



AGREEMENT ON PROVISION OF RESEARCH SUPPORT SERVICES IN 2017 Mayo Clinic Arizona and St. Anne's University Hospital – International Clinical Research Center

The Effective Date of this Agreement is March 17, 2017.

The Parties to this Agreement are:

Mayo Clinic Arizona, an Arizona charitable corporation, located at 13400 East Shea Boulevard, Scottsdale, AZ 85259 and its affiliates, defined herein (collectively "**Mayo**") and **International Clinical Research Centre of St. Anne's University Hospital in Brno (Fakultní nemocnice u svate Anny v Brne)**, having a principal place of business at Pekarska 53, 65691, Brno, Czech Republic ("**FNUSA-ICRC**"), each individually a "**Party**" and, collectively, "**Parties**".

WHEREAS: Mayo is the first and largest integrated, not-for-profit medical group in the world, in which doctors from various specialties work together to care for patients through integrated clinical practice, education and research;

WHEREAS: Investigators from St. Anne's Hospital and Mayo Clinic collaborated during 2011-2015 on joint research, exchange of staff, and transfer of knowledge and know-how within the project to develop the International Clinical Research Center of St. Anne's University Hospital, an international multidisciplinary medical research center;

WHEREAS: Contracting Parties wish to specify conditions for joint collaboration on conducting collaborative research activities in 2017, consistent with the terms of this Agreement.

NOW, THEREFORE: In consideration of the mutual promises and covenants set forth below, the Parties hereby agree to the following terms and conditions for the 2017 research activities ("**Agreement**").

Article 1.00 - Definitions

1.01 For Mayo, "**Affiliate**": any corporation or other entity within the same "controlled group of corporations" as Mayo or its parent Mayo Clinic. For purposes of this definition, the term "controlled group of corporations" will have the same definition as Section 1563 of the Internal Revenue Code as of November 10, 1998, but will also include corporations or other entities which if not a stock corporation, more than fifty percent (50%) of the board of directors or other governing body of such corporation or other entity is controlled by a corporation within the controlled group of corporations of Mayo. Mayo's Affiliates include, but are not limited to: Mayo Clinic; Mayo Collaborative Services, Inc.; Mayo Clinic Florida;

Mayo Clinic Jacksonville; and Mayo Health System entities. For FNUSA-ICRC, **“Affiliate”**: any corporation or other entity that is controlled by, or is under common control with, FNUSA-ICRC. For purposes of this definition, “control” means ownership of: (a) at least fifty percent (50%) or the maximum percentage, if less than fifty percent (50%), as allowed by applicable law, of the outstanding voting securities of such entity; or (b) at least fifty percent (50%) of the decision-making authority of such entity.

1.02 “Confidential Information”: any confidential or proprietary information or material disclosed by one Party, the disclosing party, to the other, the receiving Party, for performance of the research hereunder and identified in writing as confidential at the time of disclosure or, if first disclosed orally, identified as confidential at the time of disclosure and confirmed in writing within forty-five (45) days. Confidential Information does not include any information or material that receiving party evidences is: (a) already known to the receiving Party at the time of disclosure (other than from the disclosing Party); (b) publicly known other than through acts or omissions of the receiving Party; (c) disclosed to the receiving Party by a third party who was not and is not under any obligation of confidentiality; or (d) independently developed by employees of the receiving Party without knowledge of or access to the Confidential Information. Notwithstanding the above, Data generated in the course of conducting research hereunder is not Confidential Information for publishing purposes in accordance with the publication section of this Agreement.

1.03 “Data”: all research, pre-clinical and clinical data, including human subject data, genomic data, analytic data and other data that is generated in the performance of a Project Plan hereunder. Data does not include patient medical records or other source documentation, unless otherwise agreed and documented in a Project Plan.

1.04 “Deliverables”: specific outcomes resulting from the performance of the research as mutually agreed upon and described and approved in **Exhibit A**.

1.05 “Invention”: any invention, innovation, discovery or other developments, whether or not patentable, conceived and first reduced to practice during and in the course of performing the research undertaken in a Project Plan.

1.06 “Limited Data Set”: a limited set of identifiable patient information as defined in the Privacy Regulations issued under the Health Insurance Portability and Accountability Act (**HIPAA**).

1.07 “Principal Investigator” or “PI”: the individuals designated by each Party with authority to grant prior approvals and responsibility for overall scientific programmatic management, subject to policy. The Principal Investigator for FNUSA-ICRC is Dr. Gorazd B. Stokin. The Principal Investigator for Mayo is Dr. Yonas E. Geda. If for any reason a Principal Investigator becomes unavailable to direct the performance of the work under this Agreement for the term of this Collaboration, the Parties will be notified. If the Parties are unable to identify a mutually acceptable successor, this Agreement may be terminated

consistent with Article 9 herein. For the avoidance of doubt, the Principal Investigators serve in a leadership role for the Collaboration. They are not required, however, to also serve in a leadership role within their respective institutions (e.g. the FNUSA-ICRC Principal Investigator does not have to be the ICRC Chair).

1.08 “Intermediate Progress Report”: official document provided by Mayo to FNUSA-ICRC for the meeting of its ISAB (International Scientific Advisory Board) describing the intermediate progress of the research conducted under this Agreement. The report shall have the form of **Exhibit B** of this Agreement. The planned date of the meeting of ISAB at FNUSA-ICRC is October 2-3, 2017.

1.09 “Progress Report”: official document provided by Mayo to FNUSA-ICRC describing the progress and Deliverables of the research conducted hereunder. The report shall have the form of **Exhibit B** of this Agreement. The final 2017 Progress Report shall be submitted before November 30, 2017.

1.10 “Project Plan”: a specifically written, defined statement of work, in the form of **Exhibit C** of this Agreement. It is the agreement of the Parties that each individual Project Plan (**Exhibits C1 – C6**) shall include:

- (a) Details of the research to be conducted by each of the Parties (description of the research programs, team composition);
- (b) Research goals and milestones;
- (c) Deliverables/outcomes (publications, methods and other intellectual property); and
- (d) A budget.

1.11 “Responsible Investigator”: the individuals designated by each Party with responsibility for management of a research project under a Project Plan and the respective deliverables listed in Exhibit A.

1.12 “Scientific Director”: the individual responsible for maintaining the scientific and ethical standard accepted in the field for research managed under the Project Plans hereunder. The Scientific Director for this 2017 collaboration is Dr. Gregory A. Worrell.

1.13 “Specimen(s)”: any biologic material including, without limitation, strains and cultures, cell parts and organisms, tissues, blood, plasma, urine, spinal fluid or other fluids and derivatives thereof including DNA or RNA derived from any of the foregoing.

1.14 “Indirect costs”: costs related to using Mayo’s facilities and administrative support that cannot be claimed as direct costs (including, but not limited to general administrative, departmental, sponsored program and sponsored project administration expenses, general equipment and supplies, operation and maintenance expenses, building and equipment depreciation and use allowance). Indirect costs are part of the real costs of conducting the research activities.

Article 2.00 – Budgets/Fiscal Management

2.01 Funding. The budgeted amounts for 2017 are attached as **Attachment A** to each of the Project Plans. The Parties acknowledge that the budget(s) provided include an indirect rate of 25%; FNUSA-ICRC has agreed to pay Mayo at this indirect rate of 25%. The Parties acknowledge that the budget amounts represent an equitable exchange for the proper and timely conduct of the research projects and completion of the Deliverables in light of the professional time and expenses required for the performance of the research and fulfillment of this Agreement.

2.02 Travel Expenses. Specific Project plans hereunder include budgets for travel. Mayo will request FNUSA-ICRC's prior approval prior to initiating preparations of each travel. Any expenses (e.g. airfare, hotel, rental car) relating to the travels of Mayo personnel shall be included within the budget for each individual Project Plan. Travel arrangements, consistent with Mayo's travel policies (except the following exceptions – only economy class may be used in air transport, consumption of alcoholic beverages may not be reimbursed), will be made through Mayo.

2.03 Payment/Progress Report. FNUSA-ICRC will provide funding for the proposed Project Plans and budgets (described in Exhibit A, which may be amended from time to time) based on the below payment schedule:

- (a) 60% will be paid within thirty (30) days after Agreement execution;
- (b) The remaining 40% will be provided to Mayo within fifteen (15) days after approval of the Progress Report by FNUSA-ICRC.

The Parties agree that a Progress Report may not be approved until completion by Mayo of the research Deliverables set forth in Exhibit A. In such case, FNUSA-ICRC shall without delay request Mayo to provide evidence of completion of such research Deliverables. If the Deliverables identified in Exhibit A are not completed under this Agreement by December 20, 2017, Mayo agrees to return to FNUSA-ICRC the amount Mayo received from FNUSA-ICRC to complete such Deliverables. Such payment will be made no later than January 15, 2018.

FNUSA-ICRC will remit payment to:

Mayo Clinic – Wire Transfer

2.04 Cost-Related Prior Approvals. The Parties acknowledge that during the term of this Agreement a particular Project Plan may require changes to specific elements within its budget or to the overall budgeted amount. Every change of the budget shall be agreed upon by the Parties and approval documented in an email between the Parties or an amendment to the relevant Project Plan, as determined by the Parties.

2.05 Records. Mayo shall maintain complete and accurate accounting records in accordance with accepted accounting practices; all funds and corresponding accounting records shall be kept by Mayo separately from other activities of Mayo. These records shall be available for inspection, review and audit. Upon request, Mayo agrees to send copies of accounting records to FNUSA-ICRC within forty-five (45) days of a request by FNUSA-ICRC, or its duly authorized representative, including state or regional bodies auditing FNUSA-ICRC, as required by law. Contracting Parties undertake to archive records for the period of at least ten (10) years from the end of research hereunder. Costs of archiving shall be borne by each respective contracting Party.

2.06 Withholding Taxes. Any withholding taxes which are required by law to be withheld on remittance of any payment may be deducted from the amount paid and FNUSA-ICRC will promptly furnish Mayo (or, as the case may be, Mayo will promptly furnish FNUSA-ICRC) with original copies of all official receipts for such taxes. The Parties will obtain, or assist each other in obtaining, any tax reduction (including avoidance of double taxation), tax refund or tax exemption available to them by international treaty or otherwise.

2.07 Discrepancies in spending. If FNUSA-ICRC determines there is a discrepancy between the records provided in Section 2.05 and the budgets defined in the Project Plans hereunder, FNUSA-ICRC shall provide Mayo written notice specifying the discrepancy, and Mayo shall have thirty (30) days from its receipt of such notice to explain such discrepancy

and provide appropriate evidence that its spending is in line with this Agreement and its attachments. The Parties will work closely to resolve any disagreements in regard to their activities under this Agreement. If resolution is not achieved, such dispute shall be finally settled by arbitration in accordance with Section 10.05 of this Agreement.

2.08 Unspent Budget. The Parties agree that if a portion of individual budgets identified in the Project Plan(s) are not spent, Mayo agrees to return those unexpended funds paid by FNUSA-ICRC and held by Mayo hereunder to the bank account of FNUSA-ICRC by December 20, 2017, or according to Section 9.04 in case of an early termination of the Agreement.

Article 3.00 - Conduct of Research

3.01 Subject of the Agreement. Mayo undertakes to supply FNUSA-ICRC research support services in the amount, terms and the price defined in this Agreement, its **Exhibit A**, and in the individual Project Plans, and FNUSA-ICRC agrees to provide adequate cooperation and to pay the agreed budget(s) for completion of those research support services.

3.02 Specimen Use. The Parties agree that Specimens and other research materials exchanged during the conduct of a Project Plan are owned by the providing Party and the transfer of such materials to the recipient Party under the terms of this Agreement shall not affect the providing Party's ownership interest therein. All such materials will be maintained by the recipient Party so that they are readily identifiable. The receiving Party agrees to use such Specimens solely for research purposes as specified in the Project Plan for which such Specimens are provided and shall not transfer, deliver or otherwise release such Specimens to a third party without the express prior written consent of the providing Party. Upon termination or expiration of a Project Plan or this Agreement, and at the instructions of the providing Party, the receiving Party shall either return to the providing Party or demonstrably destroy all unused Specimens and other research materials. Any disposal of Specimens shall be always subject to the strictest laws and regulations applicable to that Party.

3.03 Data. The Parties, in performing any research pursuant to this Agreement, shall be respectful of the privacy of medical information, and shall adhere to the requirements of all international, national and state regulations applicable to that Party related to the privacy of such information. Both Parties shall comply with applicable laws and regulations, as amended from time to time, with the respect to the collection, use, storage and disclosure of any Data arising from conduction of a Project Plan, including without limitation, the Health Insurance Portability and Accountability Act of 1996 (**HIPAA**) and its implementing regulations (**45 C.F.R. et.seq.**) and seek appropriate Ethics Review Board/Institutional Review Board (**IRB**) approval, when applicable, in performing its obligations under this Agreement.

Mayo shall own Data collected by Mayo and FNUSA-ICRC shall own Data collected by FNUSA-ICRC. If applicable, any Data furnished to FNUSA-ICRC concerning Mayo patients will be furnished in a coded format, which protects patient identities. FNUSA-ICRC's ability to review a patient's medical record shall be subject to reasonable safeguards for the protection of patient confidentiality. Should the collaborative research involve processing of patient Data originating in the European Union (EU), respective EU rules on personal data processing shall be observed by the Parties, which may include also the obligation of both Parties to conclude a separate agreement on the transfer of personal data to the USA; any processing of patient data shall be always subject to the strictest laws and regulations applicable to that Party. Mayo Principal Investigators shall be responsible for informing FNUSA-ICRC of applicable U.S. laws concerning patient data; FNUSA-ICRC Principal Investigators shall be responsible for informing Mayo of applicable EU laws concerning patient data.

3.04 Limited Data Set. The Parties acknowledge that for a particular project hereunder it may be determined that a “**Limited Data Set**” of identifiable patient information as defined in the Privacy Regulations issued under HIPAA may be exchanged. A Party receiving a Limited Data Set under the terms of this Agreement shall not use or disclose the Limited Data Set other than as permitted or required under this Agreement/attached Project Plan or as required by law or as otherwise authorized by the disclosing Party. The receiving Party shall ensure that any agent, including a subcontractor, to whom it provides a Limited Data Set, agrees to the same restrictions and conditions that apply through this Agreement to the receiving Party with respect to such information. The receiving Party shall report in writing as promptly as reasonably possible after discovery by that recipient of such unauthorized use or disclosure of a Limited Data Set to the other disclosing Party. The receiving Party's obligation to protect the privacy of the Limited Data Set(s) is continuous and survives any termination, cancellation, expiration, or other conclusion of this Agreement. The receiving Party will not identify or attempt to identify the individuals whose Protected Health Information appears in a Limited Data Set. The receiving Party will not contact or attempt to contact the individuals whose Protected Health Information appears in a Limited Data Set.

3.05 Animal Studies. With respect to any research covered by this Agreement involving animal subjects, the Parties shall comply with all applicable laws, rules and regulations of any governmental authority, agency or entity having jurisdiction over the research (including, but not limited to, the 1966 Federal Animal Welfare Act [AWA] and the 1985 Improved Standards of Laboratory Animals Acts) and seek appropriate Institutional Animal Care and Use Committee (IACUC) or equivalent oversight committee approval in performing its obligations under this Agreement.

3.06 Compliance with Law. The Parties will comply with all international, federal, national and state laws and regulations which are applicable to this contract at the location at which the research is being conducted, including all laws and regulations relating to patient informed consent, protection of privacy, human subjects research, use of animals in research, and handling of hazardous materials. Each Party shall obtain and maintain current approval

from its internal oversight bodies (e.g. Ethics Review Board/Institutional Review Board [IRB]) for all research that falls under the jurisdiction of those bodies. If a Party determines that this Agreement may create a material risk of violating any law as referred to above, then the Party shall give written notice to the other, and the Parties will use good faith efforts to reform the Agreement as necessary to achieve compliance. If reformation is not possible, then the Parties will cooperate to terminate this Agreement as soon as practicable with due consideration to patient safety and research matters.

Article 4.00 - Inventions, Discoveries and Patents

4.01 No Transfer of Rights. Without prejudice to the possibility to use any right in or license to any patents, copyrights or other proprietary right in due course of research activities pursuant to this Agreement, it is expressly agreed that neither Party transfers by operation of this Agreement to the other Party such right in or license to any patents, copyrights or other proprietary right owned as of the commencement date of the Agreement or arising outside of the Project Plans conducted under this Agreement.

4.02 Ownership.

- (a) Mayo shall own all Inventions conceived and first reduced to practice solely by employees of Mayo and arising out of research carried out under the provisions of this Agreement ("**Mayo Inventions**").
- (b) FNUSA-ICRC shall own all Inventions conceived and first reduced to practice solely by employees of FNUSA-ICRC and arising out of research carried out under the provisions of this Agreement ("**FNUSA-ICRC Inventions**").
- (c) Mayo and FNUSA-ICRC shall jointly own all Inventions conceived and first reduced to practice by employees of both Mayo and FNUSA-ICRC and arising out of research carried out under the provisions of this Agreement ("**Joint Inventions**"). The share of outcomes corresponds to the contribution of the Parties. For any Joint Inventions, the Parties will agree to negotiate in good faith as to the protection, prosecution, maintenance and defense of the same and embody such understanding in a separate written agreement (**Section 4.05**).
- (d) Inventorship of any Invention shall be determined in accordance with U.S. Patent Law.

4.03 Reservation of Rights. All rights herein are subject to:

- (a) The rights and obligations to and requirements of the U.S. government, if any have arisen or may arise, regarding the Mayo Inventions and Joint Inventions, including as set forth in 35 U.S.C. §§200 et al., 37 C.F.R. Part 401 et al. ("**Bayh-Dole Act**");
- (b) Mayo's and its Affiliates' reserved, irrevocable right to practice and have practiced Mayo Inventions and Joint Inventions in connection with Mayo's and its Affiliates' educational, research and clinical programs; and

- (c) FNUSA-ICRC's and its Affiliates' reserved, irrevocable right to practice and have practiced FNUSA-ICRC Inventions and Joint Inventions in connection with FNUSA-ICRC's and its Affiliates' educational, research and clinical programs.

FNUSA-ICRC agrees to comply with the provisions of the Bayh-Dole Act, if applicable, including promptly providing to Mayo information requested to enable Mayo to meet its compliance requirements thereunder; Mayo shall notify FNUSA-ICRC of the respective obligations in the Project Plan. Mayo agrees to comply with the provisions of international and national laws and regulations, if applicable, including promptly providing to FNUSA-ICRC with information requested to enable FNUSA-ICRC to meet its compliance requirements thereunder; FNUSA-ICRC shall notify Mayo of the respective obligations in the Project Plan.

4.04 Infringement. If either Party becomes aware of a claim by a third party that its activities under this Agreement infringes a third party's intellectual property rights, it will notify the other Party. To the extent such claim may affect the rights of the other Party, both Parties will determine how to address the potential claim, which may include ceasing the alleged infringing activity. In the event either Party is sued for infringement of third party intellectual property rights because of its actions or that of the other Party under a Project Plan, the Parties will confer on an appropriate defense strategy and an equitable sharing of associated costs. Unless otherwise agreed, the Parties will bear those costs in the same proportion in which they agree to share revenue related to the Project Plan at issue.

4.05 Commercialization. Should any Invention or other intellectual property right with commercial relevance result from the collaborative research conducted under this Agreement, the principles of division of revenues with respect to contribution of the Parties shall be provided for in a separate agreement. In such separate agreement the Parties will also determine how the Parties will commercialize such Invention or other intellectual property for the benefit of patients.

Article 5.00 – Confidentiality

5.01 Treatment of Confidential Information. Except as provided for in Section 5.02, neither Party will disclose, use or otherwise make available the other Party's Confidential Information during the Term or for three (3) years thereafter, and will use the same degree of care it employs to protect its own confidential information. Both Parties agree to use Confidential Information solely as allowed by this Agreement and for the purposes of conducting the research activities hereunder.

5.02 Right to Disclose.

- (a) To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, a Party may disclose Confidential Information of the other Party to its consultants, and outside contractors on the condition that each such entity agrees to obligations of confidentiality and non-use at

- least as stringent as those therein.
- (b) If a Party is required by law, regulation, court order, or international, state, or regional controlling bodies to disclose any Confidential Information of the other Party, it will have the right to do so, provided it: (i) promptly notifies the other Party; (ii) provides the minimum amount of Confidential Information necessary to comply with law or court order as advised by its legal counsel; and (iii) reasonably assists the other Party to obtain a protective order or other remedy of other Party's election and at other Party's expense.

Article 6.00 – Publication

6.01 Publications. Each FNUSA-ICRC and Mayo researcher reserves the right, individually, to publish and present the results of research conducted under this Agreement in scholarly or professional journals, at professional meetings or conferences, or otherwise of their choosing, subject to the limitations of this Section 6.01 and in accordance with Section 6.02. FNUSA-ICRC and Mayo researchers may also jointly publish and present the results of research funded under this Agreement if it is appropriate and reasonable to do so, subject to the limitations of this Section 6.01 and in accordance with Section 6.02. In order to assure protection of future patent rights, draft publications or presentation materials will be provided prior to publication to the technology transfer office of the Party specified in the Project Plan that is directing patent filing and prosecution prior to any publication. Such technology transfer office shall notify the authors within thirty (30) days whether that Party wishes to file a patent application. In such a case, publication or presentation may be delayed for an additional thirty (30) days to permit patent filing.

6.02 Affiliation and Dedication. Each publication arising from a Project Plan shall contain Affiliation in the form “International Clinical Research Center, St. Anne’s University Hospital Brno, Brno, Czech Republic” and Dedication “Supported by the project no. LQ1605 from the National Program of Sustainability II (MEYS CR), or short Dedication “Supported by the project No. LQ1605 (MEYS CR, NPU II).

6.03 Acknowledgement of Funding. In addition to Section 6.02, each publication arising from a Project Plan shall contain a listing of investigators participating in the research that are not included in the authorship, in accordance with the International Committee of Medical Journal Editors (ICMJE) regulations.

Article 7.00 - Use of Name and Logo

7.01 Neither Party will use for publicity, promotion or otherwise, any logo, name, trade name, service mark or trademark of the other Party or its Affiliates, or any simulation, abbreviation or adaptation of the same, or the name of any employee or agent of the other Party, without that Party's prior, written, express consent. A Party may withhold such consent in that Party's absolute discretion. For the avoidance of doubt, no public relations efforts will be pursued without mutual agreement of the Parties.

7.02 Mayo's marks include, but are not limited to the terms "Mayo®," "Mayo Clinic®" and the triple shield Mayo logo. With regard to the use of Mayo's name, all requests for approval pursuant to this Section must be submitted to the Mayo Clinic Public Affairs Business Relations Group, at the following e-mail address: _____ at least five (5) business days prior to the date on which a response is needed.

7.03 FNUSA-ICRC's marks include, but are not limited to the terms "FAKULTNÍ NEMOCNICE U SV. ANNY V BRNĚ" including its logo FNUSA and the logo "FNUSA-ICRC".

7.04 Each Party shall be allowed to release the following information without the approval of other Party: (1) the existence of this Agreement and any Project Plan hereunder; and (2) any additional information as necessary to ensure compliance with requests and inspections by regulatory authorities, such as, but not limited to, the Research Ethics Board/Institutional Review Board. None of this information shall be Confidential Information. No publicity shall be given by either Party to any of the results of the investigation without the prior written approval of the other Party, except as otherwise provided in this Agreement.

7.05 The terms of this Article 7.00 shall survive the termination, expiration, non-renewal, or rescission of this Agreement.

Article 8.00 - Representations, Warranties and Disclaimers

8.01 Mutual Representations and Warranties. Each Party represents and warrants to the other that it:

- (a) Has the power to enter into this Agreement and to perform and ensure the performance of its and its Affiliates' obligations hereunder and has taken all actions necessary for the execution of this Agreement, which constitutes a binding obligation enforceable against it;
- (b) Shall comply and ensure that its Affiliates comply with all international, national, or local laws and regulations applicable to that Party in its performance under this Agreement;
- (c) Shall obtain and ensure its applicable Affiliate has obtained or will obtain all consents, including patient informed consent, as applicable, necessary to transfer any Specimens or Limited Data Sets that it transfers to the other Party hereunder.

8.02 Disclaimers.

- (a) Except as otherwise set forth in this Agreement, NEITHER PARTY HAS MADE AND DOES NOT MAKE ANY PROMISES, COVENANTS, GUARANTEES, REPRESENTATIONS OR WARRANTIES OF ANY NATURE, DIRECTLY OR INDIRECTLY, EXPRESS, STATUTORY OR IMPLIED, INCLUDING WITHOUT

LIMITATION, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, SUITABILITY, DURABILITY, CONDITION, QUALITY OR ANY OTHER CHARACTERISTIC OF ANY INVENTIONS, SPECIMENS, DATA, OR RESEARCH RESULTS.

- (b) IN NO EVENT WILL EITHER PARTY'S LIABILITY OF ANY KIND INCLUDE ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE LOSSES OR DAMAGES, EVEN IF THAT PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

8.03 Insurance. Each Party shall carry sufficient insurance coverage (whether a policy or program of insurance or self-insurance) for a time period sufficient to cover any liability assumed by that Party hereunder during the terms of this Agreement and after. FNUSA-ICRC informed Mayo before signing this Agreement about its limited possibility to take out full insurance under Czech legislation under the Act on budgetary rules no. 218/2000 Paragraph 70, as amended.

8.04 Nature of Collaboration. The Parties declare that:

- (a) Each is a non-profit research organization, whose primary goal is to provide healthcare services and conduct fundamental and clinical research and to disseminate its results by way of teaching, publication or technology transfer;
- (b) That the Collaboration according to this Agreement is solely of non-economic nature as it covers only non-economic activities between collaborating research organizations only; and
- (c) That any profits are reinvested into these primary activities: the dissemination of their results, research and related clinical practice or educational purposes, consistent with the Parties' missions.

8.05 Responsibility. Each Party agrees that it will be responsible for its own acts and omissions and the negligent acts while fulfilling this Agreement or omissions of its Affiliates, employees, agents, officers, or directors, to the extent allowed by law, and shall not be responsible for the acts or omissions of the other Party, its Affiliates, employees, agents, officers, or directors. Each Party therefore agrees that it will assume liability for itself, its Affiliates, agents or employees for any injury to persons or property resulting in any manner from the conduct of its own operations or its Affiliates, agents or employees under this Agreement, and for any loss, cost, damage, or expense resulting at any time from failure to exercise proper precautions, by itself or through its Affiliates, agents or employees.

8.06 FNUSA-ICRC Additional Representation. FNUSA-ICRC represents and warrants that for these 2017 collaborative research projects Mayo is not subject to any obligations (e.g. cost matching) or penalties under the grant FNUSA-ICRC received from the National Sustainability Fund managed by the Ministry of Education, Youth and Sports of the Czech Republic (Ref. No.: MSMT-8007/2015-1) or any other funding sources. In addition, FNUSA-ICRC agrees to indemnify and hold harmless Mayo should any claims be brought against

Mayo by the Ministry or other funding sources due to the funding provided to Mayo by FNUSA-ICRC hereunder and/or the research activities conducted under this Agreement.

8.07 The terms of this Article 8.00 shall survive the termination, expiration, non-renewal, or rescission of this Agreement.

Article 9.00 - Term and Termination

9.01 Term. The term of this Agreement shall extend until December 31, 2017 (“**Term**”), unless otherwise extended upon mutual written agreement of the Parties.

9.02 Right to Terminate. This Agreement may be terminated immediately by written agreement of both contractual Parties. In addition, this Agreement may be terminated by either Party by giving to the other a minimum of two (2) months prior written notice.

As it pertains to a specific Project Plan, such Project Plan may be terminated by either Party giving to the other a minimum of thirty (30) days prior written notice.

Other than as expressly identified in this Agreement, neither Party shall be under any obligations or penalties to the other for early termination of this Agreement or termination of a specific Project Plan.

The Parties and their respective Responsible Investigator(s) will take all reasonable efforts to stop spending of their budget or minimize further utilization of their budget under a Project Plan(s) upon issuing or receiving such termination notice.

9.03 Termination for Breach. If either Party commits a material breach of this Agreement or a Project Plan hereunder, the non-breaching Party may notify the breaching Party in writing of such breach and the breaching Party will have thirty (30) days after such notice becomes effective to cure such breach. If the breaching Party fails to cure such breach, the non-breaching Party may, at its option, immediately terminate this Agreement or the specific Project Plan by sending written notice of termination.

9.04 Settlement after Early Termination. If this Agreement or a Project Plan hereunder is terminated early, Mayo shall send FNUSA-ICRC an overview of activities carried out until termination in the same structure as the Progress Report according to Section 1.09 hereunder and an accounting will be completed and all unsupported obligations made before the termination of the Agreement, even though they may extend beyond such termination date, shall be balanced.

9.05 Return of Confidential Information/Specimens. Upon termination or expiration of this Agreement or a specific Project Plan hereunder, and at the instructions of the providing Party, all Confidential Information of a Party, and any copies then remaining in the possession of the receiving Party or its personnel (excluding any copy that either Party is authorized to

retain for archiving purposes), shall be returned or its destruction certified, at the disclosing Party's election.

Upon termination or expiration of this Agreement or a specific project Plan hereunder, the return or destruction of Specimens will be managed in compliance with Article 3 hereunder within 30 days from termination or expiry of the Agreement or an individual Project Plan.

9.06 Survival. The termination or expiration of this Agreement does not relieve either Party of its rights and obligations that have previously accrued. Rights and obligations that by their nature prescribe continuing rights and obligations shall survive the termination or expiration of this Agreement including Sections 2.05, 2.06, 2.07, 2.08, 3.02, 3.03, 3.04, 3.05, 3.06, 9.04, 9.05, 9.06, 10.03, 10.04, 10.05, 10.13, 10.14 and Articles 4, 5, 6, 7, and 8, except the obligations with regard to Confidential Information shall survive consistent with Section 5.01.

Article 10.00 - General Provisions

10.01 Amendments. This Agreement may not be amended or modified except by a writing signed by both Parties and identified as an amendment to this Agreement.

10.02 Construction. Each Party acknowledges that it was provided an opportunity to seek advice of counsel and as such this Agreement shall not be construed for or against either Party.

10.03 Export Control. The Parties agree not to use or otherwise export or re-export anything exchanged or transferred between them pursuant to this Agreement except as authorized by United States law and the laws of the jurisdiction in which it was obtained. In particular, but without limitation, items exchanged may not be exported or re-exported (a) into any U.S. embargoed countries or (b) to anyone on the U.S. Treasury Department's list of Specially Designated Nationals or the U.S. Department of Commerce Denied Person's List or Entity List. By entering into this Agreement, each Party represents and warrants that they are not located in any such country or on any such list. Each Party also agrees that they will not use any item exchanged for any purposes prohibited by United States law, including, without limitation, the development, design, manufacture or production of missiles, or nuclear, chemical or biological weapons. In the event either Party becomes aware of any suspected violations of this paragraph that Party will promptly inform the other Party of such suspected violation, and cooperate with one another in any subsequent investigation and defense, be they civil or criminal.

10.04 Governing Law. The terms and conditions of this Agreement, as well as all disputes arising under or relating to this Agreement, shall be governed by the laws of England and Wales (United Kingdom), specifically excluding its choice-of-law principles. Notwithstanding the above, the Parties agree that Section 4.02(d) is not governed by the laws of England and Wales, but, rather, by U.S. Patent Law.

10.05 Arbitration. The Parties shall work closely to resolve any disagreements in regard to their activities under this Agreement. If an issue is unable to be resolved, the Principal Investigators shall discuss, if possible, in a face-to-face meeting, and attempt resolution. If resolution is not achieved, any such dispute arising out of this Agreement shall be finally settled by arbitration administered by the Arbitration Institute of the Stockholm Chamber of Commerce (SCC) located in Sweden. There shall be a single neutral arbitrator appointed in accordance with the International Arbitration Rules. The arbitration proceedings shall be conducted in the English language, and the decision of the arbitrator shall be rendered in writing in English.

10.06 Headings. The headings of articles and sections used in this document are for convenience of reference only.

10.07 Independent Contractors. It is mutually understood and agreed that the relationship between the Parties is that of independent contractors. Neither Party is the agent, employee, or servant of the other. Except as specifically set forth herein, neither Party shall have nor exercise any control or direction over the methods by which the other Party performs work or obligations under this Agreement. Further, nothing in this Agreement is intended to create any partnership, joint venture, lease or equity relationship, expressly or by implication, between the Parties.

10.08 Limitation of Rights Created. This Agreement is personal to the Parties and shall be binding on and inure to the sole benefit of the Parties and their permitted successors and assigns and shall not be construed as conferring any rights to any third party. Specifically, no interests are intended to be created for any customer, patient, research subjects, or other persons (or their relatives, heirs, dependents, or personal representatives).

10.09 No Assignment. Neither Party may assign its rights hereunder to any third party without the prior written consent of the other Party; provided, that a Party may assign its rights without the prior written consent of the other Party to any affiliate or other entity that controls, is controlled by or is under common control with such Party. Any purported assignment in violation of this clause is void. Such written consent, if given, shall not in any manner relieve the assignor from liability for the performance of this Agreement by its assignee.

10.10 Notices. All notices and other business communications between the Parties related to this Agreement shall be in writing, sent by certified mail, addressed as follows:

To MAYO: Mayo Clinic Arizona
13400 East Shea Boulevard,
Scottsdale, AZ 85259
Attn:
Phone:

Email:

To FNUSA-ICRC: St. Anne's University Hospital in Brno
International Clinical Research Center
Pekarska 53, 656 91 Brno, Czech Republic
Attn:
Phone:
Email:

Notices sent by certified mail shall be deemed delivered on the tenth day following the date of mailing. Either Party may change its address or facsimile number by giving written notice in compliance with this section.

10.11 Severability. In the event any provision of this Agreement is held to be invalid or unenforceable, the remainder of this Agreement shall remain in full force and effect as if the invalid or unenforceable provision had never been a part of the Agreement.

10.12 Waiver. The failure of either Party to complain of any default by the other Party or to enforce any of such Party's rights, no matter how long such failure may continue, will not constitute a waiver of the Party's rights under this Agreement. The waiver by either Party of any breach of any provision of this Agreement shall not be construed as a waiver of any subsequent breach of the same or any other provision. No part of this Agreement may be waived except by the further written agreement of the Parties.

10.13 Foreign Corrupt Practices. In performing their obligations under this Agreement, both Parties shall obey anti-bribery and anti-corruption provisions or regulations such as the U.S. Foreign Corrupt Practices Act ("FCPA") (15 USC §§ 78dd-1, et seq.) or the equivalent legislation that are applicable to that Party. The Parties will cooperate for the purpose of ensuring that each of them is able to comply with its respective obligations under applicable bribery legislation.

10.14 Translation. In the event that a translation of this Agreement or a Project Plan is prepared and signed by the Parties, the English language version shall be the official version and shall govern if there is a conflict between the English language version and the translation.

10.15 Counterparts. This Agreement is written in two identical originals in English and in two identical copies in Czech, one of each language version for each Party, and may be executed in any number of counterparts which, when taken together, will constitute an original.

10.16 Entire Agreement. This Agreement constitutes the final, complete and exclusive agreement between the Parties with respect to its subject matter and supersedes all past and

contemporaneous agreements, promises, and understandings, whether oral or written, between the Parties. Specifically this Agreement supersedes the Letter of Intent dated April 5, 2016 and the Research Collaboration Agreement, effective September 23, 2011, and its amendments.

The Parties have caused this Agreement to be duly signed by the undersigned authorized representatives. The Parties, intending to be bound, hereby execute this Agreement.

AGREED AND ACCEPTED BY:

MAYO:

FNUSA-ICRC:

By _____
Virginia M. Bruce
Director, Legal Contract Admin.

By _____
Dr. Martin Pavlik, PhD, DESA, EDIC

Date: 3/17/2017

Date: 3/19/2017

By _____
Yonas E. Geda, M.D., MSc
Mayo Principal Investigator

By _____
Gorazd Bernard Stokin, M.D., Ph.D.
ICRC Principal Investigator

Date: 3/17/2017

Date: 3/19/2017



EXHIBIT A
2017 Deliverables and Other Support Services

Exhibit A - 2017 Deliverables and Other Support Services

Project plan / individual collaborations	Budget in USD	Deliverables and Other Support Services									
		Regular teleconferences Weekly or bi-weekly	Visit of Mayo mentor or designee to Brno	Visit of ICRC staff to Mayo Clinic	Mentoring during preparation of ICRC publications	Mentoring during preparation of ICRC grant applications	Joint experiments	Exchange of data for research	Joint publications (properly dedicated)	Poster/ abstract/ presentation of ICRC staff	Other activities - sharing of additional data/information and mentoring - consistent with terms of the Project Plans, the Agreement and consistent with relevant laws, regulations and national legislation
		Yes	1	1	1	1	0	Yes	2	2	1) At least ONE joint publication based on data from Mayo Clinic Study of Aging; 2) Analysis of cognitive and behavioral data in collaboration with CardioVize
		Yes	1	1	2	1	1	Yes	2	3	2 analyses of a new method of brain stimulation
		Yes	0	1	1	1	0	Yes	1	1	Analysis of stroke epidemiology in Brno utilizing the database of stroke in Brno
		Yes	1	1	2	1	1	Yes	1	2	Joint testing of novel devices for heart arrhythmia developed by Mayo
		Yes	1	1	1	1	0	Yes	1	2	Introduction of the successor to Dr. Sochor to leading researchers
		Yes	0	1	1	1	1	Yes	0	1	Development of a new generation of Holters, BME ICRC as core facility
Total	932 186	Yes	4	6	9	6	3	6	7	11	
Note		Every team agrees to have regular teleconferences with their Mayo mentor	Every Mayo mentor with budget over USD agrees to come to Brno at least once or will send a designee at least once a year	Every ICRC team agrees to send at least 1 person to Mayo for at least a week to observe project, train in methods and conduct experiments. Responsibility for scheduling visit and traveling to Mayo is with ICRC teams, not with the Mayo mentor.	Every Mayo mentor will advise ICRC team on at least 1 ICRC manuscript. Responsibility for drafting, completing and submitting publication is with ICRC teams, not with the Mayo mentor.	Every Mayo mentor will advise ICRC team on at least 1 ICRC application for international grant. Responsibility for completion and submission of application is with the ICRC team, not with the Mayo mentor.	Joint experiments can be conducted in Brno or in the USA during visits of ICRC staff members.	All mentors and ICRC teams agree to exchange data for research conducted under this Agreement.			Finalized March 17, 2017

EXHIBIT B
STRUCTURE OF PROGRESS REPORT

Progress Report shall include (binding structure):

- 1) Financial update
- 2) Description of performed activities
- 3) Achieved milestones and research outcomes
- 4) Contribution of the parties in their achievement such as:
 - Facilities/equipment used
 - Mentorship and know-how provided
 - Qualified research personnel participated
 - Other staff participated
 - Finance provided
- 5) Division of research outcomes
- 6) Planning and forecast

NOTE: The Deliverables and other support services mutually agreed upon by the Parties are described in **Exhibit A**.

The Interim Progress Report is due by September 30, 2017. The Final Progress Report shall be submitted within thirty (30) days prior to 2017 year-end.

EXHIBIT C
PROJECT PLAN TEMPLATE

This Project Plan, effective the ___ day of _____, 20__ (“Effective Date”), is by and between **Mayo Clinic Arizona**, an Arizona charitable corporation, located at 13400 East Shea Boulevard, Scottsdale, AZ 85259 and its affiliates, (collectively "**Mayo**") and **International Clinical Research Centre of St. Anne’s University Hospital in Brno (Fakultni nemocnice u svate Anny v Brne)**, having a principal place of business at Pekarska 53, 65691 , Brno, Czech Republic ("**FNUSA-ICRC**"), and is issued pursuant to the 2017 Research Collaboration Agreement, effective _____ 2017 ("**Agreement**").

For good and valuable consideration the receipt and sufficiency of which the Parties agree, the Parties hereby agree as follows, effective as of the Effective Date.

1. Governance: The terms and conditions of the Agreement, including all capitalized terms not defined in this Project Plan, are incorporated herein by reference in their entirety. In the event of a conflict between the terms and conditions of the Agreement and the terms and conditions of this Project Plan, this Project Plan shall govern provided this Project Plan expressly states the conflict and such governance. Anything contained in the Protocol (**Attachment B**) which is in conflict with this Project Plan or the Agreement, is superseded by this Project Plan and/or the Agreement. The Agreement and the Project Plan, including its Attachments, are the entire Agreement of the Parties with respect to the research project described in this Project Plan ("**Project**").

PROJECT TITLE:

MAYO RESPONSIBLE INVESTIGATOR:

PHONE:

EMAIL:

FNUSA-ICRC RESPONSIBLE INVESTIGATOR:

PHONE:

EMAIL:

PROJECT START DATE:

PROJECT END DATE:

unless terminated earlier by either Party, consistent with Article 9 of the Agreement.

IRB / IACUC #:

TOTAL MAYO BUDGET FOR PROJECT: [**ATTACHMENT A**] which may be amended (e.g. due to

change in scope) upon mutual agreement of the Parties.

COMMERCIALIZATION OF ANY INVENTIONS OR OTHER INTELLECTUAL PROPERTY WILL BE addressed in a separate agreement.

MAYO budget administrator:

NAME:

PHONE:

EMAIL:

DESCRIPTION OF THE RESEARCH PROJECT: [**Attachment B**] which may be amended from time to time upon mutual agreement of the Parties.

(Must contain well defined goals, specific aims, timelines, and roles.)

Expected 2017 Deliverables and Other Support Services [**Exhibit A** of Agreement]:

Accepted and agreed to by:

Mayo Principal Investigator

FNUSA-ICRC Principal Investigator

By _____
Name: Dr. Yonas E. Geda

By _____
Name: Dr. Gorazd B. Stokin

Date: _____

Date: _____

Mayo Responsible Investigator

FNUSA-ICRC Responsible Investigator

By _____
Name:

By _____
Name:

Date: _____

Date: _____



ATTACHMENT A
PROJECT PLAN BUDGET

ATTACHMENT B
RESEARCH PROJECT DESCRIPTION/PROTOCOL