MISSOURI HOUSE OF REPRESENTATIVES

WITNESS APPEARANCE FORM

BILL NUMBER: **HB 995**	DATE: **2/23/2021**
COMMITTEE: **Special Committee on Government Oversight**	

TESTIFYING: ☑ IN SUPPORT OF ☐ IN OPPOSITION TO ☐ FOR INFORMATIONAL PURPOSES

WITNESS NAME

INDIVIDUAL:

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I Support this Bill on its face and what its intention is.

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WITNESS NAME

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WITNESS NAME

REGISTERED LOBBYIST:

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WITNESS NAME

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WITNESS NAME

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WITNESS NAME

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WITNESS NAME

REGISTERED LOBBYIST:

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WITNESS NAME

BUSINESS/ORGANIZATION:

WITNESS NAME:	PHONE NUMBER:
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kelly@mobio.org	**In-Person**	**2/23/2021 12:51 PM**

THE INFORMATION ON THIS FORM IS PUBLIC RECORD UNDER CHAPTER 610, RSMo.

February 23, 2021Dear Chairman Taylor and members of the Special Committee on Government Oversight:The Missouri Biotechnology Association is the statewide membership group that represents those organizations, large and small, that use biology to make a product or service. Missouri's bioscience industry is helping to diversify and grow the American economy. American bioscience innovation in health, energy and agriculture are creating high-skill, high-wage jobs, driving economic growth and helping to improve the quality of life for all Missourians. According to our national organization, BIO, Missouri directly employs 29,047 biotech workers across 1,382 Missouri employers with an annual average wage of $75,959.• MOBIO has grave concerns that HB 955, as introduced, will broadly and negatively impact our entire bioscience sector. Included in this crossfire will be every laboratory, whether it is doing basic science, translational medicine, federally supported university research, and/or biomanufacturing of finished products. • These mandated state compliance rules may well be inconsistent with the already complex oversight provisions already in place across the country. • The definitions and protocols do not follow the language spoken and adhered to by industry and/or by university research departments. To assure better adherence by all laboratories, we believe we should be presenting the statute in the language that professional laboratories speak (i.e. federal regulations that have been in place since the late 1970s) instead of making up our own state approach. • The common rule was created to prevent this from happening among agencies. The state can create more stringent rules where truly appropriate, but please use the common rule language and existing federal ones to build on. In this change, they actually removed some reference to the common rule altogether.•HB 955 will increase the cost of compliance for every laboratory, of every size, that handles or analyzes any biological specimen from humans. This is a widespread solution in search of a very narrow problem, with drastic unintended consequences.• It exposes Missouri biomedical researchers who violate this section to a state Class A Felony, reserved in the past for the state's most heinous and serious crimes like murder, rape, and kidnapping. MO Class A Felonies carry minimum sentencing of ten years to life imprisonment, and such violations don't even give directions to state prosecutors to take into account those violations by Missouri researchers that clearly aren't willful or intentional. • MOBIO members have shared that there are already many existing layers of interwoven regulation and laws in play including HIPAA Privacy and Security Rules, Common Rule (45 CFR 46 - a set of a federal regulations that governs research involving human subjects), FDA, GINA (Genetic Information Nondiscrimination Act of 2008), and the NIH Data Sharing Policy among others. It is our understanding that this regulation will be imposed in Missouri and it has not been passed anywhere else in the country.• Obtaining these consents will increase the cost in multiple areas of clinical care and research, hurting Missouri science-based enterprises disproportionally to their national competitors. •

Trying to give donors and patients access to or return of their own biological samples including dried blood, plasma or urine for their own personal safe-keeping is not a standard laboratory practice, and will be difficult if not impossible to achieve in many circumstances. • We suspect that there are some state registries that have mandatory sharing, like cancer registries which would create serious conflicts. This needs to be explored.• These types of policies that put Missouri at a competitive disadvantage need to be weighed as we come together to seek re-shoring of domestic opportunities for biomedical and biopharmaceutical processing within the United States, and Missouri in particular. We are opposed to HB 955. MOBIO is however absolutely not opposed to any legislative inquiry or conversation that elevates the issues of medical research privacy, protection of genetic information for patients and consumers and citizens. We have true experts in Missouri that are national leaders, and MOBIO can tap them as an informational resource if the Missouri General Assembly is inclined to assess the state's role in best protecting our citizens.As part of my submitted testimony and comments today, I additionally wish to share (attachment below) a communication I received this morning when I work up. Leslie Wilson is a co-founder and partner for a small but mighty firm in Western Missouri, Ethical & Independent Review Services. I shared this bill with her yesterday, and she worked until 2:00 am drafting comments for the sponsor's and the committee members' benefit, and she is grateful for the opportunity to share her insights, as she has been working in this area a very long time, and cares deeply that her clients get these protocols correct for patients. Leslie gave me permission to share her comments with you. I appreciate her citizen engagement in elevating this important conversation for us all.Thank you all for your public service.Sincerely,Kelly GillespieExecutive DirectorMissouri Biotechnology Association (MOBIO)PO Box 148Jefferson City, MO 65102-0148kelly@mobio.org(573) 690-9267Hi Kelly,Thank you for giving Ethical & Independent Review Services (E&I IRB) an opportunity to provide comments on the HOUSE BILL NO 995 for proposed revisions to existing Missouri Statutes Due to the time constraints created by the emergency act that this bill is being presented under, I am providing E&I's observations and suggestions in email format in lieu of a formal comment letter.E&I's board and administration has been providing IRB reviews of human subjects research since 1984. Our objective is, and always has been to ensure that the rights and welfare of research participants are protected, including their right to autonomy, privacy and confidentiality. In 36 years of reviewing research we have seen many changes in the field, but perhaps none that pose as much promise as the potential of personalized medicine made possible by the rapidly expanding knowledge of genetics. The reason IRBs exist however, is to make certain that when human subjects are involved in the development of such knowledge through research, that the potential risks to those individuals are identified, mitigated, disclosed and appropriately weighed against the potential benefits of the research itself.In reviewing the proposed changes to 191.317 and 375.1309, RSMo, E&I appreciates the desire of Representative Taylor to protect the autonomy of Missouri residents through stronger requirements for informed consent, disclosure of intent, and by giving them the right to choose how their residual specimen samples are used. In theory, these are all value adding mechanisms of protection. Unfortunately, E&I is unable to support the current changes as presented due to significant concerns relating to 1) a lack of clear and defining language; 2) missing or incomplete elements necessary for proper implementation; and 3) the extreme severity of the penalty to laboratories and others, for any failure to adhere, which appears to far exceed any benefit created to Missouri residents.1) A lack of clear and defined language is demonstrated in a number of ways, including but not limited to the use of the term "anonymous scientific study." The current 191.317 language refers to a biological sample being released for 'anonymous study', which in the newly proposed sections is now referred to as 'anonymous scientific study', but neither of these terms have been defined anywhere in the existing or proposed sections. The term 'laboratory' is defined to assure understanding of who is responsible for not sharing samples, but "anonymous scientific study", which speaks to the sharing itself, is left undefined. As far as we are aware, this term also does not exist in any federal regulation either, leaving too much room for interpretation by the reader. For comparative purposes, when referring to data the term 'anonymized' generally refers to stripping (or sanitizing) all identifiers for protection of privacy. We were left to wonder if "anonymous study" referred to the biological sample being anonymized, or is the sample being shared with an anonymous researcher. We are assuming it is the former, but assumptions can be dangerous.2) Missing or incomplete elements necessary for proper implementation significantly increase the potential for failure of adherence by the laboratories. Examples include, but are not necessarily limited to the new proposed language in: • 191.2414., which states "...the individual from whom the specimen was obtained shall be informed of his or her right to give any direction...". This requirement is not clearly presented. Is it sufficient for the individual to be informed verbally, or is documentation required? • 191.241.5., which states...For any biological specimen in the possession of a laboratory before the effective date of this section for which consent to release the specimen for anonymous scientific study was not obtained at the time of collection, the laboratory may release the specimen for anonymous scientific study if it contacts the individual from whom the specimen was obtained and obtains his or her

consent to the release. The reader is left without clear understanding if such consent is required to be in writing, or is documented verbal consent sufficient? • The newly proposed language in 191.241.6 goes on to state...At the time a laboratory releases any specimen for anonymous scientific study, the laboratory shall inform the individual from whom consent was obtained of the fact of the release. This requirement introduces a significant burden to laboratories, as they will first need to reach out to previous donors to ask for consent to share the residual sample, prior to making it available to be share, but if time lapses prior to a demand for sharing the sample, notifying the donor that the sharing occurred could be, and from our experience, will be challenging due to issues not under the control of the laboratory, such as a donor's relocation, lack of interest, name changes, etc. The proposed language lacks sufficient information to understand if attempting to contact the donor by mail, email, phone is sufficient, or must there be documentation of their receipt, such as certified mail? Clarification is very possible here, but does not exist in the current version.• 3) The extreme severity of the penalty to laboratories and others, for any failure to adhere, appears to far exceed any benefit created to Missouri residents. As presented in the proposed changes, there is an intent to stop allowing de-identified, leftover biological specimens to be used in research where there is no intent to re-identify the samples, unless the donor gives specific, informed consent to permit such sharing for research purposes. When considering the potential risks of harm to an individual that might result from such anonymous sharing, it is first necessary to question what are the potential risks should a donor's identity become known. Further, what protections are already in place to reduce the likeliness of such harms happening? When this analysis is compared to the cost and burden placed on the laboratory, compounded by the severity of a failure to meet the obligation being considered a Class A felony offense, it would only seem reasonable that the laboratories will elect not to share data, whether donors are willing or not. It is too risky for them, while the reduction in risk to the donors would likely be considered minimal. The election of laboratories to opt out of sharing specimens for research purposes due to overburdensome regulation or statutes means that Missouri will not be contributing to, or represented in future research. We would propose that this is a significant harm imposed on Missouri residents. Further, the exceptions permitted in the proposed changes do not include allowances for public health. If, as Section B of the Bill claims, these changes are necessary for the immediate preservation of the public health, welfare, peace, and safety, we would seek clarification on how Missouri will contribute to the discovery of new COVID variants if not with laboratory samples? Following consideration of the proposed changes, E&I remains uncertain as to why this action is being taken, and why under an emergency act? We would suggest that the General Assembly look to the approved 2018 changes to the Common Rule, which introduced concepts such as 'broad consent' without clearly defined language and without all elements necessary to permit proper implementation as a demonstration of the problematic nature of rushing to pass regulation before appropriate troubleshooting and consultation has occurred. We would further suggest instead, that Representative Taylor look to the many sources inside of Missouri whose dedicated work is the protection of human subjects. There are universities, hospitals, medical centers, research centers and several independent IRBs located within the state who have human research protection programs that house experts who could assist in creating stronger protections of privacy, and fuller autonomy for Missourians using a risk balanced approach. E&I applauds Representative Taylor's vision for stronger protections, and we would be more than willing to offer our assistance in working together towards a balanced plan.Thank you again for allowing us to weigh in. If you have any questions, please do not hesitate to reach out to me.Sincerely,LeslieLeslie WilsonDirector of Operations(816) 421-0008www.eandireview.comPlease note that our business office has moved!Our new address is 304 SE Third Street, Lee's Summit, MO 64063

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WITNESS NAME

BUSINESS/ORGANIZATION:

WITNESS NAME:	PHONE NUMBER:
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Dear Chairman Taylor, Ranking Member Proudie and Members of the House 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." 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. Missouri has previously recognized the importance of this Common Rule consent standard and exempted de-identified research from consent requirements in accordance with its guidance. HB 995 specifically strikes that provision of Missouri law reversing this precedent that has been in place in the state for 14 years. 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,Rachel L. Sher, J.D., M.P.H.Vice President, Policy and Regulatory AffairsNational Organization for Rare DisordersMissouri House Bill 995. Rep. Jered Taylor. Accessed 2/22/21. https://house.mo.gov/billtracking/bills211/hlrbillspdf/1553H.01I.pdfFederal 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 Revisor of Missouri. Section 375.109. Accessed 2/22/21. https://revisor.mo.gov/main/OneSection.aspx?section=375.1309&bid=20598&hl= Missouri House Bill 995. Rep. Jered Taylor. Accessed 2/22/21. https://house.mo.gov/billtracking/bills211/hlrbillspdf/1553H.01I.pdf

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WITNESS NAME

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House Bill 995 has a broader impact than addressing the concerns about DHSS' distribution of anonymous laboratory specimens for research. The bill limits the use of anonymous lab specimens for internal as well as external research/study. This curtails the ability to set accurate reference parameters for routine laboratory tests and to use specimens to validate the accuracy of laboratory equipment. The bill calls for hospitals to store anonymous laboratory specimens for an unspecified period. It also requires them to offer to return the specimens to the patient. Returning a specimen likely would be considered to be a violation of federal and state standards governing the release of infectious or hazardous waste. We encourage the bill to be modified so that hospitals do not incur additional costs to get and submit patient consent for the release of laboratory specimens by the Department of Health and Senior Services to the federal Centers for Disease Control or other public health research.