

HIV Surveillance & Epidemiology Program

*The New York City Department of Health
and Mental Hygiene*

**Confidentiality & Professionalism in
Surveillance and Research**

(June 2004)

Definitions

- Surveillance
- Research
- Confidentiality
- Professionalism

Surveillance

- Definition: Collection and analysis of information on a disease that is reportable by law.
- ‘Reportable disease’ = every diagnosis of the condition must be reported to the New York State Department of Health.
- The New York City Board of Health has designated many additional conditions as reportable—TB, STD, vaccine-preventable diseases, etc.
- Case surveillance is a legislated public health activity.
- No patient authorization for release of data is needed in the case of a reportable disease.

Authorization for Surveillance

- Named reporting of HIV and AIDS by diagnostic providers and laboratories is required:
 - New York State Sanitary Code Section 24.1 and Article 21, Title III
 - New York City Health Code Section 11.05
- The NYCDOHMH is authorized by the NYS Department of Health to conduct HIV/AIDS surveillance in New York City

Examples of Reportable Diseases

- Tuberculosis
- Plague
- Malaria
- Cholera
- Measles
- Syphilis
- West Nile Virus
- Legionnaire's Disease
- Typhoid
- HIV/AIDS

Who must comply with public health surveillance?

- **EVERYONE.**
- Public health surveillance is needed to monitor ongoing epidemics, protect the health of the public, identify outbreaks, and provide data for planning of prevention and primary care resources.
- Surveillance is not just a good idea. It's the law.

Public Health Research

- Public health research is an activity that is designed to answer an important question or test a hypothesis or intervention that may have broad public health significance.
- It does not directly benefit the patient or participant. It may benefit others in the future. The justification for the research is the ‘benefit to society.’

Who Must Comply with Public Health Research Activities

- No one is or can be compelled to comply with any research activity.
- All participation in research is voluntary.
- Consent must be freely given by the participant after he or she has been completely informed about the purpose, methods and activities involved in the study and after he or she has had time to think carefully about whether to participate.
- Patients must be given ample opportunity to weigh and discuss the risks and benefits of participation.

Examples of Low Risk Research

- Anonymous survey
- Confidential survey
- Chart review (common form of epi research)
- Anonymous or confidential blood draw plus survey
- Participation in a behavioral intervention trial
- Testing of blinded blood remaining from a diagnostic blood test (common form of epi research)

Remember: even in low risk research participants *always* risk loss of privacy and confidentiality

Examples of > Minimal Risk Research

- Randomized controlled trial of a new treatment regimen for multi-drug resistant tuberculosis
- Randomized placebo controlled trial of an experimental HIV vaccine
- Randomized controlled trial of a new treatment for acute spinal cord injury
- Randomized controlled trial of medical vs. surgical intervention in acute myocardial infarction

Protection of Privacy and Confidentiality

- The privacy and confidentiality of all persons subject to public health surveillance or public health research is protected by:
 - Federal, state and local law
 - Ethics
 - Professional Standards
- For example, HIV-related information

New York State Public Health Law
Article 27F

Background: New York State Law

- Article 27F, Section 2782 protects confidential HIV-related information and defines the limits of disclosure—who, what, when, under what circumstances HIV information can be disclosed
- Section 2783 provides for civil penalties for violation of 2782 in the case of willful disclosure of protected information
- Penalty is levied per case occurrence, not per event

Local Law

New York City Public Health Code Section
11.05 protects confidential HIV-related
information and provides penalties for
disclosure

Federal Law: HIPAA

The Health Insurance Portability and Accountability Act

- April 14, 2003
- HIPAA defines *all* information contained on a medical record as private health information (PHI)
- Access to PHI requires informed consent for any reason other than access by a person providing direct clinical care or conducting legally mandated surveillance
- All research projects requiring access to PHI, even if there is no direct contact with the patient, require informed consent

Our Confidentiality Pledge

- You will sign a confidentiality pledge today
- The pledge is the tie that binds us all together
- It is the promise that we make to ourselves, our colleagues, and the city of New York to uphold Article 27
- It shows our respect for the patient's privacy and vulnerability, and our recognition of the patient's dignity and rights
- It shows our respect for the Department of Health's public health mission and for the important role that epidemiology plays in HIV prevention

Confidentiality in Research

- All research data are considered confidential
- In some ways they are even “more” confidential than medical data and surveillance data
- Research data are collected to benefit society or to provide non-surveillance-related public health information. The patient does not benefit personally from the research.
- Part of our respect for the patient in this situation derives from his willingness to participate despite the lack of personal benefit—his altruism.
- An ‘incentive’ is not a benefit—it is a reimbursement for time and effort.

The Trust of the Patient

- Patients and research participants trust that we collect these data for a legitimate public health or research purpose.
- They are doing us a favor by agreeing to participate and allowing their medical and behavioral information to be entered into the study.
- Research participants entrust us with maintaining the confidentiality of their data and respecting their dignity as persons.
- This is a sacred trust that can never be violated.
- This trust and the confidentiality promise does not ever “expire,” even after the study is over.

Understanding the Meaning of Confidentiality and Data Security

- Pre-employment Screening—has the applicant ever worked in a confidential medical, epidemiological or legal environment?
- Employer References—ask the right questions about the person's attitude, understanding and adherence to confidentiality protocols
- Interview—ditto re: the right questions
- Attitude, maturity and good judgment are essential characteristics to look for

New Employee

- First Confidentiality Pledge. Go over it carefully with your new staff. Just like informed consent, it's a process, not just a signature on a piece of paper. It's not *pro forma*. We really mean it!
- Confidentiality training
- Mentoring—do it, and accept it!
- Shadowing—do it, and accept it!
- Assessment of “field readiness” and full-performance status—gauge capacity for independent work; look for good judgment, adherence to protocols, acceptance of the program's values

Seasoned Staff

- No matter how long one has been on the job, there is value to repeat instruction
- There may be changes in the legal or epidemiological environment that result in new procedures, e.g., HIV reporting, STARHS results, and that require new training and reinforcement
- Annual Training—think of the issues you have faced this year, the questions you'd like to raise
- Annual Renewal of Pledge—we should all read it carefully every time we renew!

Confidentiality Pledge

- Information that you have access during your employment at the New York City Department of Health and Mental Hygiene in the HIV Surveillance and Epidemiology Program is confidential information. This information includes, but is not limited to medical, social, personal, and financial information relating to a patient.

What are some examples of 'personal' information?

Confidentiality Pledge

- Even if you are authorized to access client or patient files, **you may not:**

Examine any document or computer information unless examination of that specific file is required in the performance of your official duties and responsibilities

If you aren't reviewing that chart, that lab report or that survey instrument as part of your assignment, you shouldn't be looking at it!

Confidentiality Pledge

You may not:

Remove from the site or copy any documents or computer information unless you are authorized to do so.

Who would have the authority to issue such an authorization?

Confidentiality Pledge

You may not:

Discuss the content of such documents or computer information with any person unless you are authorized to do so.

Who are the appropriate people with whom such a discussion would be permitted?

Is it OK to talk about work with friends and family, or talk on the subway with one of your colleagues on the way back to the office?

Confidentiality Pledge

- **You may not:**

- Discuss, disclose, report, present, or otherwise disseminate surveillance or research data without prior authorization and without *official clearance* from the Department of Health.

- Discussion or dissemination of aggregate data must be cleared.

- Under no circumstances would discussion or dissemination of individual data of any kind be permitted.

Confidentiality Pledge

- When you sign this pledge, whether you sign it once or 20 times, your promise is binding for the rest of your life.
- Even after you leave the Department of Health or any agency that is collaborating with the Department of Health, you have pledged to keep confidential all of the information that you have seen, and you must honor that pledge.

Confidentiality Pledge

You may not:

Discriminate, abuse, or take any adverse action against a person to whom the information applies.

What is an example of an 'adverse action'?

Penalty for Violation

Violation of your confidentiality pledge can result in disciplinary action, termination, and can lead to civil and/or criminal charges

State law also provides for fines in the case of unlawful disclosure

Principles of Data Security

- Create a solid protocol, train everyone, and review the protocol periodically
- Maintain vigilance
- Think of all the ‘accidents’ that can happen
- Think of your own close calls, e.g., leaving something out on your desk, having someone try to grab your backpack on the street, encountering a participant outside of a work situation
- Look for opportunities to improve the procedures
- Tell us when you see a hole in our procedures—they are there to protect everybody and can always be improved.

The Golden Rule

- When you think about confidentiality and data security, think about what you would want for yourself!
- Think about how it would feel to have to trust the Department of Health or one of its collaborating agencies with information about you, your HIV infection, your sexual behavior, your STD diagnosis, your sex partners, etc.

Discretion and Good Judgment

- Discretion is an important part of confidentiality and respect for others.
- What does discretion mean in the context of our work in surveillance and/or research?
 - Exercise good judgment. Be careful when and where you discuss work, the program, and the DOH—not advisable on the subway, in a restaurant, at a party or large gathering, in the hospital or clinic, or in any public space
 - Discuss work only in general terms with persons who are not your colleagues
 - Obtain clearance, and have a representative present, *whenever* you talk to the press or a public official
 - Do not discuss ongoing analyses with persons other than your colleagues—preliminary trends and results should not be released or discussed in public without clearance
 - Remember that anything you say about the AIDS epidemic can be misinterpreted, re-interpreted, or repeated out of context

Ethics and Professional Boundaries

- In any setting in which you have direct contact with a patient or participant, you must maintain a professional boundary between yourself and that person
- Remember that your only relationship with that person is a professional one
- You are representing the study, your agency, and the Department of Health and must conduct yourself with dignity, decorum, professionalism, and respect, even when you are off duty

Do Not Mix Work and Life

- The professional boundary between you and the participant must be maintained at all times.
- You may not use any survey activities to meet people socially—do not ever call a respondent or approach him socially.
- If you encounter him in public, wait for the person to acknowledge you before acknowledging him. Be civil, courteous, and *move on*.
- You must not show any personal interest in the participant other than the professional level of interest that is required for counseling.
- You must show empathy for the participant without becoming personally involved with him and without permitting any social ‘opening’.

What if You Already Know Someone Who is a Reportable Case or Potential Study Participant?

If you already know somebody that is a reportable case or is being recruited for a study:

- You cannot review his chart.*interview him.*
- You cannot recruit, interview or counsel him.
- You cannot divulge anything you know about him to the study team.
- You cannot have any study-related contact with him or his information.
- You cannot read his survey or view his test results.
- You cannot talk to your colleagues about him.
- You cannot talk socially to him about the study.

What if you have a strong personal feelings about a participant?

- You must maintain that professional boundary, or you must separate yourself from the research relationship. Even after separation from the research relationship, you may not pursue the relationship socially.
- You should talk to your supervisor about how to maintain professional boundaries.

What if a Patient or Participant Shows Strong Personal Feelings Toward You?

- You must deflect those feelings
- You must not react to them personally
- You must maintain that professional boundary at all times during your interaction and afterward
- If you cannot deflect the person's interest, excuse yourself and ask the supervisor to assign another counselor to the person
- Consult with your supervisor about how best to handle participants who come on to you

How to Make it Happen Right

- Use common sense; remember the rules about confidentiality and professional conduct
- Talk to your supervisor
- Supervisors, talk to your staff and help them think through these problems. Give examples. Practice.
- Restrict access and technology to those with a “need to know”. *Access creates opportunities, even if no malice is intended. No internet access, no floppy, zip or CD drives for computers with names data.*
- Leave extra time—put your papers away in your desk; bring material back to the office
- Don’t be in a rush—it’s a setup for an accident
- Help each other
- Don’t think it can’t happen to you!

Summary: Confidentiality

- It's the law.
- It's the right thing to do:
 - Think about the respect that you would want surveillance or research staff to have for information about you. *Do unto others....*
 - It's good for epidemiology. If providers and patients trust us, they will willingly cooperate with us. They will report cases and help us with our research studies. The more we learn about HIV, the more we can do to stop it from spreading and keep HIV+ people healthy
- Good epidemiology ultimately depends on the trust of the public. We have to earn that trust.

Welcome to the Department

- We welcome you to the Department of Health
- You are joining a program that is committed to high quality reporting *AND* respect for the privacy of our ‘patients.’
- The pledge that binds you to this surveillance and research family also binds you to a relationship of trust with the public.
- Guard that trust carefully. It is what makes good public health possible.
- Confidentiality always comes first.