



AN ACT ; AND PROVIDING AN EFFECTIVE DATE; AND PROVIDING A TERMINATION DATE.

WHEREAS, with a growing population of aging citizens, Montana will be particularly hard hit in the coming decades by currently incurable diseases like Alzheimer's and related dementias. The number of Montanans with Alzheimer's disease is expected to reach 27,000 by 2025. This act will give hope to thousands of Montana families who live with the effects of this devastating disease; and

WHEREAS, by funding potentially curative, early-intervention therapies, this Act seeks to reduce the increasing costs to the state of caring for Alzheimer's patients; and

WHEREAS, organizations across Montana engaged in biomedical research have been at the forefront of biomedical research for brain disease, brain injury and mental illness. Providing a sustainable and responsible stream of funding for these organizations will allow Montana to attract and retain world-class talent, making the state a leader in the field of brain research and therapy development; and

WHEREAS, one in four Montanans suffers from a brain disease, injury or mental illness at some point in their lives. This act will eventually give thousands of Montanans suffering from brain disease, brain injury or mental illness early access to promising treatment options and experimental medications that could, in some cases, be the difference between life and death; and

WHEREAS, the biomedical research that will be funded by this act is expected to generate state revenues from royalties, patents and licensing fees that can be invested in additional medical research or used for other vital state services; and

WHEREAS, this act will create new, good-paying jobs, boosting our local economies and helping communities across the state thrive; and

WHEREAS, for all of these reasons, the people of Montana find that promoting the development of therapies and cures for brain diseases, brain injuries, mental illness and other chronic diseases is a vital public purpose.

THEREFORE, it is the intent of the people of Montana to provide funding to develop new therapies to treat and cure brain diseases, brain injuries and mental illness, to develop centers of research and clinical

excellence, to provide quality jobs for Montanans and to bring world-class students and researchers into Montana.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Montana biomedical research authority. (1) There is created a public body corporate designated as the Montana Biomedical Research Authority. The authority is constituted a public instrumentality, and its exercise of the powers conferred by [sections 2 through 19] must be considered and held to the performance of an essential public function.

(2) The authority consists of 13 members, appointed by the governor and confirmed by the senate as prescribed in 2-15-124, except that none of the members is required to be licensed to practice law in the state. The governor shall appoint members as follows:

(a) Seven members who are Montana representatives of regional, state or national patient advocacy groups for diseases including but not limited to those diseases listed in [section 5(1)], except that no more than two members may be representatives of the same group or disease; and

(b) Six members who will provide a balance of expertise and public interest and accountability and who include:

(i) One or more members from among Montana representatives of a veterans' health advocacy group;

(ii) One or more members from among Montana representatives of an Indian health advocacy group;

(iii) One or more members from among Montana physicians or nurses specializing in neurology or gerontology; and

(iv) One or more members from among Montana physicians or nurses specializing in psychiatric disease or substance abuse.

(3) The authority is designated as a quasi-judicial board for the purposes of 2-15-124.

(4) The authority is allocated to the department of commerce for administrative purposes only as provided in 2-15-121, and has authority over its own personnel as provided in [section 9].

Section 2. Short title. [Sections 2 through 19] may be cited as the Montana Biomedical Research Authority Act.

Section 3. Definitions. As used in [sections 2 through 19], the following definitions apply:

(1) "Administrative cost" means any cost incurred in the administration of the authority, including but not limited to costs of issuing debt; program startup costs; financial, management, accounting, audit and legal consulting fees and expenses; fees and expenses of the panel of scientific consultants and other costs associated with peer review of grant applications; and reimbursement costs for support services from other state agencies.

(2) "Authority" means the Montana Biomedical Research Authority created in [section 1].

(3) "Biomedical research fund" means the biomedical research fund established in [section 19].

(4) "Bonds" means general obligation bonds of the state issued pursuant to [section 16] and Title 17, Chapter 5, Part 8, and, to the extent applicable, provisions of related parts in Title 17, Chapter 5, including refunding bonds issued pursuant to [section 17] and bond anticipation notes issued pursuant to [section 18], for the purposes of [sections 2 through 19].

(5) "Eligible grantee" means an entity that is eligible to apply for and receive grant funds under [sections 2 through 19] and that meets the criteria established in [section 6].

(6) "Eligible project" means a project that is eligible for grant funding under [sections 2 through 19] and that meets the criteria established in [section 5].

(7) "Indirect cost" means any cost incurred by a grant recipient in the administration, accounting, general overhead, and general support costs for implementing a grant from the authority.

(8) "National funding agency" means any nationally recognized organization that funds or supports research in furtherance of the purpose of [sections 2 through 19], including but not limited to, NIH, Alzheimer's Association, Michael J. Fox Foundation and the United States Department of Defense.

(9) "NIH" means National Institutes of Health.

(10) "Panel of scientific consultants" means the panel of research scientists described in [section 11].

Section 4. Purpose. The purpose of the Montana Biomedical Research Authority is to oversee scientific peer review of grant applications, evaluate grant applications for grant funding, and, if appropriate, award grants to fund eligible projects that:

(1) Promote development of therapies and cures for brain diseases, brain injuries and mental illness that affect thousands of Montanans and their families;

(2) Promote biomedical research in genetics and molecular biology, the applications of which extend to

a wide variety of illnesses afflicting Montanans, including cancer and diabetes;

(3) Support Montana's biomedical research organizations in attracting and retaining world-class students and faculty;

(4) Support the transformation of existing organizations into centers of research and clinical excellence so that Montanans can avoid travelling out of state to receive top-quality healthcare; and

(5) Benefit the state economy by creating quality jobs for Montanans, generating royalties, patents and licensing fees, and eventually reducing state health care costs by shifting toward early-intervention therapies for chronic diseases and injuries.

Section 5. Eligible projects. A project is eligible for grant funding from the authority if the project consists of one or more of the following:

(1) an investigator-initiated research proposal or a pre- or post-doctoral fellowship proposal related to:

(a) development of therapies and cures, in any stage from laboratory research through clinical trials, related to brain diseases, brain injuries and mental illness, including, without limitation, Alzheimer's disease, Parkinson's disease, glioblastoma and other brain cancers, dementia, traumatic brain injury, post-traumatic stress disorder, stroke, multiple sclerosis, epilepsy, autism, depression, substance abuse and addiction, Lou Gehrig's disease, spinal cord injuries, Huntington's disease, bipolar disorder, schizophrenia and other mental illness; or

(b) biomedical research in genetics, molecular and cellular biology with applications extending to a wide variety of illnesses, including cancer and diabetes; or

(2) a proposal to transform an existing organization into a center of research and clinical excellence through:

(a) acquisition and installation of scientific equipment costing, individually or in the aggregate, at least \$10,000, including any necessary improvements to the facility where the equipment will be located. Contracts for any necessary facility improvements under this paragraph must contain a provision giving preference to the employment of bona fide Montana residents in the performance of the work. Examples of eligible scientific equipment include, without limitation, microscopes, optics technology, fluorescence-activated cell sorters, PET scanners, magnetic resonance imagers and electrophysiology equipment; or

(b) recruiting leading scientists, research staff, laboratory technicians, students and other research or medical professionals.

Section 6. Eligible grantees. The following organizations or entities are eligible to apply for and receive grant funding from the authority:

(1) Any organization engaged in biomedical research, provided that the organization:

(a) is a nonprofit organization or is controlled by one or more nonprofit organizations or is a Montana university, and

(b) is organized or incorporated in the state under Title 20, Chapter 25 or Title 35, or is headquartered in Montana; and

(c) has a proven history of administering scientific, biomedical or clinical research grants and contracts.

(2) For-profit entities engaged in biomedical research in partnership or in collaboration with any organization or organizations described under (1) above, provided that:

(a) The for-profit entity is organized or incorporated in the state under Title 35 or is headquartered in Montana;

(b) The nonprofit partner or collaborator is the grant recipient and controls distribution of the grant funds; and

(c) The grant application is for an eligible project described in [section 5(1)] and the panel of scientific consultants and the authority each make findings that the proposal to be funded has high merit and that the proposed research or therapy is likely to be accelerated as a result of the collaboration.

Section 7. Authority -- quorum -- mode of action -- expenses. (1) Seven members of the authority constitute a quorum for the purpose of conducting business. Action may be taken by the authority upon the affirmative vote of a majority of the members. A vacancy in the membership of the authority does not impair the right of a quorum to exercise all the rights and perform all the duties of the authority.

(2) The authority shall hold at least two public meetings per year, which may be held by any means of communication by which all members participating may simultaneously hear each other during the meeting. The authority may hold additional meetings as it determines are necessary or appropriate. Each meeting of the authority must be open to the public as provided for in Title 2, chapter 3, part 2.

(3) Each member is entitled to be paid \$50 for each day that the member is engaged in the performance of authority duties plus cost of travel, lodging, and meals as provided in 2-18-501 through 2-18-503.

Section 8. Powers of authority. The authority may:

- (1) sue and be sued;
- (2) adopt all standards and procedures necessary for the administration of [sections 2 through 19];
- (3) request that the board of examiners issue bonds or incur other debt as described in [sections 2 through 19], including the issuance of notes or refunding bonds;
- (4) consult with scientific experts and advisors as needed;
- (5) award grants to eligible grantees for costs, including indirect costs, of eligible projects;
- (6) invest any funds that are not required for immediate use, subject to any agreements with its bondholders and noteholders, as provided in Title 17, chapter 6, except that all investment income from funds invested by the authority, less the cost for investment, must be deposited in the biomedical research fund to the credit of the authority to be used to carry out the purposes of [sections 2 through 19];
- (7) contract in its own name for the investment of funds or any other purposes it considers appropriate to carry out the purposes of [sections 2 through 19];
- (8) accept gifts, grants, or loans from a federal agency, an agency or instrumentality of the state, a municipality, or any other source;
- (9) enter into contracts or other transactions with a federal agency, an agency or instrumentality of the state, a municipality, a private organization, or any other entity consistent with the exercise of any power under [sections 2 through 19]; and
- (10) perform any other acts necessary and convenient to carry out the purposes of [sections 2 through 19].

Section 9. Staff of authority. The authority may employ or contract for any professional staff or consultants necessary. Employment and contracting, other than contracting with the panel of scientific consultants, must be done in consultation with the department of commerce.

Section 10. Establishment of standards. (1) The authority shall establish medical and scientific accountability standards applicable to grant applications similar to standards in place from time to time for research funded by the NIH, with modifications to adapt to the mission and objectives of the authority, to ensure

that grant-funded research is conducted safely and ethically.

(2) The authority shall establish standards for grant applications, including minimum thresholds for sending grant applications for external review by the panel of scientific consultants as provided in [section 12].

(3) In addition, the authority shall establish standards requiring all grant awards to be subject to intellectual property agreements that balance the opportunity of the state of Montana to benefit from the patents, royalties, and licenses that result from research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements.

Section 11. Panel of scientific consultants. The peer review described in [section 12] must be conducted by a panel of six to twelve eminent research scientists selected from time to time by the authority, who must be based outside of the state of Montana and who have no ties to or collaborations with investigators working at eligible grantee organizations. Members of the panel of scientific consultants must be demonstrated leaders in biomedical research with active research programs at top-ranked universities, research institutions, medical schools or hospitals. Qualifications of panel members may include a strong track record in producing highly cited peer-reviewed publications, membership in the National Academy of Sciences, receipt of national or international scientific awards, past service on peer-review panels or national advisory committees, and expertise in brain diseases, brain injuries, mental illness or other eligible projects described in [section 5(1)]. In any panel of scientific consultants the authority convenes, at least two members should have experience in successfully introducing new disease therapies to clinical practice.

Section 12. Peer review. (1) Peer review must take one of two forms, depending on whether the grant application requests funds for eligible projects described under [section 5(1)] or [section 5(2)]:

(a) Grant applications for eligible projects described under [section 5(1)] must be for projects that were submitted to national funding agencies and reviewed by expert scientific panels but did not rank sufficiently high to receive funding from the national funding agency or agencies. Grant applications for eligible projects described under [section 5(1)] must be accompanied by a summary statement resulting from peer review of the research proposal conducted by a study section of the NIH or comparative deliberative body. Summary statements may be dated up to 18 months prior to the submission of the grant application to the authority. The authority shall include the accompanying summary statement when submitting grant applications to the panel of scientific

consultants for peer review.

(b) Grant applications for eligible projects described under [section 5(2)] do not need to have been submitted to national funding agencies for peer review, but must be submitted by the authority to an appropriate panel of scientific consultants.

(2) At least two times each year, the authority shall convene an appropriate panel of scientific consultants to review applications and recommend priority rankings.

(a) With respect to applications for eligible projects described under [section 5(1)], priority rankings shall be based on factors including innovation, demonstrated ability of the principal investigator and team or the fellowship candidate and mentor, project relevance, priority rankings and scores resulting from review by the national funding agency or agencies and relevance to the development of disease therapies.

(b) With respect to applications for eligible projects described under [section 5(2)], applications of equivalent merit, as determined by the panel of scientific consultants, shall receive priority to the extent that they provide higher proportions of non-state matching fund amounts.

(3) The priority rankings assigned by the panel of scientific consultants must be provided to the authority for final funding determinations. The recommendations of the panel of scientific consultants are not determinative, but must be taken into account by the authority in making grant award determinations, as described in [section 13].

Section 13. Evaluation of grant applications by authority. The authority shall evaluate grant applications for grant funding considering the following factors:

(1) the priority ranking assigned to the application by the panel of scientific consultants, as described in [section 12];

(2) the financial, managerial, and technical ability of the applicant to manage the grant and conduct the proposed research;

(3) the total amount of grant funds available in the grant allocation account in the biomedical research fund;

(4) whether and to what extent the applicant has non-state matching funds available to leverage grant funds;

(5) the total amount requested in other applications that have been received or that are likely to be

received; and

(6) any other criteria that the authority determines appropriate, considering the purposes of [sections 2 through 19].

Section 14. Biennial audit and annual report.(1) The authority's books and records must be independently audited at least once each biennium, by or at the direction of the legislative auditor. The costs of the audit must be paid from the authority's funds.

(2) By September 30 of each year, the authority shall issue an annual report to the public describing its activities for the preceding fiscal year. Each annual report must include:

(a) for the prior fiscal year, the number and dollar amounts of research grants awarded, the grantees, and the authority's administrative expenses;

(b) a summary of research findings, including promising new research areas;

(c) an assessment of the relationship between the authority's grants and the overall strategy of its research program; and

(d) a discussion of the authority's strategic research and financial plans.

Section 15. Creation of debt. The people of Montana, through the enactment of this law by a majority of the electors voting on the question, authorizes the creation of state debt in a cumulative amount not to exceed \$200 million, over a period of 10 years, in principal amount of general obligation bonds issued as provided in [section 16], not including any refunding obligations issued pursuant to [section 17], for the purposes set forth in [sections 2 through 19].

Section 16. Issuance of bonds -- allocation proceeds. (1) The authority shall determine, from time to time, whether it is necessary or desirable to issue bonds authorized by [section 15] for the purposes set forth in [sections 2 through 19] and, if so, the authority shall make a written request to the board of examiners to issue bonds, which request must include the principal amount of bonds to be issued. The total amount of bonds authorized to be issued in any fiscal year must not exceed \$20 million, exclusive of any refunding bonds issued pursuant to [section 17] or bond, grant or revenue anticipation notes issued as provided in [section 18]; except that, if less than this amount of bonds is issued in any fiscal year, the remaining authorized but unissued amount

may be carried over to one or more subsequent fiscal years up to a period of 10 full fiscal years, concluding with the fiscal year ending June 30, 2027.

(2) Upon receiving the written request of the authority, the board of examiners shall issue and sell bonds of the state in the requested amount. The bonds are general obligations to which the full faith, credit, and taxing powers of the state are pledged for payment of the principal and interest. The bonds must be sold and issued as provided by Title 17, chapter 5, part 8 and other applicable provisions of Title 17, Chapter 5, if any, except that each series of bonds may have a term of up to 40 years.

(3) The proceeds of the bonds are allocated to the biomedical research fund and applied as provided in [section 19]. The proceeds must be available to the authority and may be used for the purposes authorized in this part without further budgetary authorization.

Section 17. Refunding bonds. Upon request of the authority to the board of examiners, for so long as any of the bonds issued under [section 16] are outstanding, refunding bonds may be issued as provided in Title 17, chapter 5, parts 3 and 8, and other applicable provisions of Title 17, chapter 5, if any. Refunding bonds do not count against the \$200 million limit set forth in [section 15]. Refunding bonds issued under this section exclude bonds issued to refund bond, grant or revenue anticipation notes.

Section 18. Bond, grant, or revenue anticipation notes. Upon request of the authority to the board of examiners, bond, grant or revenue anticipation notes may be issued as provided in 17-5-805. Bond, grant or revenue anticipation notes do not count against the \$200 million limit set forth in [section 15].

Section 19. Biomedical research fund -- uses of funds. (1) There is established outside the state treasury a separate account designated as the biomedical research fund. There are established in the biomedical research fund as subaccounts a grant allocation account, an administration account, and a costs of issuance account.

(2) There must be credited to:

(a) The grant allocation account:

(i) The net proceeds of bonds other than refunding bonds, less any proceeds deposited to the administration account as provided in subsection (b);

(ii) The net proceeds of bond, grant, or revenue anticipation notes, less any proceeds deposited to the administration account as provided in subsection (b); and

(iii) Money appropriated by the legislature;

(b) The administration account, an amount not to exceed 5% of the proceeds of bonds or bond, grant, or revenue anticipation notes; and

(c) The costs of issuance account, proceeds of the bonds or notes or other funds to be used to pay costs of issuance of the bonds or notes.

(3) Funds in the grant allocation account must be used to provide grants to eligible grantees for eligible projects as provided in [sections 2 through 19].

(4) Funds in the administration account must be used to pay administrative costs of the authority, unless they are not needed, in which case such funds may be transferred to the grant allocation account or a debt service account for outstanding bonds or notes.

Section 20. Statement of intent to legislature. By approving [this act], the people of the state of Montana intend and request that the legislature enact legislation to implement [this act] at the legislative session immediately following the general election at which [this act] was approved. Such implementing legislation is expected to include providing for reasonable startup costs of the authority to be repaid from bond proceeds upon the issuance of bonds as provided in [section 16] and providing for a statutory appropriation of amounts in the biomedical research fund, including without limitation bond proceeds, to achieve the purpose set forth in [this act].

Section 21. Codification instruction. [Section 1] is intended to be codified as an integral part of Title 2, chapter 15, part 18. [Sections 2 through 19] are intended to be codified as an integral part of Title 90.

Section 22 Severability. If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

Section 23. Effective date. [This act] is effective January 1, 2017.

Section 24. Termination. [Sections 15, 16, and 18] terminate June 30, 2027.

- END -

I hereby certify that the within bill,
SB 0402, originated in the Senate.

Secretary of the Senate

President of the Senate

Signed this _____ day
of _____, 2016.

Speaker of the House

Signed this _____ day
of _____, 2016.

_____ BILL NO. _____

INTRODUCED BY TAB DOUGHERTY

AN ACT ; AND PROVIDING AN EFFECTIVE DATE; AND PROVIDING A TERMINATION DATE.