Recruiting subjects for clinical research outside the academic setting

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Why recruit outside the home institution

- Generalizability
- Need to access a larger sample
- Complete recruitment faster
- Ethical imperative
Recruiting outside practices

• Provide incentives
  - Payment/reimbursement for staff time
  - Honorarium to physician or practice (this will vary by site)
  - Non-monetary incentives
    ✓ What added value can the study have for the practice?
  - Make the study easy
    ✓ Do not expect a lot of assistance
    ✓ You can’t pay enough to recompense for staff time
    ✓ Have study procedures that the study research staff can perform
Recruiting outside practices

- The staff must be recruited too
- Make contact with the office gatekeeper
- Use a detailing approach
- Personal visits are preferred: bring food or a ‘chachka’ when you visit
Can these approaches be successful in recruiting outside clinical practices?

YES!
Clinical sites recruitment map n=117
Case finding and recruitment of outside practice patients
HIPAA regulations: revisions to rules as of August 2002 § 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.† (67 Fed. Reg. 53,270 (August 14, 2002, final rule)

Exact wording of the rule:
A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section.

(i) Standard: Uses and disclosures for research purposes.
   (2) Documentation of waiver approval.

   (iii) Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

   (A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

   (1) An adequate plan to protect the identifiers from improper use and disclosure;
   (2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
   (3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

   (B) The research could not practicably be conducted without the waiver or alteration; and
   (C) The research could not practicably be conducted without access to and use of the protected health information.
What are the practical implications of HIPAA

The ability of researchers to use and disclose PHI to recruit potential research subjects continues to be an issue of concern for researchers, research institutions and commercial sponsors of research, all of whom depend on sufficient enrollment for the reliability of the research they conduct, oversee and fund.

What are the practical implications of HIPAA

- The NIH's guidance on Clinical Research and the HIPAA Privacy Rule, (the February 2004 Guidance), states that Covered Entities may use the preparatory review exception to use or disclose PHI to researchers to aid in study recruitment. NIH also indicated that researchers who are members of the Covered Entity's workforce may contact potential study participants as part of the Covered Entity's "health care operations."

- The Covered Entity can also do this activity through a "business associate" agreement. Researchers who are not members of the Covered Entity's workforce can be retained as business associates for the purposes of case finding and contacting identified potential subjects.

Business Associate Agreement

- Purpose of a BAA is develop an agreement that will allow the researcher to act as the agent for the clinical site.
- Allows researcher ability to facilitate case finding and contacting of potential subjects
- Elements of a BAA
  - Who the agreement is between
  - Obligations and activities of Business Associate
  - Permitted uses and disclosures by Business Associate of PHI
  - Termination of agreement
Example Protocol to Recruit Patients

- Clinical staff assist research staff to identify potentially study-eligible patients
- List of names provided to practice physicians for permission to contact
- Patients with no permission to contact deleted from list
- Research staff send letter on behalf of practice and one from study investigators inviting them to consider study participation
  - Phone number for practice provided in letter telling them to call if they do not wish to be contacted
- Patients who call are deleted from contact list
- Remaining individuals contacted by research staff to discuss study participation
Regulatory and Ethical Issues

• How does this balance the right to privacy with the ethical duty to conduct useful research?

• How should we balance autonomy and privacy?

• Do patients frequently complain about this form of case finding?
NonVCU Patient response to contact by VCU research staff

- Letters sent to nonVCU patients: 282
- Patients asking for no contact: 9 (3.2%)
  - None complained about VCU having their names but called to ask for no contact as knew they were uninterested in the study

- Study consent rate (nonVCU): 85.6%
- Study consent rate (VCU): 91.7%
Conclusions

• Recruitment outside VCU has many benefits.

• Recruitment has to be conceptualized in two phases: 1) recruiting the clinical site and 2) recruiting patients.

• Incentives and detailing techniques to get a ‘foot in the door’ are essential.

• We can recruit subjects more directly (and successfully) by using mechanisms such as a BAA. This allows compliance with HIPAA regulations and makes the study more self-sufficient and therefore more acceptable to busy clinical practices.
Conclusions

• As a society we value and support research.

• In considering the ethics of recruitment must remember that privacy is not the only ethical imperative.

• Other ethical principles such as autonomy and the need to assure that the research we do is valid must be part of the ethical equation.