This **Agreement** is made by and between:

(1) **European Clinical Research Infrastructure Network (ECRIN)** with the legal form of a European Research Infrastructure Consortium (ERIC), with is statutory seat located at 7 rue Watt, 75013 Paris, France, represented by Pr. Jacques Demotes, Director General (hereinafter referred to as "**ECRIN-ERIC**");

and

(2) **Masarykova univerzita**, Reg. No. *00216224*, a public univerity incorporated under the laws of the Czech Republic, having its registered office in *Žerotínovo náměstí 9, 601 77, Brno, Czech Republic*,

Represented by prof. MUDr. Jiri Mayer, CSc. the dean of the**Faculty of Medicine**, located in Kamenice 5, 602 00, Brno (the "**Institution**").

Each of ECRIN-ERIC and the Institution is hereinafter referred to as a "**Party**" and jointly as the "**Parties**".

BACKGROUND

ECRIN-ERIC is a Pan-European distributed clinical research infrastructure with the objective to provide, on a non-economic basis, advice and services to multinational clinical studies, in any medical field and for any category of clinical research, observing high scientific, ethical and quality standards.

ECRIN-ERIC was created on 8 December 2013 (**Decision 2013/713/EU- Official Journal of the European Union-5/12/2013**) and is governed under the European Research Infrastructure Consortium status, incorporated under the provisions of Regulation (EC) N° 723/2009 of 25 June 2009.

As specified in the ECRIN-ERIC Statutes (the "Statutes") the ECRIN-ERIC collaborator hosted in national clinical research hubs and coordinating centres (the "European Correspondent") may be an employee of the Institution seconded to ECRIN-ERIC and acting under its management authority. The selection of such a correspondent shall be based on guidelines set out in the Statutes and Internal Rules of Procedure of ECRIN-ERIC, and shall necessitate the agreement of both ECRIN-ERIC and the Member, Observer or Partner.

In accordance with the aforementioned provisions, ECRIN-ERIC and the Institution have agreed that the Institution shall second an employee to ECRIN-ERIC in order to act as relay to the national clinical research network and hub for the various ECRIN-ERIC activities.

1. SECONDMENT

1.1 The Institution shall second an employee (the "**Secondee**") to ECRIN-ERIC in accordance with the terms set out in this Agreement. The Secondee is identified in Schedule 1.

1.2 The secondment of the Secondee shall be for a renewable period of 3 (three) years commencing on 1st of January 2015 and terminating on 31st of December 2017.

1.3 During the secondment, the Secondee shall be located at University campus of Masaryk university, Kamenice 5, Brno Bohunice, 625 00.

1.4 The main duties to be carried out by the Secondee during the secondment are outlined in the Job description added to Schedule 2.

1.5 The Job Description shall be jointly agreed between the Institution and the ECRIN-ERIC Director General as specified in the Annex III of the Statutes.

1.6 The Secondee shall remain an employee of the Institution and shall not be deemed to be an employee of ECRIN-ERIC by virtue of the secondment. If the Secondee ceases to be employed by the Institution for any reason, the secondment will come to an end automatically.

1.7 During the period of secondment, ECRIN-ERIC will exercise day-to-day supervision and control over the Secondee. The Institution shall require the Secondee to carry out all reasonable instructions of ECRIN-ERIC.

1.8 During the period of secondment, the Secondee shall comply with all applicable statutes, regulations, policies and procedures of ECRIN-ERIC.

1.9 The Institution shall indemnify ECRIN-ERIC from or against any cost, expense, damage or liability arising out of any negligent acts or omissions or improper performance by the Secondee.

2. PAYMENT ARRANGEMENTS

2.1 The Secondee shall be on the payroll of the Institution as per the conditions of *her* employment with the Institution. The Institution will thus pay salary to the Secondee.

2.2 In accordance with the conditions laid down in Annex III of the ECRIN-ERIC Statutes, the cost of salary :

- shall be part of the in kind contribution of the Czech Republic;

2.3 The Institution (and the Secondee, if applicable) shall be responsible for all income tax liability, social security contributions, pensions, insurances and any other charges in respect of the Secondee.

2.4 If the Secondee is required to travel abroad in the course of the Services, the Institution shall be responsible for any necessary insurances, inoculations and immigration requirements.

2.5 All taxes, charges and fees of whatever nature which may be imposed by any authority on the amounts paid to the Institution under this Agreement shall be paid and borne by the Institution.

2.6 In the event of early termination of this Agreement, the Institution shall promptly account for all costs and expenses for the secondment under this Agreement up to the time of termination.

3. OWNERSHIP OF RESULTS

3.1 "**Results**" means the results, including information, whether or not they can be protected, arising from the Secondee's Services or other work during the period of secondment, as well as copyrights or rights pertaining to such results following applications for, or the issue of patents, designs, plant varieties, supplementary protection certificates or similar forms of

protection.

3.2 All the Results shall, automatically and immediately upon their creation, be the exclusive property of ECRIN-ERIC with full and free right of disposal, including for the avoidance of doubt the right to make changes, developments, transfers and licenses and make publications in current and future media. ECRIN-ERIC will thus have the exclusive right to use the Results for any purpose, including commercial use, and to protect the Results in its own name.

3.3 Upon completion or termination of the secondment, the Secondee shall immediately deliver to ECRIN-ERIC all correspondence, documents, specifications, papers and other property containing Results or which have been provided to the Secondee from ECRIN-ERIC for the secondment which may be in *her* possession or under *her* control, all of which shall rightfully belong to and remain the property of ECRIN-ERIC.

4. CONFIDENTIALITY

4.1 "**Confidential Information**" means any scientific, technical, financial, commercial or other information of any nature and in any form provided by either Party to the other Party, prior to or after the Effective Date, in connection with the Agreement and which information is designated as proprietary and confidential by an appropriate stamp, legend or other notice in writing or which otherwise is of a confidential character.

4.2 If either Party (the "**Receiving Party**") receives Confidential Information from the other Party (the "**Disclosing Party**"), the Receiving Party shall

(a) keep the Confidential Information strictly confidential;

(b) make available the Confidential Information only to those of its officers and employees who need to have access to it for the purpose of this Agreement;

(c) not pass the Confidential Information to any third party, even under a confidentiality agreement, without the prior written consent of the Disclosing Party (however, ECRIN-ERIC shall be entitled to disclose Confidential Information to consultants and persons temporarily assigned to ECRIN-ERIC that meet requirement 4.2.(b) above); and

(d) use the Confidential Information only for purposes of this Agreement.

4.3 The foregoing obligations shall not apply to any portion of Confidential Information which the Receiving Party can establish,

(a) was known to the Receiving Party prior to its receipt from the Disclosing Party; or

(b) at the time of disclosure was, or thereafter becomes through no fault of the Receiving Party, generally available to the public by publication or otherwise; or

(c) was received without any obligation of secrecy from a third party which, to the best knowledge of the Receiving Party, has the right to disclose the same; or

(d) was independently developed by the Receiving Party without access or reference to the Confidential Information of the Disclosing Party; or

(e) was disclosed in order to comply with applicable laws or regulations or with a court or administrative order.

4.4 The Receiving Party shall impose the same obligations as set out above on all of its officers and employees having access to the Confidential Information, both during and following their retention by the Receiving Party. Notwithstanding the foregoing, each Receiving Party shall be liable for any breach of this Agreement by its officers and employees.

5. TERM AND TERMINATION

5.1 This Agreement will come into effect when it has been signed by both Parties and shall remain in effect until the end of the period of secondment under Section 1.2 above, at which date it shall automatically terminate unless prolonged by the Parties in writing.

5.2 Either Party may terminate this Agreement with immediate effect by notice in writing to the other Party if the other Party is in material breach of any of its obligations hereunder and such breach is not remedied within 30 days after written notice from the non-breaching Party.

Without limiting the generality of the foregoing, the following shall be considered a material breach by the Institution:

(a) The Secondee fails or neglects efficiently and diligently to carry out the reasonable instructions of ECRIN-ERIC.

(a) The Secondee is guilty of any serious or gross misconduct.

5.3 It is understood by ECRIN-ERIC and the Institution that upon early termination, for any reason whatsoever, or expiration of the Agreement, the provisions hereunder relating to confidentiality and to communications and publications, intellectual property and applicable law and dispute resolution and any other rights and obligations which by their nature are intended to survive the termination or expiration of this Agreement shall remain in force.

5.4 Upon early termination, for any reason whatsoever, or expiration of the Agreement, each of ECRIN-ERIC and the Institution having received tangible material or facilities that are still in its possession shall return it or destroy it, upon instruction of the owning Party and shall certify such destruction in writing.

6. MISCELLANEOUS

6.1 Independent Contractors

6.1.1 The relationship established by this Agreement constitutes a contract for the Institution to supply the services of the Secondee under the terms set out in this Agreement to ECRIN-ERIC and neither constitutes a partnership between the Institution and ECRIN-ERIC nor renders the Secondee an employee of ECRIN-ERIC.

6.2 Entire Agreement

6.2.1 This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements, whether written or oral, with respect to the subject matter of the Agreement.

6.3 Invalidity of a clause

6.3.1 If one or more provisions of the Agreement are considered to be invalid or held to be invalid pursuant to a treaty, a law or a regulation, or following a final and binding decision by a competent court, the other provisions will remain in full force and effect. The Parties will then

make the necessary amendments according, to the extent possible, to the common intentions existing at the time of signature of the Agreement.

6.4 Force majeure

6.4.1 Each Party will be excused for failure to fulfil in all or in part its obligations under this Framework Agreement and may not be held responsible or liable for damages with regard to the other Parties, if the non-performance is due to a force majeure event, or such as the disruption of its services as a result in particular of resignation or any other event beyond its control. The Party which finds it impossible to perform its contractual obligations due to a force majeure event shall immediately notify the other Parties in writing. If this impossibility or delay in performance due to a force majeure event continues after a period of three (3) months as from such notification, the latter Parties may terminate in all or in part this Agreement ipso jure by written notice sent to the other Party.

6.5 Amendments

6.5.1 Amendments to or changes of this Agreement shall, in order to be valid, be made in writing and signed by authorized representatives of each of the Parties and shall be clearly stated as amendments to or changes of this Agreement.

6.6 Assignment

6.6.1 Except with the prior written consent of ECRIN-ERIC, the Institution shall not assign or otherwise transfer partially or totally any of its rights or obligations under the Agreement.

6.7 Use of images or logos of the other Party

6.7.1 Without the prior written consent of the other Party, which shall not be unreasonably withheld, neither Party shall use or make reference to any images or logos of the other Party.

6.8 Publicity

6.8.1 Without the prior written consent of ECRIN-ERIC, the Institution shall not publicise the Agreement or any part thereof unless it is obliged to do so to comply with applicable laws or regulations or with a court or administrative order.

6.8.2 The Institution shall not use the fact that it is cooperation with ECRIN-ERIC in any related publicity or advertisement without the prior written consent of ECRIN-ERIC. The Institution shall also not use the name, logo or emblem of ECRIN-ERIC in any manner for advertising or other promotional purposes without written consent of an authorized staff member of ECRIN-ERIC.

6.9 Notices

6.9.1 All notices, requests, consents, claims, demands, waivers and other communications hereunder (the "Notice") shall be in writing and addressed to the respective Party's contact person set out in this Agreement (or to such other address that may be designated by the receiving party from time to time in accordance with this Section 6.8).

6.9.2 All Notices shall be delivered by personal delivery, nationally recognized overnight courier (with all fees pre-paid), certified or registered mail (in each case, postage prepaid), facsimile or e-mail. Except as otherwise provided in this Agreement, a Notice is effective only (a) upon

receipt by the receiving party, and (b) if the party giving the Notice has complied with the requirements of this Section 6.8.

7. SETTLEMENT OF DISPUTES AND GOVERNING LAW

7.1 Any dispute, controversy or claim arising out of or in connection with this Agreement, or the breach, termination or invalidity thereof, shall be settled amicably. Any dispute between the Parties arising from the interpretation or application of the Framework Agreement, which cannot be settled amicably, will be referred to the competent French court.

7.1 Given its balanced representation between ECRIN-ERIC Partners and the ECRIN-ERIC Assembly of Members, the ECRIN-ERIC Steering Committee (supported when relevant by a panel of external experts) is in charge of streamlining the negotiation and proposing appropriate solutions.

7.2 This Agreement shall be governed by and construed and enforced in accordance with the substantive laws of France without giving effect to any choice of law rules and principles thereof.

IN WITNESS WHEREOF, this Agreement has been executed in two originals, of which the Parties have received one each.

ECRIN-ERIC	**Masarykova univerzita**
2-10-2015	18-09-2015
[redacted]	
Prof. Jacques DEMOTES	prof. MUDr. Jiri Mayer, CSc.
Director General	Dean of the Faculty of Medicine

SCHEDULE 1

Acknowledgement by the Secondee

I have read the above Agreement between ECRIN-ERIC and the Institution and agree to undertake the secondment in accordance with the terms and conditions of the Agreement. I agree to adhere to and be bound by the terms and conditions concerning Ownership of Results (Section 3) and Confidentiality (Section 4) of the Agreement as if I myself was a party to the Agreement. I hereby assign to ECRIN-ERIC full and unlimited ownership to any and all Results (as defined in the Agreement) as may be proprietary to myself following the work performed as set out in Section 3 of the Agreement. I further undertake to sign any such additional document as may be reasonably requested by ECRIN-ERIC for the application of patent protection or other intellectual property protection and any other related documents and to further confirm the assignment herein. To the best of my knowledge, any and all Results I create will not infringe the rights of any third party. Any consideration to which I may be entitled under mandatory law for the aforementioned assignment shall be subject to an agreement between the Institution and myself, and ECRIN-ERIC shall not be obliged to pay any consideration whatsoever for the assignment set out herein.

2. 10. 2015

Date

[redacted]

Signature

[redacted]

Name (in block letters)

SCHEDULE 2

Job description

The ECRIN-ERIC European Correspondent for Czech Republic plays a pivotal role in the coordination of the activities within the ECRIN-ERIC, strengthening the interaction of ECRIN-ERIC and the national network in order to facilitate and support participation in European multinational collaborations and within the national network.

The main duties of the ECRIN-ERIC European Correspondent will include the following:

- Providing the key contact point in Czech Republicfor ECRIN-ERIC and the network of European Correspondents in other ECRIN countries
- Participating, as part of the ECRIN-ERIC Management Office, in the development and maintenance of ECRIN Quality Assurance systems, and regulatory knowledge facilitating the activity of the national representatives in the ECRIN activities
- Providing advice and support to national investigators and sponsors wishing to develop European multinational studies through ECRIN, providing the key communication link with other ECRIN partners through the network of European Correspondents
- Providing support to foreign investigators and sponsors wishing to undertake clinical research studies in Czech Republic, ensuring that information relating to foreign studies are appropriately disseminated to national and international researchers
- Provide leadership for ECRIN- adopted clinical projects carried out in Czech Republicand participating in the management of multinational projects within the national network as well as in services provided by ECRIN as appropriate
- Ensure that specific pieces of project work under the ECRIN initiative are introduced and completed successfully, in line with planned timelines and contribute to the delivery of these projects
- Compiling and distributing regular communications about the progress of ECRIN projects and details of new initiatives to national network
- Ensure that ECRIN-ERIC activities and mission are communicated efficiently to other stakeholders in Czech Republic. Particularly the information should be timely distributed within the national partners ensuring that they have the opportunity to contribute to relevant initiatives on time
- Be required to work closely with other members of national network, research stakeholders and Czech Republic regulatory authorities and any other relevant professional bodies/organisations. In addition, excellent external links will be required with ECRIN team (core group and other European correspondents in other countries)
- Maintain within national network in Czech Republic a thorough understanding of the current clinical research regulatory environment
- Develop and maintain a good appreciation of the regulatory environment in other EU members states, particularly in relation to the interpretation and implementation of EU clinical trial legislation
- Assist the country specific Training and Education Team in identifying training needs and requirements of local network staff and clinical trials unit staff in relation to multinational clinical trials and regulatory and governance issues, and contribute to the development and delivery of training programmes as appropriate
- Undertake any ad hoc initiatives as required by the ECRIN-ERIC Management office

Additional special conditions

- University degree in Health or Life Science.
- Extensive multinational clinical research experience.
- Management experience required
- Strong knowledge of the clinical development process and of GCP and local and international regulatory requirements.
- Desirable complementary knowledge of experimental design, statistics and data management.
- Excellent organisational skills demonstrated by a proven ability to manage a range of different projects simultaneously. Ability to interact positively with a wide range of professionals, including senior staff, across a range of organisations including clinical research staff and regulatory authorities. Ability to participate constructively and enthusiastically in meetings and decision making processes and to use own initiative, as appropriate
- Strong oral and written communication skills
- Excellent written and spoken English (working language)
- Computer and software knowledge