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Impact of HIPAA on Subject Recruitment and Retention

Deidre D. Wipke-Tevis, RN, PhD [Associate Professor] and

Member, Health Sciences Center Institutional Review Board, S329 School of Nursing Building, MU Sinclair School of Nursing, University of Missouri-Columbia, Columbia, MO 65211, (W) (573) 884-8441, Fax (573) 884-4544, Email: wipketevisd@missouri.edu

Melissa A. Pickett, RN, BSN, MS Student [Research Nurse]

S337 School of Nursing Building, MU Sinclair School of Nursing, University of Missouri-Columbia, Columbia, MO 65211, Phone (573) 884-8672, Fax (573) 884-4544, Email: map7t4@mizzou.edu

Abstract

Recruiting and retaining an adequate sample of subjects is critical to the success of any research project involving human subjects. Recent reports indicate the Health Insurance Portability and Accountability Act (HIPAA) Privacy rule has adversely impacted research. Few resources are available to help researchers and their staff navigate the challenges to subject recruitment and retention after the implementation of the HIPAA Privacy rule. This article will address obstacles to subject recruitment in prospective, clinical research studies related specifically to the HIPAA Privacy rule as well as HIPAA compliant strategies to enhance subject recruitment and retention. Recruitment challenges discussed include evolving interpretations of the HIPAA regulations, inability to directly contact potential subjects, complexity of the HIPAA required documents, the increased cost of subject recruitment, and an expanding administrative burden. Among the strategies addressed are preparatory research reviews, use of clinical collaborators/staff liaisons, pre-screening of potential subjects, minimizing subject burden during the consent process, enhancing follow-up of subjects, facilitating recruitment for future studies and streamlining compliance training for research staff.

Keywords

HIPAA; privacy rule; subject recruitment; subject retention

Recruitment and retention of research subjects is challenging at best. At its worst, recruitment can be a nightmare. The proverbial “disappearing sample” is an all too common phenomenon experienced by many human subjects researchers (Wilson-Barnett & Griffiths, 2002). A number of researchers have examined the challenges of subject recruitment and retention in specific patient populations across a number of different settings (Blanton et al., 2006; Heiney et al., 2006; Im & Chee, 2005; Loftin, Barnett, Bunn, & Sullivan, 2005; Northouse et al., 2006; Rose, 2000; Villarruel, Jemmott, Jemmott, & Eakin, 2006). Most of the recent work in this area includes little information regarding the Health Insurance Portability and Accountability Act (HIPAA) Privacy rule.

The HIPAA Privacy rule became effective in April of 2003. While the original intent of HIPAA had nothing to do with research, by the time the regulations were enacted, they impacted research directly. In the wake of the implementation of the HIPAA Privacy rule, researchers have begun to document that HIPAA is hindering research by increasing researchers’

administrative burden (Clause, Triller, Bornhorst, Hamilton, & Cosler, 2004; Lydon-Rochelle & Holt, 2004), delaying initial project approval (Heiney et al., 2006; O'Herrin, Fost, & Kudsk, 2004), impeding subject recruitment processes (Albert & Levine, 2005; Blanton et al., 2006; Heiney et al.; Kaiser, 2004; Ness, 2005; Wolf & Bennett, 2006), escalating recruitment costs (Albert & Levine; Heiney et al.), hampering medical record and registry research (Inglefinger & Drazen, 2004; Lydon-Rochelle & Holt; O'Herrin et al.), and generating data sets that are less than adequate for good research (Clause et al.; Inglefinger & Drazen; Maas, Kompanje, & Stocchetti, 2005).

The purpose of the article is not to discuss the impact of HIPAA on research per se, but rather to address the impact of HIPAA on subject recruitment and retention issues in prospective, clinical research studies. Proactive HIPAA compliant strategies for subject recruitment and retention are emphasized. Since the interpretation of the HIPAA Privacy rule continues to vary widely, often depending on the local level of risk avoidance of the Institutional Review Board (IRB) or Privacy Board (Albert & Levine, 2005; Ness, 2005), researchers should consult with their institution's IRB/Privacy Board policies to ensure local compliance.

The impact of HIPAA on subject recruitment and retention can be broken down into seven basic areas: 1) preparatory research, 2) initial contact of potential subjects, 3) pre-screening potential subjects, 4) consenting subjects, 5) long-term follow-up of subjects, 6) recruitment for future studies, and 7) training of research staff. Administrative burden will be addressed as it pertains to these areas.

Preparatory Research

In planning a study and preparing a grant application, it is essential to know the potential study population available for recruitment. An accurate estimate of the percentage of subjects available who will meet the study's inclusion criteria also is necessary. When planning an intervention study, it is quite useful to know what the current standard of care is at each institution. This type of information can be obtained via chart review at potential recruitment sites. Prior to HIPAA, these activities were not regulated by the IRB. Under HIPAA, accessing individually identifiable protected health information (PHI) for these purposes requires IRB/Privacy Board approval (Erlen, 2005; Olsen, 2003). Some institutions initially interpreted HIPAA regulations to mean a researcher could not access any medical records for preparatory research or recruitment without patient consent (Ness, 2005; Russell, 2004b). These restrictions resulted in a significant barrier to subject recruitment. As institutions have become more familiar with the Privacy rule, initial interpretations have been altered to allow HIPAA waivers and preparatory research reviews (Ness; Russell, 2004a).

The purpose of preparatory research is to review PHI to prepare a research protocol or to facilitate subject recruitment by identifying prospective research subjects for purposes of seeking their authorization to use or disclose PHI for a research study (U.S. Department of Health and Human Services [US DHHS], 2004). Prior to performing preparatory research, the researcher completes a Preparatory to Research form and submits it to their local IRB or Privacy Board. On the form, the researcher outlines the following: 1) the purpose of the review, 2) what specific PHI will be used and/or disclosed, 3) why the PHI is necessary for the research, 4) where the information is located, and 5) how and by whom the information will be accessed. The researcher agrees not to remove any PHI from the covered entity and to follow the minimum necessary standard. The minimum necessary standard requires the researcher to use only the information necessary to answer the specific questions outlined on their form (Muhlbaier, 2002). For example, the researcher should examine records only for the approved clinic(s) or health care provider(s) and should not review information unrelated to their research topic. If no treatment relationship exists between the researcher and prospective subjects, the

researcher should work with hospital and/or clinic staff to contact potential research subjects identified in the preparatory research.

A covered entity may require the individual who accesses medical records for preparatory research or recruitment to be an employee of the covered entity. If the researcher is not an employee, a co-investigator who is an employee (of the covered entity) can perform the review. In instances where all the investigator needs is the number of cases of a particular ICD-9 code, the medical records department and/or clinic staff may be able to perform an electronic review for the researcher. Researchers need to be aware some covered/hybrid entities may charge a fee for the generation of de-identified data (Gunn et al., 2004; Olsen, 2003) or a “medical record pull fee” (Lydon-Rochelle & Holt, 2004).

Initial Contact of Subjects

Gaining access to potential research participants with particular health conditions is a challenge for nurse researchers (Rose, 2000; Wilson-Barnett & Griffiths, 2002), but the HIPAA regulations have made the initial contact of potential research subjects even more complicated. Prior to HIPAA, many researchers reviewed daily patient lists with clinic/hospital staff to identify potential eligible subjects and then approached patients directly (Muhlbaier, 2002; Ness, 2005; Wolf & Bennett, 2006). Under HIPAA, it is considered inappropriate for personnel at the covered/hybrid entity to disclose the names and/or contact information of potential subjects to a researcher without the subject’s explicit authorization. In other words, the researcher cannot obtain a list of clinic/hospital patients and directly approach patients in person, over the telephone, or by sending out letters. Unless a HIPAA Waiver can be obtained, a health care provider should introduce the study to the patient and obtain the patient’s assent before the researcher may approach the potential subject.

As a result, some researchers have described substantial decreases in subject accrual as well as increases in recruitment costs after the implementation of the HIPAA Privacy rule. Ness (2005) reported recruitment of pregnant women for a preeclampsia prevention project decreased from an average of 12.4 subjects/week before HIPAA to 5.7 subjects/week after HIPAA. In the Selenium and Vitamin E Cancer Prevention Trial (SELECT) researchers found subject recruitment declined from 7.0 subjects/week to 1.9 subjects/week after HIPAA (Wolf & Bennett, 2006). Wolf and Bennett also determined that recruitment costs increased from \$49/subject to \$169/subject after the implementation of the HIPAA Privacy rule. Increased recruitment costs have been particularly problematic for studies already “in progress” at the time of the implementation of the HIPAA Privacy rule.

In response to the HIPAA Privacy rule, researchers have found it helpful to have one or more clinical collaborators or staff liaisons to facilitate subject recruitment. The most direct way the clinical collaborator/staff liaison can assist the researcher with subject recruitment is to personally inform their patients about the study during a clinic/hospital visit. Although a patient is more likely to participate in a study if asked by their primary care provider/physician (Loftin et al., 2005), having a physician or other clinic/hospital staff determine study eligibility and introduce the study to potential subjects may be challenging given the patient care responsibilities in a busy clinic or hospital unit. In fact, researchers indicate the more work required of physicians, the greater the resistance to assist with a study (Heiney et al., 2006). A number of challenges to and strategies for obtaining gatekeeper “buy in” have been identified previously by others (Rose, 2000; Northouse et al., 2006; Villarruel et al., 2006). To facilitate patient referral in the post-HIPAA era, Wolf and Bennett (2006) found the following strategies helpful: 1) add the clinic medical director as study key personnel, 2) involve desk clerks, nurses, and physicians in patient referral, 3) make sure the research staff are visible to the clinic staff,

4), have research staff attend clinic daily, and 5) have the researcher visit the clinic frequently to encourage patient referral.

If research staff cannot be available on a daily basis for subject referral, an alternative strategy is to have the clinical collaborator/staff liaison obtain authorization from the patient to give the researcher the patient's contact information. In a recent National Institute of Nursing Research funded study examining a smoking cessation intervention during pregnancy (Principal Investigator-Linda Bullock RN, PhD), the researcher recruited subjects from Women, Infant, and Children (WIC) clinics at rural health departments in the Midwest. Pregnant women who visited the WIC clinic were informed of the study by the clinic staff. Interested patients signed a form allowing their contact information to be given to the researcher. The clinic placed a copy of the form in the patient's chart so women were not asked more than once about participating in the study. After the researcher received the contact information, the patient was contacted via telephone by the research staff. This strategy allowed the researcher to recruit from multiple WIC clinics simultaneously while remaining HIPAA compliant.

An additional strategy is to have the clinical collaborator write a letter to their patients with the particular health condition of interest, informing them of the study. To facilitate the process, the researcher can draft a letter which the clinician can place on his/her letterhead. To prevent the impression the clinician revealed patients' PHI to the researcher, the letter should be signed by the clinician only and then mailed by the clinician's administrative staff (Olsen, 2003). Depending exclusively on a letter from clinical collaborators for recruitment has been criticized since it is an impersonal means of approaching potential subjects, generates a biased sample, and lengthens the recruitment process (Albert & Levine, 2005; Kaiser, 2004; Rose, 2000). Sample bias can be minimized and recruitment success can be increased by utilizing multiple methods of subject recruitment.

In addition to clinical collaborator referral, a number of other HIPAA compliant strategies remain available to researchers (Table 1). With prior approval of the local IRB, the use of flyers, advertisements, and the electronic media are acceptable methods for making initial contact with subjects. For researchers with limited recruitment budgets, flyers and electronic media tend to be less expensive methods compared to newspaper, magazine, radio, or TV advertisements (Loftin et al., 2005). Flyers can be posted at health care institutions such as hospitals and clinics, as well as in community locations such as pharmacies, public libraries, and senior and community centers. Many academic health sciences centers have a webpage advertising current clinical trials and nurse researchers can request to have their projects posted on the webpage (see example at https://apps.muhealth.org/clinical_research/). Researchers who are faculty members at a school of nursing can utilize their school's web page to advertise their project (see example at <http://www.missouri.edu/%7Efinfgeldd/>). Webpage advertisements can be designed to include contact information for the study coordinator or have a study interest/sign up form embedded on the webpage that is sent to the researcher or webmaster upon completion (see Clinical Trials Sign Up Form on https://apps.muhealth.org/clinical_research/).

With institutional approval, electronic advertisements can be sent out via email to faculty, staff, and students. In our recent American Heart Association funded study examining the skin microvascular responses to compression bandaging and leg elevation in healthy young and older adults, we found younger men (age 20 to 30 years) were particularly responsive to electronic advertisements, whereas our mid-life and older adults were more likely to have seen a flyer in the community or heard about the study from a friend. Our experience is consistent with reports from the Pew Internet & American Life Project indicating the demographic characteristics of Internet users tend to be young, male, White, educated, and from a high socioeconomic status (Lenhart, Horrigan, & Fallows, 2004). When advertisements and flyers

are a major mode of recruitment, researchers must keep their research office telephone manned every day, respond as quickly as possible to all inquiries, and need to anticipate that a high portion of the calls will be from individuals who do not meet study criteria (Heiney et al., 2006; Loftin et al., 2005).

Pre-Screening Potential Subjects

When flyers, advertisements, or snowball/reactive recruitment are utilized, the first contact the researcher has with the subject is over the telephone. Since the researcher would be collecting PHI without a signed HIPAA Authorization, some institutions initially interpreted HIPAA regulations to mean pre-screening of potential subjects over the telephone could no longer occur. This interpretation decreased recruitment efficiency because researchers were spending time scheduling and consenting potential subjects only to find at the first study visit, the subject did not meet study criteria.

A researcher can pre-screen potential subjects over the telephone with the use of a HIPAA Waiver of Authorization. The researcher completes a HIPAA Waiver or Alteration of Authorization form and submits it to their local IRB or Privacy Board. On the form, the researcher describes their project, the PHI and sources of the PHI to be collected and agrees to adhere to the minimum necessary standard. The researcher needs to demonstrate the following: 1) the research could not practicably be done without a waiver (or alteration), 2) the research could not practicably be done without PHI, 3) the subject's rights/welfare will not be adversely affected, 4) there is a reasonable risk to benefit ratio, 5) the use or disclosure plan involves no more than minimal risk to privacy, and 6) a plan to protect identifiers and destroy identifiers at the earliest opportunity (US DHHS, 2004). The researcher agrees to destroy all the data collected if the subject fails the telephone screening or is not interested in participating. For privacy purposes, the data collected should be disposed of by shredding. If the subject passes the telephone pre-screening and desires to participate, the researcher obtains informed consent and a HIPAA Authorization from the subject as soon as possible (i.e. during the first study visit).

Alternatively, some institutions may determine that a HIPAA Waiver or Alteration of Authorization is not required if a potential subject calls the recruitment number and is screened at that time, as the person is freely volunteering to provide his/her health information. As previously mentioned, consultation with the researcher's local IRB/Privacy Board is strongly recommended to verify local HIPAA Privacy rule interpretation.

The Consent Process

HIPAA impacts the number, length, and complexity of the forms in the subject consent process, which can be a deterrent to the recruitment of potential subjects (Heiney et al., 2006; Ness, 2005; Steinke, 2004). If the researcher is part of a covered/hybrid entity and collecting PHI, there are three aspects to the consent process: 1) provision of a copy of the institution's Notice of Privacy Practices (NPP), 2) obtaining informed consent, and 3) obtaining a HIPAA Authorization. Each institution has its own NPP which informs patients as well as research subjects about the institution's privacy practices and responsibilities under the law, the uses and disclosures of PHI, the subject's rights and how to exercise them, and the process for subjects to gain access to their records. The researcher should obtain written acknowledgement that the subject received the NPP. At our institution, the written acknowledgement that the subject has received a copy of the NPP is part of the HIPAA Authorization form.

Although HIPAA regulations require the Authorization form and NPP to be "written in plain language" (US DHHS, 2004), recent research indicates both HIPAA Authorization forms and NPP from top-ranked healthcare institutions do not meet that criteria. HIPAA Authorization

forms are written above the 8th grade reading level and are similar in complexity to that found in “corporate annual reports, legal contracts, and the professional medical literature” (Breese, Burman, Rietmeijer, & Lezotte, 2004). The NPP forms are quite long (~ 6 pages), use a small font size (≤ 10 point font) and contain difficult language (reading levels between 11th - 13th grade) (Breese & Burman, 2005).

While the researcher does not have control over the legal jargon and/or the overall length of the HIPAA Authorization template utilized by their institution, there are mechanisms by which the researcher can minimize participant burden during the consent process. Prior to submitting their HIPAA Authorization form to the IRB/Privacy Board, the researcher needs to anticipate two things: 1) all possible types of PHI needed for the study, and 2) all possible uses and disclosures of PHI. The researcher should use descriptive categories of PHI to be collected (e.g. blood tests rather than liver function tests) and generic titles of persons to whom the PHI might be used by and/or disclosed (e.g. graduate students or co-investigators rather than a specific individual’s name). In the event of protocol or personnel changes, these proactive strategies will benefit both the researcher and the subjects. The researcher will not have to submit an amended HIPAA Authorization to the IRB/Privacy Board, and the subjects will not have to read and sign an amended Authorization form.

During the initial contact with the subject, it is critical for the researcher to explain all the study details using simple lay language. When explaining the required forms to the subject, each document needs to be presented separately. The researcher can offer to read the documents to the subject. This allows subjects with limited vision and/or low reading levels an opportunity to understand the forms without the embarrassment of having to admit to a disability. For medically frail subjects, reading the forms aloud reduces the physical and mental effort required by the subject. The researcher must ask the subject if they understand what is involved in the study and if they have any questions or concerns before the subject signs any forms. If these strategies are utilized, subjects will be well informed and less likely to feel overwhelmed by the consent process and the HIPAA required documentation.

Streamlining the consent and HIPAA document process can be challenging when the researcher is employed at one institution/covered entity (e.g. local university) but will recruit subjects and/or collect data at another institution/covered entity (e.g. community hospital). While reciprocal IRB approval is possible, many institutions required researchers to submit an IRB application to each institution during the initial implementation of HIPAA (Heiney et al., 2006; Lydon-Rochelle & Holt, 2004), thus, increasing administrative burden. With advanced planning and clear communication between the researcher and the compliance officer at each institution, both participant burden and administrative time can be minimized. To facilitate the process, the researcher needs to discuss the planned project with the compliance officer at each institution prior to submitting an IRB application. One IRB should agree to “rely on” the other institution’s IRB approval and consent/HIPAA documents. Obtaining reciprocal IRB approval not only decreases administrative burden, but also ensures the subject will be required to read and sign the consent and HIPAA documents from only one institution, thus minimizing participant burden during the consent process.

Long Term Follow-up of Subjects

For longitudinal or time series studies, it is essential for the researcher to be able to follow up with the subject. Retention of subjects is known to be enhanced by utilizing appointment reminders (Villaruel et al., 2006), however, the researcher must be cognizant of participant privacy. Postcard reminders are discouraged under HIPAA since the subject’s medical diagnosis may be inferred to anyone seeing the postcard (by virtue of the study logo, and/or the researcher’s or clinic name). Mail reminders should be sent in an envelope and the return

address should not include the name of the study (e.g. the Breast Cancer Research Group). Care should be taken to make sure the mail reminder does not look like a hospital bill or the subject may delay opening it (Heiney et al., 2006). If reminder telephone calls are utilized, PHI should not be revealed on answering machines or to family members answering the telephone. A generic message such as "This is Dr. Jane Doe calling to remind you of your appointment on such and such a date and time. If you have any questions or need to reschedule, please call my office at (phone number)." Utilizing a mail reminder several days in advance, followed by a telephone reminder 24 to 48 hours in advance of a follow-up appointment has been shown to be an effective strategy for retention of subjects (Loftin et al., 2005; Villaruel et al.). In the computer age, electronic mail (emails) has become another option for appointment reminders. One must be cognizant that some older adults are not computer savvy and some minorities may not have email access (Lenhart et al., 2004); in which case, other strategies will need to be utilized.

Reimbursement of subjects is a well-known strategy for the retention of subjects. The processes by which subjects are reimbursed need to be consistent with subject privacy. The standard subject reimbursement process involves the university's accounting department sending a check to the subject's home. This reimbursement process can be problematic if the subject perceives the disease being studied may have negative social and/or economic consequences (e.g. HIV, alcoholism or breast cancer). For example, in a small college town where the university is the largest employer in the area, subjects may be concerned that personnel in the accounting department will know they have been treated for a particular disease by virtue of processing their reimbursement paperwork. To solve this dilemma, many researchers at our institution have established a personal research checking account for their study using a university approved expense advance process. Alternatively, other researchers have bypassed this potential problem by reimbursing subjects with gift cards, books of stamps or other monetary equivalents (Loftin et al., 2005).

Recruitment for Future Studies

Depending on the type of research performed, it is possible to utilize subjects from previous studies in future studies. If the researcher did not have a HIPAA Authorization to collect contact information during a study (e.g. address, email address, telephone number), then they may not be able to contact previous subjects directly for future studies without additional IRB/Privacy Board approval. If the researcher plans ahead, there are HIPAA compliant strategies to assist with recruitment for future studies while minimizing administrative burden.

The creation of a recruitment database is a useful strategy for nurse researchers who do not have a clinical practice and do not have an existing treatment relationship with their population of interest (Erlen, 2005). A recruitment database or research registry contains individuals interested in participating in future studies (Schwartz, Brecher, Whyte, & Klein, 2005). A recruitment database is different from a clinical registry (which many health care providers keep) that contains all the patient's contact information and PHI. During our recent National Institute of Nursing Research funded study testing the effects of position and compression bandaging in venous ulcer subjects, we established an IRB approved recruitment database. Our database is setup as two separate password protected electronic database files. The first file is the Subject Contact file. The Subject Contact file contains the following information: 1) subject's name, 2) home telephone, 3) work telephone, 4) cell phone number, 5) mailing address, 6) email address, and 7) preferred mode of contact. Each subject is given a coded identification (ID) number. The ID number in the Subject Contact file is identical to the corresponding entry in the Subject History file. The Subject History file contains minimal PHI such as: date of birth, gender, healthy control (yes/no), venous ulcer subject (yes/no), other microvascular disease (yes/no), and taking exclusion criteria medications (yes/no). A limited

number of research staff have access to the database, and those who do must sign a privacy statement agreeing not to use the information for any other purposes. For future studies, the investigator can search the Subject History file, identify potential subjects and write down their ID number. Then, the investigator can obtain the relevant contact information from the Subject Contact file and can contact the subject to ascertain interest in the new study.

We started our recruitment database after we had already completed several preliminary studies. To take advantage of our previous work, we obtained approval from our IRB to contact our previous subjects and obtain consent (using waiver of documentation of consent procedures) to add previous subjects to the database. Any subjects who fail our telephone screening in our current venous ulcer study are offered the opportunity to be in our recruitment database for future studies. This is helpful for subjects who are disappointed at not qualifying for the study. In all our current consents, we have a question (that the subject must initial beside the “yes” or “no”) asking if the subject is willing to be contacted for future studies. Subjects indicating a “yes” response are added to the recruitment database.

Training of Research Staff

New research staff require extensive training specific to the study protocol and procedures. The HIPAA Privacy rule has added extra requirements for the training of new research staff and students. HIPAA privacy and human subjects compliance training is required of all research team members including staff and students. This training is time intensive and can be overwhelming, especially for undergraduate or graduate students with little exposure to research. Some recruitment sites (e.g. Veterans Administration Hospitals) may require additional HIPAA Privacy, Good Clinical Practices (GCP), and Cybersecurity training before staff or students can have any direct contact with subjects, their data, or their medical record. If a student is doing an independent study with the research group, a lot of time can be spent completing the compliance training. We try to arrange independent studies the semester before, include compliance training as part of the course objectives, content, and evaluation process, and ask the student to complete the training in advance. This allows us to submit an amendment to add the student to our research team before the semester starts so the student can assist immediately with subject recruitment, screening, and data entry activities. We have found students get more out of the research experience and it helps us proceed with subject recruitment and retention activities with minimal interference.

Since IRB procedures and interpretation of HIPAA regulations continue to evolve (Conner, Smaldone, Bratts, & Stone, 2003; Erlen, 2005), annual training updates are necessary to ensure compliance by researchers, their staff, and students. If co-investigators or research staff do not complete their training updates on time, processing of IRB amendments and/or continuing research reviews may be delayed. At our institution, all IRB submissions are electronic and the researcher is unable to submit any form if one research team member has expired compliance training. Such delays can be prevented by developing a system to track the training dates of each research team member and sending email reminders prior to their training expiration. While these proactive measures prevent undue delays, they increase the administrative duties required of the researcher.

In conclusion, the HIPAA Privacy rule was designed to protect the privacy of the individual's PHI. While subject recruitment and retention have undoubtedly been impacted by the HIPAA Privacy rule, careful consideration of the regulations and prior planning can facilitate rather than hinder recruitment and retention efforts. Preparatory research reviews are helpful in determining study feasibility and sample populations. A HIPAA Waiver of Authorization may be needed to allow for pre-screening over the telephone and careful preparation of HIPAA Authorization forms can prevent the need for amendments. The development of a recruitment

database can facilitate recruitment for future studies. More than ever before, researchers will find it useful to work closely with healthcare providers to ensure continued access to potential research subjects (Gunn et al., 2004; Loftin et al., 2005). Establishing systematic procedures and records of HIPAA compliance training and renewals will prevent unnecessary delays when studies are amended and renewed. Researchers and staff who are knowledgeable of HIPAA regulations will experience fewer delays in the initiation of study protocols and will be better prepared to recruit and retain subjects for their studies. Utilizing multiple methods of recruitment can reduce accrual time and create a more generalizable sample. Even with thorough preparation, researchers and funding agencies need to recognize that recruitment of subjects for prospective clinical research studies in the post-HIPAA era requires additional time, manpower and personnel dollars (Loftin et al.; Lydon-Rochelle & Holt, 2004; Wolf & Bennett, 2006). Grant timelines and personnel budgets need to be adjusted accordingly.

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Table 1**HIPAA Compliant Strategies for Initial Subject Contact.**

Advertisements in newspapers, the radio and/or television
Physician, advanced practice nurse, and/or clinic staff referral
Electronic media advertisements
Flyers and pamphlets in clinics and surrounding community
Presentation at churches and/or advertisement in church bulletin
Presentation at support group and/or advertisement in newsletter
Presentation at community or senior center
Recruitment booth at local health and wellness fairs
Snowball/Reactive recruitment