ALERT | Act before MIDNIGHT to Protect Patient Privacy

DEADLINE: 11:59 p.m. TONIGHT, Wed., January 6

The federal government has issued proposed rules for research, focusing on DNA and other biospecimens (blood, tissue, bones, etc.) -- but encompassing your private medical records too. It's for federally-funded research, but also for any institution that gets federal funds even if their research is privately funded.

BABIES AND BABY DNA: CCHF has just taken issue with the proposal *(press release below*), exposing how it will eviscerate the parent consent requirements we secured in a federal newborn screening law last year for federally-funded research using newborn DNA.

While the proposed rule includes a "broad consent" provision, there are basically 11 EXCLUSIONS, meaning these research activities are excluded from the authority and oversight of the rule, including any consent requirements, among them public health surveillance, including monitoring and tracking of conditions of public health importance (which would naturally include state newborn screening test results and newborn DNA).

These exclusions are exactly how newborn DNA will be accessed

without parent consent. There's also an exclusion for test development, which can include state or institutional use of newborn DNA for analysis to develop new state newborn screening tests by comparing the DNA of children with a condition to the DNA of children without a condition — in this case, without parent consent.

COMMENT TODAY AT: REGULATIONS.GOV

SEARCH FOR: "Federal Policy for the Protection of Human Subjects (HHS–OPHS–2015–0008)

SAMPLE COMMENT - see below

EVERYONE'S DATA & DNA: The federal proposal includes a requirement to provide ALL PATIENTS with a "broad consent" form if you want to use them for research (NOTE: only for all non-excluded, non-waivered research). If you sign it, you'd give a vast array of outsiders access to your current and future identifiable medical records, DNA and other biospecimens (blood, urine, organs, tissues, hair, nails, urine, sputum, etc) for 10 years without the researcher coming back to remind you or to tell you how your identifiable information is being used, analyzed, shared, linked, or assessed. Outsiders would ALSO, as above, have access to YOUR data, DNA, and other biospecimens through exclusions and waivers, where there's no consent.

The proposed rule expects you to take only 5-10 min to complete the "broad consent" process — I guess they expect fast readers and no questions — perhaps while you're in pain or afraid or under duress of

the clinic's time schedule; perhaps without your full understanding; perhaps feeling pressured to please the doctor or nurse.

SAMPLE COMMENT:

Do not undo the parent consent requirement for federally-funded or any other research use or storage of newborn DNA. I also want informed written consent for every researcher access to and use of my and my family's medical records, DNA, blood and other biospecimens. No exceptions. No exclusions. No waivers. **(Add in at least one personal sentence to this sample to MAKE IT YOUR OWN COMMENT.)**

CCHF COMMENTS: http://bit.ly/1OxOg22

PROPOSED FEDERAL RULE: http://www.regulations.gov/...

Thank you for speaking up for newborn citizens and your privacy and autonomy rights!

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President and Co-founder