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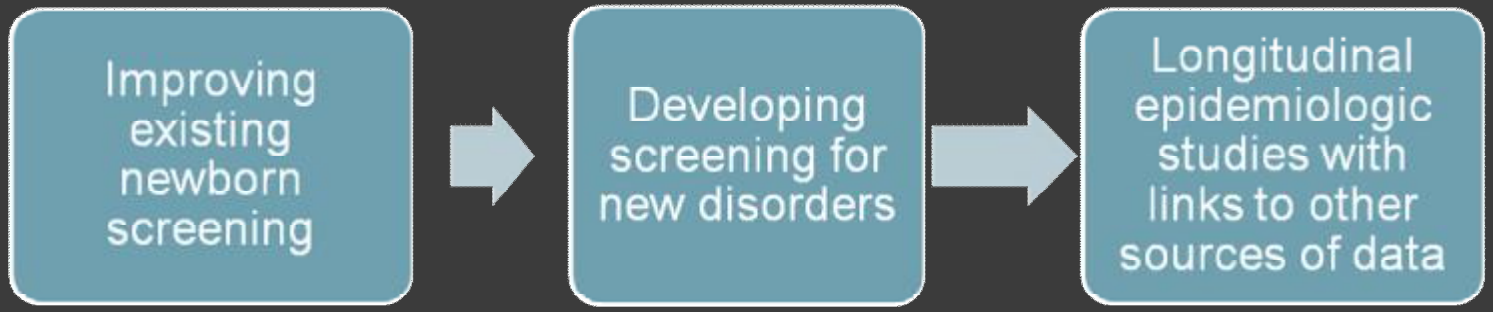
LEGAL ISSUES RELATED TO THE USE OF NEWBORN SCREENING SAMPLES FOR RESEARCH

What kind of “research” with what kinds of data?



Quality improvement

May need only presence or absence of particular trait

Research

Often requires linkage to other data sets

Federal law

45 CFR 46

But see

OHRP does not consider research involving **only coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:**

- (1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
- (2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because of [agreement with key holder, IRB, legal limits]

http://www.dhhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf

Rapidly changing state law landscape regarding privacy and choice

- Law suits
  - MN – newborn screening law and state Genetics Privacy Act
  - TX – constitutional claims based on search & seizure, privacy, liberty
- Legislative activity re parental choice
  - Ten states give parents choices about destroying/retrieving samples or prohibiting research
  - Three states have relevant privacy legislation
  - Bills giving parents choice have been introduced in many states

Rapidly changing state law landscape regarding oversight and control

Utah Admin Code R398-1-15. Blood Spots.

- (1) Blood spots become the property of the Department.
- (2) The Department includes in parent education materials information about the Department's policy on the retention and use of residual newborn blood spots.
- (3) The Department may use residual blood spots for newborn screening quality assessment activities.
- (4) The Department may release blood spots for research upon the following:
  - (a) The person proposing to conduct the research applies in writing to the Department for approval to perform the research. The application shall include a written protocol for the proposed research, the person's professional qualifications to perform the proposed research, and other information if needed and requested by the Department. When appropriate, the proposal will then be submitted to the Department's Internal Review Board for approval.
  - (b) The Department shall de-identify blood spots it releases unless it obtains informed consent of a parent or guardian to release identifiable samples.
  - (c) All research must be first approved by the Department's Internal Review Board.

Mixed messages? A step in the right direction?

Some other issues need to be addressed

- What else will samples be used for?
- Parental request
- Forensics
  - Abducted children?
  - Comparison data base?
  - Population based data base?
    - Compare debates about taking samples from adults who have been arrested for or convicted of crimes