



February 23, 2021

The Honorable Jered Taylor
Chair, Special Committee on Government
Oversight
Missouri House of Representatives
201 West Capitol Avenue
Jefferson City, Missouri 65101

The Honorable Raychel Proudie
Ranking Member, Special Committee on
Government Oversight
Missouri House of Representatives
201 West Capitol Avenue
Jefferson City, Missouri 65101

Dear Representative Taylor and Ranking Member Proudie and Members of the Special Committee on Government Oversight,

Thank you for the opportunity to submit testimony on House Bill 995 (HB 995) on behalf of the National Organization for Rare Disorders, or NORD. NORD is a unique federation of over 300 voluntary health organizations and is dedicated to helping the 25-30 million Americans living with a rare disease. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

We are deeply concerned about the impact HB 995 would have on research, including critical research that is conducted in the context of newborn screening programs in Missouri. The bill as written would have profound effects on how research on a variety of types of biological specimens is conducted in Missouri. The bill's imposition of a consent requirement in a host of research settings in which consent is not currently required under either Missouri or federal law would erect unnecessary hurdles that will jeopardize critical research that benefits patients in the rare disease community and patients with common conditions alike. Specifically, H.B. 995 would prohibit the release of "any biological specimen collected or received by a laboratory" even "for purposes of anonymous scientific study unless the individual from whom the specimen was obtained consents to such release."¹

The question of whether it is necessary to obtain consent in the case of anonymous testing of de-identified biological specimens is one that has been considered extensively at the federal level. In 2017 the Department of Health and Human Services (HHS) issued a major revision to what is known as the "common rule," which sets ethical standards for government-funded human research. In this revision, HHS considered this issue of consent in biological testing and determined that de-identified biological specimens do not require the same consenting process as other specimens.² Missouri has previously recognized the importance of this Common Rule consent standard and exempted de-identified research from consent requirements in accordance

¹ Missouri House Bill 995. Rep. Jered Taylor. Accessed 2/22/21.

<https://house.mo.gov/billtracking/bills211/hlrbillspdf/1553H.01I.pdf>

² Federal Register. Federal Policy for the Protection of Human Subjects. Accessed 2/22/21.

<https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf>

with its guidance.³ HB 995 specifically strikes that provision of Missouri law reversing this precedent that has been in place in the state for 14 years.⁴

NORD is extremely concerned that this newly imposed requirement would be unworkable for researchers in Missouri, imposing costs and delays that would be detrimental to the critical research work conducted in the state, if not prohibitive. It is also unclear what problem HB 995 is attempting to solve.

Prior to advancing HB 995 further, NORD urges the Committee and the Missouri legislature to consult with NORD as well as federal and local researchers to provide you with a better understanding of the impacts and costs this legislation would have. NORD strongly opposes HB 995 in its current form.

Thank you again for the opportunity to submit testimony. NORD stands ready to work with you to ensure that HB 995 does not have the serious, unintended effect of endangering research that benefits Missouri rare disease patients.

Sincerely,

A handwritten signature in black ink that reads "Rachel Sher". The signature is written in a cursive, flowing style.

Rachel Sher, J.D., M.P.H.

Vice President, Policy and Regulatory Affairs

NORD

cc: Members of the House Special Committee on Government Oversight

³ Revisor of Missouri. Section 375.109. Accessed 2/22/21.

<https://revisor.mo.gov/main/OneSection.aspx?section=375.1309&bid=20598&hl=>

⁴ Missouri House Bill 995. Rep. Jered Taylor. Accessed 2/22/21.

<https://house.mo.gov/billtracking/bills211/hlrbillspdf/1553H.01I.pdf>