## DATA TRANSFER AGREEMENT

The colour-shaded blocks explain why we consider the respective rules necessary.

## [Date]

ÚPT AVČR, v. v. i., ("Provider") agrees to provide the Recipient Investigator and the Recipient Institution identified below (collectively referred to herein as "Recipient") with data developed by the Provider's Magnetic Resonance Core Facility under the following terms and conditions:

The purpose of these conditions is to promote interaction with a wide range of social and economic activities, including, as appropriate, business, industry and public services, in order to maximise the return on investment in the research infrastructure and to drive innovation, competitiveness and efficiency in terms of use of the scarce resources, within the legal framework of the Czech law and general principles of research ethics.

1. The data to be provided to the Recipient are MRI data including descriptions of measurement and data analysis results ("Data"). The Data newly created by the Provider for the Recipient constitute a Provider's intangible asset that by itself is not intellectual property; intellectual property issues are not the subject of this Agreement. The proprietary rights to Data produced with no public support will be transferred from the Provider to the Recipient immediately upon the Recipient's acceptance of this Agreement, otherwise the Provider will retain the rights. The designated Data **owner** ("Licensor") agrees to grant a limited Data use license to the other party ("Licensee") as specified below. Except as provided in this Agreement, no other licenses or rights are provided to the Licensee.

The subject of the delivery is the **MR data** created by the Provider's employees in its laboratories for the benefit of the Recipient and the data derived from them, as well as descriptions enabling the reproduction of the experiment, i.e. **metadata**. The metadata primarily includes the information items that are generated automatically by the instrument and describe the measurement method applied, the coding of the binary image data and its relationship to space, time and other independently variable measurement parameters. These metadata, denoted as "**intrinsic metadata**", contains information technically indispensable for any loading, postprocessing or visualisation of the experimental results. MR data and intrinsic metadata can be delivered in the proprietary native format of the scanner, or converted (typically with some information loss) to an open format. Additional information ("**extrinsic metadata**") will be provided as needed for reproduction or interpretation of the experiment.

The **MR data** itself and the "**intrinsic metadata**" are intangible assets that aren't intellectual property (IP) – as an objective representation of reality the data per se isn't the result of creative human mental activity; on the contrary, data objectivity excludes such dependence. Therefore, in accordance with the spirit of the Civil Code (Act 89/2012 Coll., §979, §2631-2635, §2586, §2599), we treat data similarly as if they were tangible assets created by the institution (Provider) as part of a service. Hence at the time of creation the Data is considered

to be a property of the Provider; under certain conditions the Provider agrees to transfer certain rights to the Recipient so that the Recipient may use them as intended and declared in advance. In some cases, even intrinsic metadata may convey some traces of IP of the Recipient as well as of the Provider in that the MR method choice and parameters reflect the opinions on what measurements may answer a specific question; though machine-generated being a purely technical necessity, such contextual content may be an unintended subject of intellectual property.

**Intellectual-property content**, marginally present in the intrinsic metadata, is more likely in **extrinsic metadata** because it is likely to provide contextual information connecting the data to hypotheses, related research, animal experiment design, experiment division into studies, etc., which all are intellectual property of the Recipient or the Provider or both. IP issues are not the subject of this Agreement. Instead, issues of background as well as newly created intellectual property are dealt with by the superior institutional standard "<u>General Terms and Conditions for contractual research</u>".

Both this "Data Transfer Agreement" and the "General Terms and Conditions for Contractual Research" are understood as the **default wording** of the agreements, which has been preapproved by the Provider. If some conditions do not suit the Recipient's needs, a modification may be discussed with the Provider, but then administrative delay may occur.

The separation of Data from the intellectual property has some clarifying **legal consequences**. For instance, it makes it clear that the Provider cannot claim co-authorship or other participation on the Recipient's IP solely on the grounds of delivering experimental data. On the other hand, if the Provider adds some relevant IP, the Recipient would be expected to recognise this contribution in due manner.

In most cases, the service and the Data will be provided at a subsidized price, and therefore under certain **conditions**. These have been chosen such that the legitimate interests of both the Recipient and the Provider are satisfied as much as possible. Such a practice is in compliance with guidelines for research infrastructures (such as the "European charter for access to research infrastructures") and the Czech law. Specifically, the default rules for a service resulting in intangible property are proposed by the Civil Code (Act 89/2012 Coll., §2631-2635): the transfer of a product of intangible work is considered completed if the Recipient receives it in the form and with the rights that enable the Recipient to use the Data for the specified purpose.

Without setting any restrictions, the Provider would be in risk of providing illegitimate public support, cross-funding or damaging free market, unless the service were provided at a price not lower than the full cost of the service. On the other hand, if the **full-cost price** has been paid, the Recipient may get "full ownership" of the Data and exclude others completely from using it. Even in this case the contract proposes a limited license for the Provider, but section 2 shows that this requirement is not absolute. Some stipulations, most notably those of sections 3 (legality and ethics) and 5 (acknowledgments), and the conditions of the "General Terms and Conditions for Contractual Research" remain in effect despite the reversed ownership.

2. The Recipient may not use the Data for the **purpose** of diagnosis or treatment of humans. The Provider may use the Data for service quality assessment, validation of standard operating procedures, and experimental method development, unless the Recipient who is the Licensor explicitly restricted such use in advance.

This section defines the usability of the data on the part of the Recipient and the Supplier.

Neither the device nor the methods we use in the infrastructure have been approved for medical use, therefore we contractually exclude such use by the Recipient.

If the data is provided under the conditions of public support, we ask that the value that legitimizes such support is the usability of the Data for the qualitative progress of the infrastructure – for the assessment of data quality, verification of standard procedures, comparison of methods, economic evaluation of methods, etc. Such use, together with the rule on non-distribution in section 4 in no way limits the Recipient's rights for use in their own research.

3. Any Data use will be in **compliance** with Czech laws and regulations, and research ethics. Any party may terminate the Agreement upon written notice in the event of rule violation by the other party. Upon such termination, the offending party shall promptly destroy all Data in its possession and shall take corrective action to protect the other party's legitimate interests.

This stipulation is intended to protect the good name of the infrastructure and promote the intention to direct public support in a socially acceptable direction. If the Recipient uses the data in a way that is illegal or unethical, they violate this Agreement and our permission to use the Data would be revoked. Even if such an incident happens inadvertently, the Recipient should refrain from further use of the Data and should take measures that will prevent moral or economic damage to the infrastructure (e.g. by withdrawing the article, revoking a notice, etc.).

4. Data will not be transferred, distributed, disclosed or released to any **third party** unless prior written permission has been obtained from the other party (except in fulfilment of obligations imposed on recipients of public subsidies). Without limiting the foregoing, the Recipient acknowledges and agrees that the Data may not be used in research that is subject to consulting, a first option right to negotiate a license or other licensing obligations to another party without prior express written consent by the Provider. Both parties agree to comply with all Czech export control laws, rules and regulations with respect to the use and any permitted distribution of the Data, and will similarly oblige their affiliates, agents and subcontractors.

The purpose of this point is to strengthen the protection of the interests of the data owner (the Licensor).

If the Licensor is the Provider, this rule is intended to prevent the public research institution of the Recipient, which received a publicly supported service under preferential terms, from reselling the Data at a commercial price to private entities that would not have received the preferential financial terms directly from the Provider, or to entities subject to export embargo. It also prevents the Recipient from possibly drawing the Provider into their own business contracts as a subcontractor, without the Provider having the possibility to influence the content of the contracts. Nothing prevents the Provider from pre-authorizing dissemination of the Data on a non-discriminatory basis if it is clear that the circumstances specified in point 9 will not occur.

If the Licensor is the Recipient, it is a Recipient who has paid the full cost, and this rule increases their protection by not allowing the Provider, if it has been granted a license under point 2, to distribute the Data (even without the context of the original project) without prior assessment by the Recipient of whether such dissemination may damage their interests (for instance by leakage of intellectual property through the metadata context).

5. Either party agrees to provide the other party with any manuscript of a **publication** that contains experimental results obtained from the use of the Data at least seven days before its intended submission. The Recipient will acknowledge the Provider as the source of the Data, and the relevant Provider's grants for co-funding unless the Recipient has paid the full cost.

With this condition, we strive primarily for the truthfulness and completeness of the published data regarding MR measurements and the derived results. Our users are usually biochemists or medical researchers who have only limited knowledge of MR, and are not always able to collect the minimum set of parameters that describe the MR measurement sufficiently for their reproducibility and interpretation. The manuscript review should help the readers and perhaps shorten the editorial process and increase the publication success rate. We do not assert the right to prevent publication, for example, due to differences of opinion, nor is it a matter of pressure to acknowledge co-authorship.

At the same time, it is a milestone at which we can check the correctness of the acknowledgments to our grants, which provided public support for the creation of the publication. This connection motivates our interest in proper presentation; we don't want to be associated with vaguely described and therefore unverifiable experiments, and we see the public support as a sufficient moral reason to push for this kind of quality.

6. The Licensee shall not **commercialize** any product that contains the Data without the prior written approval of the Licensor. The Recipient may file patent application(s) claiming inventions made by the Recipient through use of the Data but agrees to notify the Provider within sixty days

of any such filing. The Recipient also agrees to provide a copy of such application under appropriate terms of confidentiality to the Provider if requested.

This section expands article 4 in that not only the Data, but also their derivates (statistics, images, databases, etc.) will not be distributed commercially without respecting the Licensor's interests. This provision seeks

- to control conditions of providing public support, and
- keeping records of further use of the Data for the purposes of evaluation, determination of the strategy for further development of the infrastructure, etc.

We are obliged to ensure that public support is provided on a nondiscriminatory basis. It is also a gentle pressure to reflect the invested costs and intellectual property of both parties, and to reaching agreements promptly once such need is realized. This rule shouldn't be an obstacle to commercialization in principle.

In the event that the Provider who is in the position of the Licensor refuses to allow a certain type of commercialization, the Recipient can still override such a decision by refusing the public support and assuming the role of the Licensor.

In order to diminish the fear of abuse by the Provider, patenting is explicitly stated as an action that the Recipient can perform independently of the opinion of the Provider; in this case there is no reason for objections because patenting is a non-discriminatory form of disclosure. The possible sale of licenses to the patent can no longer be seen as the sale of a product containing Data, therefore the patent holder is not limited by this condition.

7. The Data provided are experimental in nature, and are provided without any **warranties**, express or implied, including without limitation warranties of merchantability and fitness for a particular use. The Provider provides no warranty that the use of the data will not infringe any patent or other proprietary right. The Provider shall not be liable for any indirect, incidental or consequential damages, even if advised of the possibility of such damages. In the event of discovering a Data defect, the Provider is obliged to inform the Recipient immediately and correct it, if the defect is repairable.

When processing data, we use the proprietary software of the scanner manufacturer, our own software and third-party software. It is beyond our power to guarantee that all third-party software products we use have proper licenses for all the modules they use, and therefore we disclaim this guarantee. It is also not always possible to guarantee correctness - every data is accompanied by noise and sometimes artifacts, an estimate of confidence intervals is not always available, and, therefore, especially when the measurement is non-standard and very experimental, we recommend the Recipient to rationally check all results and intermediate results.

8. Except to the extent prohibited by law, the Recipient assumes all **liability** for damages that may arise from the use of the Data. The Provider, its corporate affiliates and Boards of Governors, Directors, officers, staff, representatives and agents will not be liable to the Recipient for any damages, expenses (including without limitation legal expenses), losses, claims, demands, suit or other actions (collectively hereinafter "Claims") made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent such Claims are solely caused by gross negligence or wilful misconduct of the Provider.

Animal experiments can mean significant financial value. The price of a commercially acquired mouse can be anywhere from 20 to 5 000  $\in$  and with a moderate number of 100 animals in a study the batch can be worth up to 500 000  $\in$  Other costs are related to the preparation of the animal model and the subsequent evaluation of the results, as well as to other research activities before or after the MR experiment. We have found that insurance for biological and electromagnetic risks is unavailable in the Czech Republic. Risk factors (infection, confusion of animals or data, evaluation errors) are minimized by technical (overpressure, sanitation regulations, data backup) and organizational (training, restriction of entry of persons, cross-checks, coding of animals and studies, etc.) measures, but they can't be excluded completely. Due to the possible extent of the damage, we limit our liability and can offer the users videorecordings of certain space and operations should a crisis occur.

9. Each party shall refrain from such use of Data that could compromise the background **intellectual property** and the legitimate intellectual property interests of the other party stated at the time of signing the Data acquisition contract, unless prior written consent has been provided by the other party.

This point more explicitly formulates what was already formulated more generally, but more covertly, in section 4. While section 4 focused more on the conditions of direct Data misuse that would lead to providing illicit public support or damaging user's even undeclared interests by the Data, here the concern is on indirect leakage of intellectual property indirectly through the Data. While, for example, no individual MR image included in the Data constitutes intellectual property, image sets already take on the character of a database and can be considered as IP. Presumably, protection of the Recipient's biomedical research until its realization in a publication or a patent or a license sale is an ever-present, and hereby protected, interest of the Recipient. Less frequent, but not impossible, may be the interest of the Provider to prevent premature disclosure of the details of the applied MR methods, if both parties have agreed in advance to use newly developed techniques; data about it can be contained in the "intrinsic" metadata of the Data. Formulation of the interests to be protected before the service is done, as suggested by this section, should also facilitate proper briefing of the facility staff.

**Provider Institution:** [Name] **Recipient Investigator:** 

**Recipient Institution:** [Name]

## [Address]

[Address]

[Authorized Signature for Provider] [Printed Name and Title]

[Signature] [Printed Name and Title] [Authorized Signature for Recipient] [Printed Name and Title]