Infrastructure for Conducting Registry-Based Research

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Growing Your Data

- ✓ Surveillance
- ✓ Research

Research Involves Balancing Two Competing Goals

- ✓ Protect the confidentiality of cancer patients and their families
- ✓ Reduce the burden of cancer in the population

Infrastructure

- ✓ Statutes
- ✓ Rules and regulations
- ✓ Policies
- ✓ Procedures

Four Principle Types of Data Release

1. No personal identifiers, aggregated
   - ✓ Example: Tabulated data
2. De-identified but case-specific
   - ✓ Example: Public use file
3. Personal identifiers, no patient contact
   - ✓ Examples: Research involving medical record review, Cohort linkages
4. Personal identifiers, patient contact
   - ✓ Example: Case/control studies

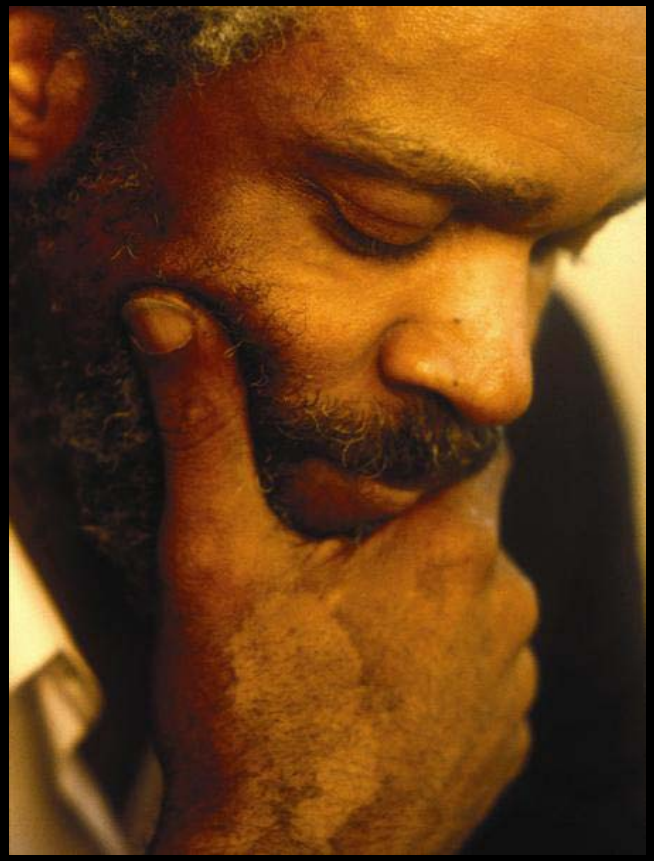
The VERY First Thing You Need to Get a Handle On


Photo by Andy Kraushaar, 1997

What are the "rules" regarding release of registry data?

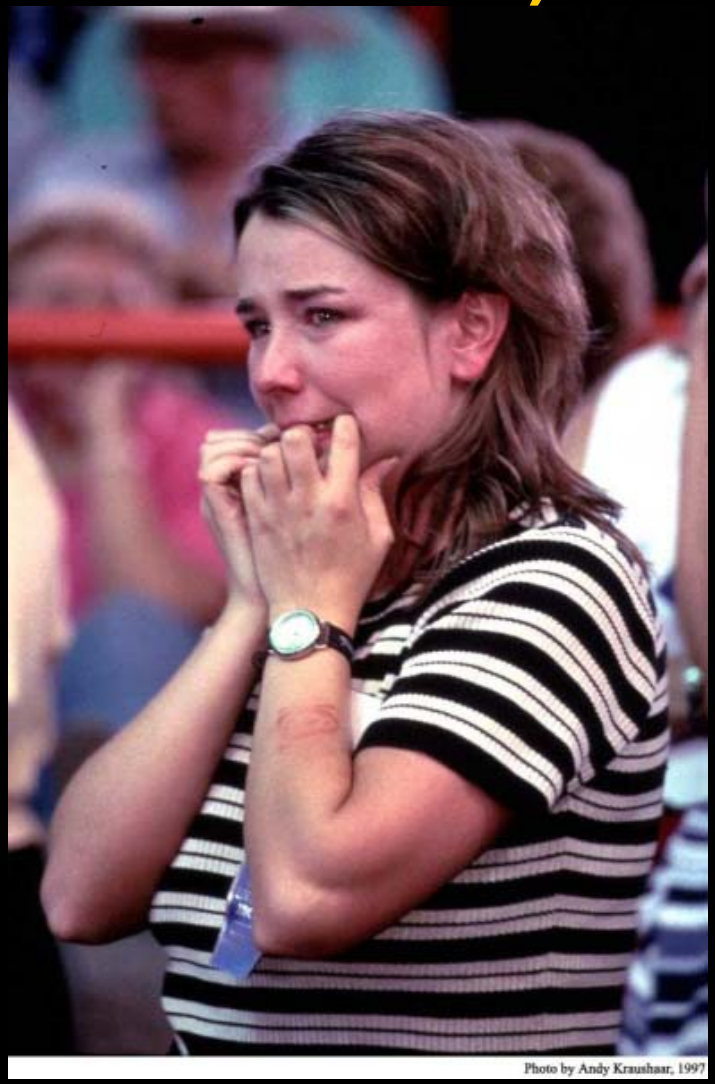
What defines the limits of what data can be released?

- ✓ Legal mandates: Statutes, Rules and Regulations
- ✓ Departmental/Organizational policy
- ✓ Registry practice
- ✓ Political climate



How do you interpret these limits (if they are ambiguous or in conflict)?

- ✓ Data Practices Coordinator
- ✓ Legal Counsel
- ✓ IRB
- ✓ Other registries
- ✓ Other research programs
- ✓ Common sense



Limits on Data Release

1. Purpose of data request
2. Person/agency requesting data (type and/or qualifications)
3. Data requiring consent to release
4. Requirements for obtaining consent
5. Approval process and criteria
6. Charges

Purpose of the Data Request

Minnesota Statute 144.69

"…data collected on individuals by the cancer surveillance system… may only be used for purposes set forth in this section [monitor trends, target interventions, inform the public, promote high quality research]. Any disclosure other than is provided for… is declared to be a misdemeanor and punishable as such."

Minnesota Rules 4606.3307

"The research proposed to be conducted will assist in improving the diagnosis, treatment, or prevention of cancer and the public health."

"No researcher… shall release any personal identifier… that could be used for identification of an institution, a physician, or an individual."

Person/Agency Requesting the Data

Minnesota Rules 4606.3307

> "The commissioner of health may enter into contracts to conduct research… with public and private research agencies or with individuals who satisfy all of the following criteria: …B. there is documented evidence that the principal investigator for the research proposed is qualified (1) by [degree of MD, DO, DSc, PhD, or equivalent] and (2) by [training or experience]."

Registry practice: We can return data to the registry that originally provided it.

Requirements for Consent

Minnesota Statute 144.69

"…data collected on individuals by the cancer surveillance system, including the names and personal identifiers of persons required… to report… shall be private…"

Minnesota Statute 13.05

"Private data may be used by and disseminated to any person or agency if the individual subject or subjects of the data have given their informed consent."

Obtaining Consent

Minnesota Statute 144.69

"…an officer or employee of the commissioner of health may interview patients named in any such report… only after the consent of the attending physician or surgeon is obtained."

Minnesota Rules 4606.3307

"Under no circumstances will researchers be provided access to personal identifiers that would allow contact of a patient without attempting to obtain physician consent..."

Approval Process and Criteria

Minnesota Rules 4606.3307

Subp. 3. “The Commissioner shall evaluate proposals based upon the criteria in items A to E. A… has social and scientific merit… B. … all investigators are qualified… C. The hypotheses to be tested are explicit… D. The methods… [are clearly defined] E. The results provide… an important contribution to the understanding of cancer diagnosis, treatment, or prevention in Minnesota.”

Subp. 4. “…the commissioner may appoint up to seven scientists to conduct scientific peer review.”

Charges

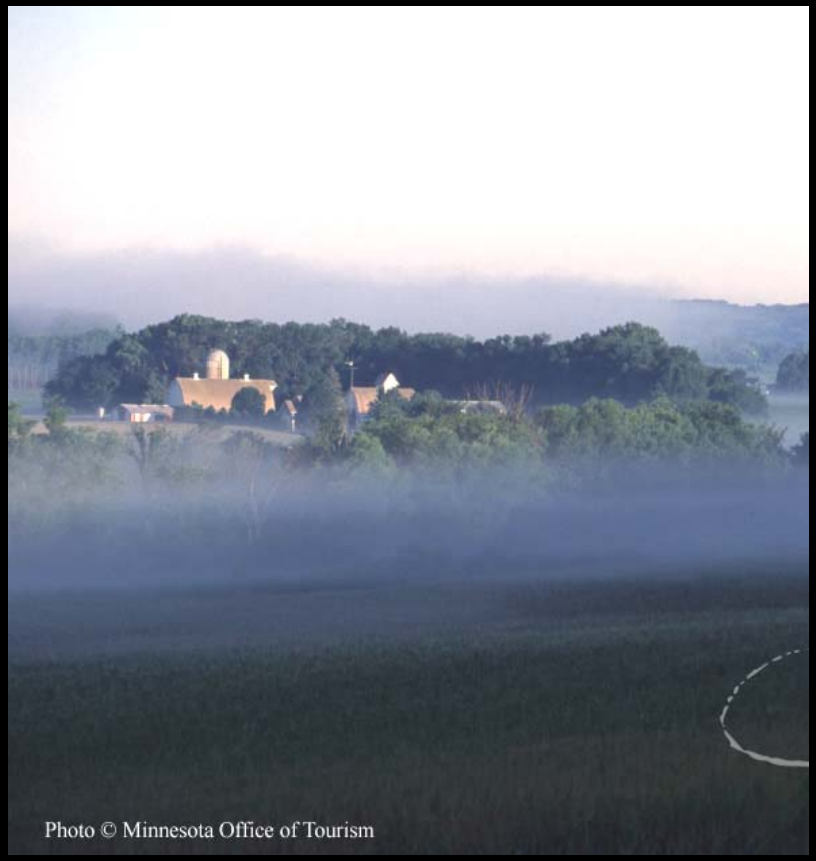
Minnesota Rules 4606.3307

Subp. 1. “The commissioner of health may enter into contracts to conduct research… with public and private research agencies or with individuals…”

Minnesota Rules 4606.3309

“The commissioner may charge fees… for expenses.. Incurred as a result of requests by agencies for summary data compilation or analyses…”

MCSS Practice



- ✓ No release of identifying data without patient consent even if no contact will take place
- ✓ No contact of patient to obtain consent without MD active or passive consent
- ✓ Mayo physicians require internal collaborator
- ✓ MCSS personnel are paid by researchers to contact MDs and patients
- ✓ Peer review committee must approve study
- ✓ IRB approval required

What Researchers Need to Know Up Front

- ✓ Who to contact
- ✓ Data release rules
- ✓ Overview of process
- ✓ How much it will cost
- ✓ Registry reference date, reportable cancers, available variables
- ✓ Data quality and timeliness
- ✓ Capacity for rapid case ascertainment
- ✓ Time frame to complete process -- Allow time to work out details before submit grant!

Helping it Move Along Smoothly

- ✓ Receive data request
- ✓ Evaluate and refine request
- ✓ Submit for approval
- ✓ Establish contract/MOU
- ✓ Release data
- ✓ Follow-up and Oversight

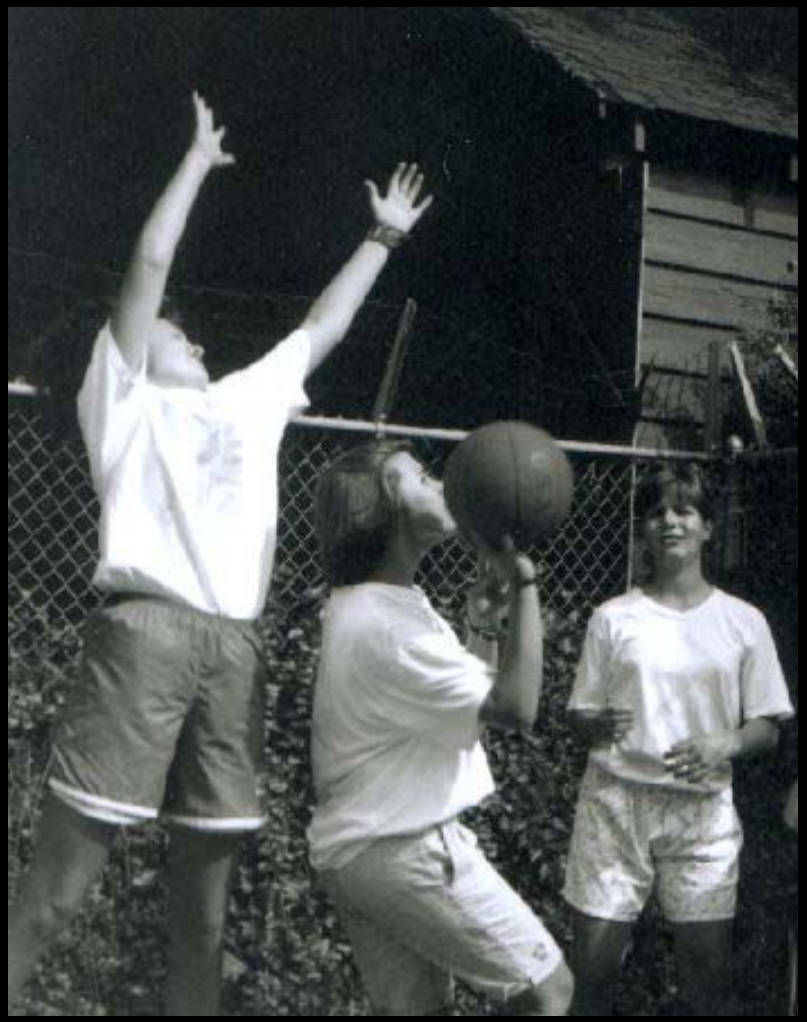
Data Request Process

- ✓ Who receives?
- ✓ In writing or oral?
- ✓ Many examples on registry web sites
- ✓ Date of request
- ✓ Requestor info
- ✓ Purpose of research
- ✓ Patient contact?
- ✓ Case selection criteria
- ✓ Variables needed
- ✓ Status of funding
- ✓ Require letter of support?

Process for Evaluating and Refining Data Requests

- ✓ Does it meet criteria for data release?
- ✓ Does registry meet research requirements?
- ✓ If not, can research be modified to meet registry limitations?
- ✓ How much will it cost to provide data and does researcher have resources?
- ✓ Are patients already being contacted for research?

Approval Process



- ✓ Process, criteria, and forms for internal review, if any, should be in writing
- ✓ IRBs will have their own approval processes and forms
- ✓ IRB approval is researcher's responsibility
- ✓ Approval for both in-house and external must be in writing

Institutional Review Boards

- ✓ If human subjects are involved, you need IRB approval or exemption
- ✓ Yours or the researchers or both?
- ✓ May or may not review scientific merit
- ✓ Close examination of components of informed consent
- ✓ Written informed consent can be waived under some circumstances, informed consent almost never
- ✓ IRBs require annual re-review

Contract or Memorandum of Understanding

- ✓ No "protected" data should be released with a written agreement signed by both parties
- ✓ Should include acknowledgments/ disclaimers for publications, requirements for pre-review
- ✓ Should specify what happens to data on completion of study
- ✓ Requirement to submit annual IRB approval

Process for Data Release

- ✓ Data selection criteria
- ✓ File layout and format
- ✓ Data dictionary
- ✓ Encryption method
- ✓ Require confidentiality statements from all personnel with access?
- ✓ Once or periodically as cases reported?
- ✓ If periodically, must be able to identify cases already sent

Oversight and Follow-up

- ✓ Someone needs to have primary responsibility for tracking progress of research, including annual approval from IRB(s), publications resulting, potential problems, etc
- ✓ Consistent and smooth application of processes will encourage more research