Impact of Proposed Changes to the Common Rule on Infectious Disease Activities

The Minnesota Perspective

MDH Minnesota Department *of* Health

Public Health Laboratory Division

- **First revision since 1991**
- **Goal: Enhance protection and autonomy of study subjects**
- **Changes include**
  - Stronger informed consent provisions
  - Single IRB for multisite studies
  - Requiring written consent for use of biological specimens
  - New data security standards

MDH

Open Comment Period

- **Closed January 6, 2016**
- **2189 comments received**
- **General support for goals but..**

“More than 95 percent of those submitting comments on the major proposed changes to the Common Rule oppose at least one of them…”

From Life Sciences Law & Industry Report

Excluded Activities

- **Not deemed to be research**
  - QA/QI
  - Public health surveillance
  - National defense
- **Inherently low risk**
  - Information publicly available or not-identifiable
  - Already regulated by HIPAA
- **Low risk and do not diminish subject's autonomy**
  - Generate information about individual that is already known
  - Development and validation of tests and assays, PT, QA/QC

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Public Health Surveillance

"Public health surveillance is the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health."

Updated Guidelines for Evaluating Public Health Surveillance Systems *MMWR* 2001 50(RR13); 1-35

Surveillance Data

- Guide immediate action
- Measure the burden of a disease
- Monitor trends in the burden of a disease, e.g. outbreaks and pandemics
- Guide planning, implementation, and evaluation of programs to prevent and control disease
- Evaluate public policy
- Detect changes in health practices and impact
- Prioritize allocation of health resources
- Describe clinical course of disease
- Provide basis for epidemiologic research

NPRM Surveillance Exclusion

Surveillance is excluded

"when a public health authority conducts public health surveillance activities to fulfill its legal mandate to protect and maintain the health and welfare of the of the population it oversees"

Sounds good, but…

- **Surveillance definition is vague**
- **Excludes necessary activities that public health agencies perform under state and local law**
- **Examples of public health surveillance provided in NPRM are incomplete**

Surveillance vs Research

- **Difficult to know where to draw the line**
- **Same techniques may be used in both**
- **Generally, the difference is in the purpose or context and role of public health authority**

ASTHO Survey Question

2.36. Which of the following research activities has your state public health agency participated in over the past two years? (Select all that apply)

- **Identifying research topics and questions that are relevant to public health practice**
- **Developing or refining research plans and/or protocols for public health studies**
- **Recruiting study sites and/or study participants**
- **Collecting, exchanging, or reporting data for a study**
- **Analyzing and interpreting study data and findings**
- **Disseminating research findings to key stakeholders**
- **Applying research findings to practices within your own organization**
- **Helping other organizations apply research findings to practice**

Examples

- **Case-control methodology (may look like research)**
- **Investigating unknown or new risk factors (NPRM specifies known risk factors)**
- **Exploratory studies (not excluded in NPRM)**
  - Understand risk factors for chronic disease
  - Elucidate relationship between biomarkers and disease
  - Relationship between behavioral factors and environmental exposures
- **Evaluation of activities, programs, and policies should be explicitly identified as not research**
- **Surveillance surveys, e.g. BRFSS**
- **Patient case management (TB, STD)**

Potential Impact if No Clarity

- **Disagreement over surveillance vs research studies**
- **Increased risk of liability to public health agency if rules are misinterpreted**
- **Lack of responsiveness**
- **Public health agencies may be unable to conduct routine and mandated public health surveillance activities**

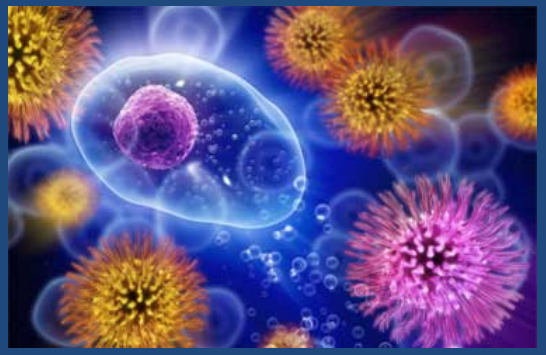
Biospecimens in NPRM

- **Considered human subjects even if "non-identifiable"**
- **Secondary use will require broad informed consent, with exceptions**
- **Consent for maintenance and storage of biospecimens (and PII) must be collected using a form developed by HHS**

- Validation, verification, and proficiency testing activities
- Quality assurance and quality control activities
- Use of known “positive” or “negative” biospecimens allowed for test development without obtaining consent.

Why Biospecimens?

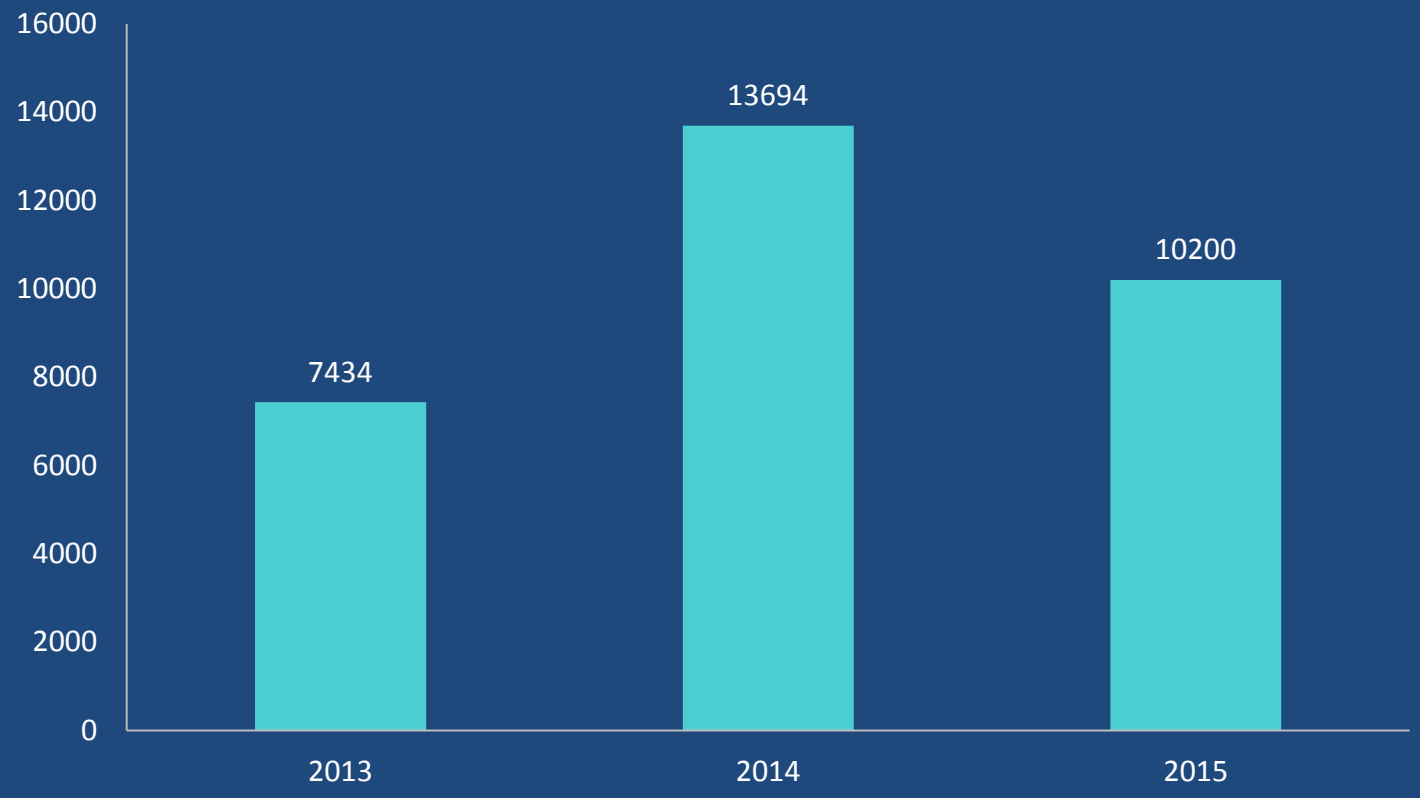
- **Quality Assurance/Quality Control**
- **Method development/validation/verification**
  - Negatives as well as positives
- **Historical specimen archives**
- **Unsolved outbreaks**



Infectious Disease Specimens at MDH

- **Approximately 1/3 of specimens received by MDH-PHL ID lab are archived**
- **Most positive for agent of interest**
- **Negative specimens from unsolved outbreaks, UNEX**
- **Most diagnostic tests are performed for agents listed in MN disease reporting rule**

Number of Specimens Retained



Infectious Disease Specimens at MDH

- **57,959 human clinical specimens in inventory**
- **Breakdown:**
  - Upper respiratory 28,845
  - Stool 13,852
  - Blood/serum/plasma 4,161
  - CSF 1,011
  - Lung 511
  - Urine 115
  - Other 9,464

Applicable Exclusions (?)

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Potential Impacts if Changes Implemented

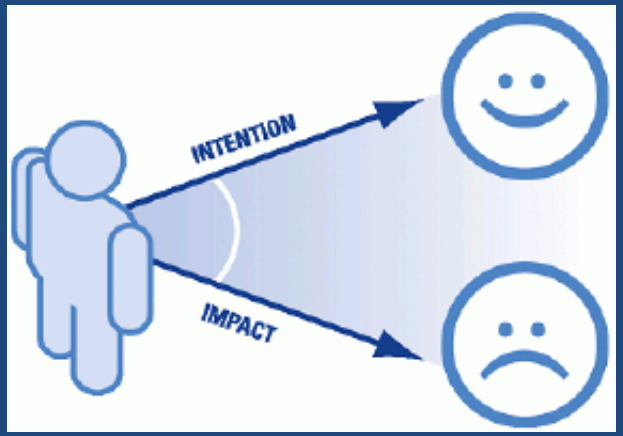
- **It kinda depends…**
  - Will the proposed exceptions allow for long-term storage of specimens?
  - Does the surveillance exception apply to biospecimens?

Barriers to Obtaining Consent

- **No mechanism for obtaining and tracking consent**
- **Extra work for healthcare facility with no stake in secondary use of the specimen and little/no incentive to obtain consent**
- **Infectious disease cases may not be identified until specimen is tested at a PHL**
- **Hundreds (402) unique submitters of human clinical specimens for ID testing**
- **No mechanism to recoup costs**

- **Will broad consent constitute meaningful informed consent?**

Potential Negative Impacts



- **Destruction of "valuable" specimens**
  - Impact may not be immediately obvious
- **Litigation**
- **Delay or halt development and implementation of new tests**
- **Reduction in biodiversity of specimens available for research**
- **Adverse effect on health equity**

Potential Positive Impacts

- Clarity surrounding the storage and use of biospecimens
- Gain public trust by addressing autonomy and privacy concerns
- Establishment of shared biobanks
- Opportunity to develop systems to engage and educate the public
- Positive impact on health equity