTC may also inquire about the impact of Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations on the conduct of the research. Plans for de-identifying data and notifying residents' families or external healthcare providers of their participation should be clearly articulated, as should the burden that such procedures may impose upon staff (e.g., de-identifying records, making phone calls on behalf of the project). Given that the cost of recruiting nursing home subjects for clinical research has been estimated to be as high as $515 per subject (Gismondi et al., 2005), there exists both a moral and a pragmatic imperative to negotiate such details in advance. Table 1 provides a list of practical recommendations for ensuring an ongoing informational process with long-term care facilities.

Implications for recruitment—Early conversations with LTC administrators should address the extent to which facility employees may be involved in the recruitment of individual residents to participate in the proposed research (Mentes & Tripp-Reimer, 2002). According to the Belmont Report (DHHS, 1979), the requirement that research participation be *voluntary* may be compromised when those who have commanding influence "urge a course of action for a subject." Because LTC residents depend upon their paid caregivers for shelter, food, health and social services, it is critical that residents or their proxies do not worry or fear that refusal to participate would hinder the delivery of any needed services.

Care must also be taken to ensure that residents do not perceive that refusal to participate would compromise their interpersonal relationships with staff or other residents. Investigators should bear in mind that once a facility agrees to serve as an investigational site, the research project effectually becomes an activity that is endorsed by the LTC community, opening the door for

misconceptions about expectations regarding cooperation. As LTC administrators and other decisional bodies consider the appropriateness of proposed research, they must evaluate the feasibility of providing residents with an opportunity to make their own decisions about research participation while minimizing the risk of an implicit expectation that participation is expected.

Administrators, resident representatives, or other decisional bodies require the above-mentioned information to make well-informed decisions. Thus, investigators bear an obligation to provide such information and work to ensure its understanding on the part of appropriate decisional entities and staff.

Authorization at the Community Level: Who Decides?

Composition of decisional bodies—We have described several ways in which onsite research studies can impact residential care communities. In doing so, we have highlighted potential advantages of engaging resident or family councils in deliberations concerning the fit of a particular research study with the values and wishes of a LTC community. Because federal regulations governing the conduct of research do not specify the composition of decisional bodies at the institutional level it is unclear whether resident and family members have a legally recognized right to participate in such deliberations.

In the public health literature, community advisory boards have been proposed as a vehicle for consulting with community representatives to ensure that a study's design and implementation plan respect the values and cultural practices of a given community (e.g., Quinn, 2006). Yet, Dickert and Sugarman (2006) distinguished such consultation from the process of community consent to research, pointing out that those who provide such consultation may lack the authority to consent to research on behalf of a given community. In the case of nursing home research, the American Medical Directors Association asserted that medical directors should act as the primary gatekeepers for clinical research (Boult, Dentler, Volicer, Mead, & Evans, 2003). Daly and Maas (2000) suggested that facilities form Research Review Committees comprised of administrators, practitioner and educators to oversee and manage research in these settings. Other commentators have more flexibly recommended that initial permissions be obtained from the nursing home (NH) administrator, the director of nursing (DoN), and/or the medical director (Sachs, Rhymes, & Cassel, 1993).

It is important to note that in addition to having the authority (both legal and moral) to consent to being a research site on the behalf of a LTC community, decisional bodies should be free of potential or apparent conflicts of interest. For example, if an administrator is a co-investigator on a research project, then he or she has a vested interest in its success and should not serve as the sole authorizer of his or her own facility as a research site. Because formal regulations to this effect are lacking, investigators must take extra care to educate others about, and facilitate the management of such potential conflicts of interest.

Examples from our experience as investigators in LTC—We have observed wide variability with respect to gatekeeping. In two studies involving nursing home residents (Jablonski, Utz, Steeves, & Gray, 2007; Jablonski, Swecker, Munro et al., 2008; Jablonski, Munro, Grap et al., 2008), author R.J. used a two-step approach by initiating discussion with the NH administrator, then conducting group informational sessions involving the administrator, lead investigator, and director of nursing. Author, M.B., had a different experience in a four-site research project designed to describe the work of licensed nurses in nursing homes when older adults were admitted from hospitals to their facilities. Initial discussions with administrative personnel revealed that each facility had a different approach to research oversight. One facility had a research review committee consisting of the board of directors, with the medical director in charge of vetting proposals for approval. In the second

facility, the medical director served as the sole research oversight entity. The third facility used a team approach that was composed of the medical director, director of nursing, and nursing home administrator. The final facility had no formal mechanism for research oversight. In this facility the medical director self-identified as the ad hoc entity. To the authors' knowledge, research oversight activities did not allow for decisional input from direct care nursing staff, long-term care residents or their representatives (either through resident councils or family member input) at any of the eight facilities participating in the exemplars described here. In no cases did discussion leading to facility access involve direct communication between the research team and the residents or their representatives.

Despite following a common sequence of obtaining institutional review board (IRB) approval from the investigator's home institution, then following facility-dictated channels for obtaining access permissions, the decisions to allow research to be conducted in individual facilities was ultimately both unilateral and informal. Our experiences suggest that following a conventional, permissions-driven approach to gaining entrée provides no assurance that decisions around site access are well-informed, are free of conflicts of interest, and account for the interests of key stakeholders within the LTC community, namely its residents.

Summary of Community Consent Issues

Elements of a community consent model (e.g., resident representation in the authorization of a community as a study site) have potential relevance for many large-scale studies in LTC, and the need for adding this layer of human participant protection should be considered by investigators on a study-by-study basis. For example, the notion of advancing informed consent at a community level holds particular significance for investigators seeking a community participatory approach to research implementation (Strauss et al., 2001).

At a more general level, the above sections underscore the pressing need for investigators, regulators, and LTC communities to advance the discourse on human participation protection in LTC by considering three key issues. First there is need for consensus regarding which parties are best suited to deliberate about and authorize the conduct of research in LTC settings. Second, there is a need to identify ways of improving resident representation in such deliberations be improved, including those in which final authorization for the study rests with an administrative figure. Third and last, there is a need for clear guidelines concerning the nature and type of information required to ensure that such decisions are sufficiently informed and that conflicts, or apparent conflicts, of interest are disclosed and managed.

Part Two: Informed Consent at the Individual Level

Informed Consent to Research among LTC Residents

The process of procuring informed consent from individual research subjects, including those who are considered vulnerable, is regulated at both the federal and local levels and has been the subject of much discussion in the research ethics literature. In the following sections we describe the standard of practice for obtaining informed consent and highlight recent empirical work in this area. An overview of related regulatory considerations is provided in Table 2.

Assessment of decisional capacity—Given the prevalence of cognitive impairment in LTC settings (Magaziner et al., 2000), issues of informed consent within this population are inextricably linked to concerns about decisional capacity. Models of informed consent that guide regulatory bodies generally seek to balance the ethical principle of beneficence with that of individual autonomy (Berg, Applebaum, Lidz & Parker, 2001). Autonomous decisions have been described as those which are voluntarily executed by informed, decisionally capable individuals. Decisional capacity is a clinical term referring to a person's ability to use cognitive

processing skills for making voluntary and informed choices (Applebaum & Grisso, 2001). Capacity for making meaningful decisions about research participation entails having the ability to understand the purpose of the research and any associated risks and benefits, as well as the ability to deliberate about alternatives to participation (Applebaum & Roth, 1982). Also requisite is the ability to effectively communicate such understanding. Decisional capacity is not an all-or-nothing state, but varies according to the context within which the decision is being made (Beauchamp and Childress, 2001).

The determination of decisional competence by investigators is a two step process: assessment of decision-making abilities followed by a carefully weighed judgment on competence (Kim, Caine, Currier, Leibovici & Ryan, 2001). Probably the most widely used model for determining decisional capacity is that developed by Applebaum and Grisso (1998). Four abilities are identified in this model and include: the ability to understand relevant material, the ability to appreciate the consequences of the choice, the ability to give reasons for the choice, and the ability to communicate a choice.

Investigators have developed a number of instruments to measure decisional abilities (Kim, Karlawish & Caine, 2002; Resnick, Gruber-Baldini, Poretzer-Aboff, Galik, Buie, Russ & Zimmerman, 2007; Sturman, 2005), with the MacArthur Competence Assessment Tool for Clinical Research being the most widely utilized in research settings (Applebaum & Grisso, 2001). The current trend is to consider relevant abilities rather than rely on medical diagnosis for a determination of competence in persons with cognitive impairment (Moye & Marson, 2007). Capable decision making is related to multiple domains of intellectual functioning but measures of executive functioning seem to most closely reflect reasoning and the ability to appreciate the consequences of research participation (Marson, Hawkins, McInturff et al, 1997; Schillerstrom, Rickenbacker, Joshi & Royall, 2007).

A major concern raised in many studies of decisional competence is a lack of reliability between assessment methods and clinician judgment. Decisional ability is highly individualized. A recent study suggests that even individuals with mild cognitive impairment (MCI) demonstrate differences in their decisional capacities; 40% of Jefferson and colleagues' sample of individuals with MCI was judged to be incapable of providing informed consent (Jefferson, Lambe, Moser, Byerly, Ozonoff & Karlawish, 2008). Much more empirical work is needed to address essential and complex questions that surround the assessment of decision-making capacity in older adults with cognitive impairment.

A judgment of competence considers the decisional capacity of the individual as well as the risk/benefit ratio of participating in a particular research protocol. Studies that carry a high degree of risk or burden require a fairly high degree of decisional capacity as opposed to studies that pose minimal risk. In any event, a diagnosis of a cognitive disorder does not automatically preclude individuals from providing consent to research, particularly in minimal risk studies where the probability of harm is no greater than that encountered in every day life.

In at least two minimal risk studies, up to 83% of subjects with mild to moderate dementia had adequate decisional abilities on "appreciation," "reasoning," and "choice" (Bassett,1999; Marson, Ingram, Cody et al, 1995). However, a recent pilot study revealed wide variability in how the informed consent process is conducted with persons with dementia (Black, Kass, Fogarty & Rabins, 2007). While explanations of procedures dominated the conversation, the rights of subjects were mentioned much less often and in only a minority of cases were the individuals' capacity to consent actually assessed. To help improve understanding of the research protocol, enhanced consent procedures, such as the presentation of slide shows and other visual materials, are being developed and used with some success in persons with dementia (Mittal, Palmer, Dunn et al, 2007).

Finally, decisional capacity declines as cognitive impairment progresses and this has implications for research involving longitudinal designs (Moye & Marson, 2007). The Federal Office for Human Research Protections offers some guidance on this issue: "enrolled subjects may be competent to consent on their own behalf at the outset, yet may experience effects of progressive disorders that lead to decisional impairment during the course of the study. In these situations IRBs and investigators should consider the need to discuss with the prospective subjects whether they should designate someone to serve as a legally authorized representative at the outset of the study, consistent with all applicable laws. Even if a subject has consented on his or her own accord, a designated representative would be ready to step in as the legally authorized representative if the subject's ability to assess his or her own needs and interests becomes compromised during the study" (http://www.hhs.gov/). Another approach may be to reassess the decisional capacity of subjects with progressive cognitive impairment at appropriate intervals (Delano, 2006). An independent medical monitor may be appointed to review each subject's ability to continue participation and to recommend withdrawal from a study when clinically indicated. Data safety and monitoring boards may also be given an expanded role to provide direction for assessing decisional capacity over time.

Identification of an appropriate decisional proxy—When a potential subject lacks the capacity for giving informed consent, a legally authorized representative may act as a decisional proxy (Sugarman, Roter, Cain, Wallace, Schmechel & Welsh-Bohmer, 2007). Proxy decision makers are generally encouraged to promote the autonomy of their charges by using their knowledge of the person's values, wishes, and preferences to guide the decision-making process.

A legally authorized representative is an individual or other body authorized under law to consent on behalf of the potential subject. Who may act as a legally authorized representative varies from state to state, but may include one's next-of-kin, a court-appointed legal guardian, a durable power of attorney or a health care representative (Slaughter, Cole, Jennings & Reimer, 2007). While healthcare powers of attorney typically lack the authority to enroll an individual in research, they may do so if such authority was explicitly granted by the potential subject, as in the case of a research advance directive (Sachs, 1994). When a legally authorized representative can not be identified, an individual with decisional impairment can not be enrolled in a protocol. The only exception to this involves the rare circumstance in which an IRB has waived the requirement for consent in a particular protocol. Waiver of consent for decisionally impaired individuals is unusual and only done in studies where there is minimal risk to participants.

Although research advance directives are infrequently executed (Bravo, Dubois, & Paquet, 2003; Wendler, Martinez, Fairclough, Sunderland, & Emanuel, 2002), recent research indicates that persons at risk for dementia generally view surrogate consent for dementia research to be acceptable, particularly for minimal risk studies to which the impaired individual assents (Kim, Kim, McCallum & Tariot, 2005). High rates of participant assent were observed in one recent study involving persons with dementia and their surrogate decision makers (Sugarman, Roter, Cain, Wallace, Schmechel & Welsh-Bohmer, 2007). Of note, participants spoke much less than surrogates and physicians, and in the majority of situations agreed with and approved of what was said. The authors point out that these high levels of assent without interaction on the part of the subject raises questions about the utility of the assent requirement.

Obtaining Informed Consent to Research Involving Long-term Care Staff Members

While investigators are accustomed to considering the above points at the level of residents (Cassel, 1985; Maas, Kelley, Park, & Specht, 2002; Miller & Evans, 1991; Sachs, Rhymes, & Cassel, 1993), many study designs require that investigators categorize staff members as human

subjects of research (Hilton, 2006). Federal law defines a human subject as "a living individual about whom a researcher obtains either, (a) data through intervention or interaction with the individual, or (b) identifiable private information" (DHHS). When indicated, investigators must procure staff consent, ensuring that participation decisions are both informed and voluntary. Hilton (2006) delineated the need to better address human subjects concerns when conducting research involving staff of drug and alcohol rehabilitation centers, but there is a relative paucity of discourse on the topic on consent for nursing home and other long-term care staff (Cassel, 1985; Maas, Kelley, Park, & Specht, 2002; Miller & Evans, 1991; Sachs et al., 1993). A notable exception was a recent study involving electronic surveillance research in the nursing home setting (Bharucha et al., 2006). These investigators reported obtaining informed consent from staff members working on a unit in which care activities were being both video- and audiotaped. The staff members provided consent with the specification that their voices and images would be de-identified. Staff members who did not provide consent to be recorded were accommodated by being permitted to work on other units for the duration of the data collection.

Examples from our experience as investigators in LTC—In author M.B.'s study, it was noted that staff participants held a general suspicion concerning the true intent of the study. Although unasked, it appeared that staff questioned whether their supervisors wanted information about their job performance. Staff members' expressions of suspiciousness were especially evident in the two facilities where the director of nursing or the medical director selected staff to be interviewed. This phenomenon is congruent with Phillips and Van Ort's (1995) observations that LTC staff members' perceptions of a research study can have a major influence on its implementation and may even threaten its internal validity.

In author R.J.'s study of an educational intervention to reduce dental plaque among nursing home residents, the protocol involved observation of certified nursing assistants (CNAs) providing routine oral care before and after a mouth care class. The research team was concerned about the susceptibility of the CNAs to administrative pressure. CNA participants were predominantly women of ethnic minority status with low educational attainment who served on the lower tier of the institutional staffing hierarchy. To minimize institutional pressure to participate and to promote voluntariness (Nelson and Merz, 2002), the CNAs were given choices about the level of their involvement in the study. The choices were: no participation at all; partial protocol completion (survey only); or full protocol completion (attend a mouth care class and be observed providing such care). To further minimize any pressure to participate, CNAs were given the option of receiving the educational intervention and a certificate of attendance without being enrolled in the study. As a way of thanking the CNAs for their involvement and further distinguishing study participation from an obligation of employment, the research team offered modest incentives for participation.

Protecting staff from coercion to participate—During the conduct of the above-described CNA study, the investigators responsibilities to protect staff participants' ability to make informed, voluntary decisions required them to actively safeguard against situations where the NH administration mandated participation. Serious ethical concerns arose when individual unit managers attempted to "make" the CNAs attend the mouth care class. This was problematic even though the protocol allowed for class attendance irrespective of whether a CNA consented to the research study. In addition to unfavorably influencing staffs' perception of class attendance and study participation as voluntary endeavors, managerial pressure posed methodological problems. In particular, the research team had hypothesized that the intervention would have sustainability if the participating CNAs willingly "bought in" to the project; however, managerial pressure limited the ability of staff members to assume ownership of their involvement. It is unclear to what extent a form of therapeutic misconception may have caused borderline coercive behavior on the part of unit managers.

The above examples illustrate the range of issues that arise when LTC staff members are subjects of research, serving in roles that extend beyond that of research informant, data collector or facilitator of resident consent and assent, to encompass that of human subjects. Investigators must take care to ensure, throughout the conduct of a study, that such research participation on the part of facility employees is adequately informed and completely voluntary.

Conclusions

A full account of informed consent to LTC research entails procuring informed consent at a general level from the community and at the specific level of individual participants. LTC research literature contains numerous review articles and research reports addressing the protection of vulnerable older adults as human subjects, but issues concerning the involvement of LTC staff members and communities are less well documented. Scrutiny of the authors' own research experiences revealed that nurse investigators and LTC administrators had significant responsibilities related to research oversight in ensuring that consent to research involving nursing home residents, communities, and staff is both informed and voluntary. Further ethical analyses and empirical research efforts are needed to enhance the practice of informed consent for these groups. Resident and/or family councils are an especially promising resource for improving the representation of the LTC community in early discussions of potential research projects.

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TABLE 1

Recommedations for Researchers Conducting Research in Long-Term Care Facilities

When conducting research in a long-term care facility, the researcher should:

- Provide key elements of the protocol, consent forms, and IRB approval documentation. Ideally. This should be in a binder with a table of contents and each component in a different section.
- Provide 24-hour contact numbers for the principal investigator or designee.
- Provide a written list of all responsibilities or activities expected of thenursing home staff.
- Have researchers meet with resident councils, family councils, and staff to explain the study.
- Establish plans for specific actions to take for potential problems, such as discovering a previously undiagnosed medical or nursing problem, charting or medication errors, inappropriate or inadequate care, mistreatment of residents, and conflicts of interest. These plans should be negotiated with the nursing home administration.
- If the research will involve protected health information, integrate a HIPAA release form into the consent form into the consent form or properly de-identify protected health information.

Note: HIPAA = Health Insurance Portability and Accountability Act; IRB = institutional review board

TABLE 2

Issues to Address When Individuals with Potential Decisional Impairment Are Involved in Research

- Is decisional impairment temporary or permanent?
- What methods will be used for assessing decisional capacity?
- Who will perform the assessment?
- What methods will be used to enhance decisional capacity?
- What criteria will be used to determine need for proxy consent?
- Who will be accepted as a participant's legally authorized representative?
- Who will interact with the legally authorized representative to obtain the consent?
- When will the consent be obtained?
- Will assent be obtained? How will it be done? If not, explain why assent will not be obtained.
- What additional safeguards will be used (e.g., an independent part to monitor the consent process, use of a waiting period)?