**PLAN ZARZĄDZANIA DANYMI**

DATA MANAGEMENT PLAN

**Formatka ze wskazówkami i przykładami do personalizacji we własnym projekcie**

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| 1. **Opis danych oraz pozyskiwanie lub ponowne wykorzystanie dostępnych danych** |
| **Sposób pozyskiwania i opracowywania nowych danych i/lub ponownego wykorzystania dostępnych danych** |
| **WSKAZÓWKA:** Tu należy wskazać metodę badawczą, dzięki której uzyskujemy dane/informacje. Np. powtarzalność eksperymentu, ankieta, obserwacja próby.  **PRZYKŁAD:** In this project, new data will be collected during the realization of the experiments designed in all tasks in a measurable and descriptive form, using methods described in the project description. Data will be obtained in digital form after analysis by the appropriate software tools. All research equipment will be calibrated before intended use as well as all of the methods will be validated to perform the experiments. In case of any doubts about the quality of the obtained results, any experiment will be repeated if necessary. No existing data will be reused during the project realization. |
| **Pozyskiwane lub opracowywane dane (np. rodzaj, format, ilość)** |
| **WSKAZÓWKA:** Tu należy doprecyzować w jaki sposób będą rejestrowane te dane oraz w jakiej ilości.  **PRZYKŁAD1:** Experimental research data will consist of procedure documentation, raw and analyzed/summarized data, collection  documentation, photocopy, and biological sample. After gathering, quantitative data will be converted to Stata, SPSS, R, Excel, CSV formats supported by the MMRI, which will perform archival format migration, metadata extraction, and validity checks. Deposit in these formats will also enable on-line analysis, search, data extraction, re-formatting, and other capabilities. Documentation will be deposited in PDF, or plain-text formats, to ensure long-term accessibility, along with sound, video, or images separate from the documentation deposited as JPEG files or uncompressed TIFF files. Labeled biological samples (tissue, cells, cellular extract, DNA, RNA, proteins) will be stored according to identification protocol in preserving conditions (+4, -20, -80C, liquid nitrogen).  **PRZYKŁAD2:** Data will be obtained as:  - images from different kinds of microscopes (fluorescence, light and confocal) as formats: .jpg, .tiff, .lsm, .czi.  - calculations of measuring of fluorescence intesities of images (Zen software) in .xls formats  - calculations of fluorescence/absorbance (readers) in .xls formats  - calculations of raw mRNA concentration and purity measurement results as .txt / .csv format  - calculations of raw qRT-PCR data as .eds and .xls format  - raw data from RNAseq as .fastq  - documentation and processed data will be converted to common formats: .doc, .xls, .ppt, .pdf, .mov.  Biological samples (derived in the project cell lines, constructs/vectors, fixed and stained organoid samples, RNA samples) will be accordingly labeled and stored. |
| 1. **Dokumentacja i jakość danych** |
| **Metadane i dokumenty (np. metodologia lub pozyskiwanie danych oraz sposób porządkowania danych) towarzyszące danym** |
| **WSKAZÓWKA:** Tu należy doprecyzować, jak te dane statystyczne będą dokumentowane. Czyli np. raport, analiza statystyczna w programie X itp.  **PRZYKŁAD1:** There will be three levels of data documentation: 1. Methodology and procedures description – for rigor and reproducibility of tasks, 2) raw data collection (digital or biological samples) for reusing data in the future, 3) final data preparation (quantitatively and qualitatively analyzed numerical and/or micrographic data) ready for publication in peer-reviewed journals and presentations of preliminary results at professional meetings. All these levels will be consistent with standard scientific practice as detailed below:  The project will create documentation detailing the sources, coding, and editing of all data, in sufficient detail to replicate them from original sources, and descriptive metadata for each dataset, including a title, author, description, descriptive keywords, and file descriptions. The project will also include bibliographic information.  **PRZYKŁAD2:** The data will be obtained from proposed experiments performed using methods described in project description. The detailed description of all procedures will be performed, in the name of the collected raw data the information about the type of experiments, time point of sample collection, type of performed analysis, name of authors will be described. These data will be analyzed using statistical programs indicating their significance and prepared for the publication in the peer-reviewed journals. The end point (final) data will be organized in the folders allowing metadata preparation having the title, author, keywords,  file description. |
| **Stosowane środki kontroli jakości danych** |
| **PRZYKŁAD1:** The rigorous experimental approaches will include all of the following: randomization, appropriate controls, biological  and technical replicates, sufficient sample size to achieve statistical significance, statistical analysis, blinded reviews. Additional specific considerations include sample size chosen to ensure adequate power to detect a pre-specified effect size, samples, or animals included/excluded from the analysis and inclusion/exclusion criteria and whether they were pre-established. When appropriate, biological covariates and batch and plate effects will be incorporated into experimental designs and controlled in the analysis by use of covariates or ANOVA based approaches.  **PRZYKŁAD2:** Only validated analytical method and calibrated equipment will be used to perform all of the experiments in the tasks. All necessary reference probes, blanks, negative and positive or other appropriate controls, randomization, blinded reviewers, will be run at each performed experiments. The size/number of probes/samples will allow proper statistical assessment. All devices will be calibrated and serviced according manufacturer recommendations. Using of standardized methodology and devices checkout ensure data reproducibility. |
| 1. **Przechowywanie i tworzenie kopii zapasowych podczas badań** |
| **Przechowywanie i tworzenie kopii zapasowych danych i metadanych podczas badań** |
| **WSKAZÓWKA:** Tu warto również określić częstotliwość wykonywania kopii zapasowych.  **PRZYKŁAD1:** Data and metadata will be stored and archived on an account configured with Cloud Storage, the backup of the data will be stored automatically on the Cloud managed by the IT Department at MMRI. A paper hardcopies will be created and stored. The access to Cloud Storage account is protected by our IT Department with an encryption and secured against the unauthorized attempt.  **PRZYKŁAD2:** Raw and processed data will be stored in electronic form at device memory where it has been acquired and also at mass storage devices, locked in a safe place, PI's business computer and Cloud Storage secured against the unauthorized attempt.  PI will be responsible for administering all of the created, processed and collected data during the research project realization. |
| **Sposób zapewnienia bezpieczeństwa danych oraz ochrony danych wrażliwych podczas badań** |
| **WSKAZÓWKA:** Przy back-up’ie warto dopisać że dane są zabezpieczane poprzez stosowanie rozwiązań organizacyjnych opisanych w Polityce Bezpieczeństwa Danych Osobowych.  **PRZYKŁAD1:** The MMRI complies with requirements for good computer use practices. MMRI has developed extensive technical  and administrative procedures to ensure consistent and systematic information security. “Good practice” requirements include system security (e.g., idle session timeouts; disabling of generic accounts; inhibiting password guessing), operational requirements (e.g., breach reporting; patching; password complexity; logging); and regular auditing and review. The security of sensitive data stored at separated account will be physically protected with a patent lock and digitally secured against any unauthorized attempt (hackers, viruses) with fully security compliant software’s implemented by our IT Department.  **PRZYKŁAD2:** The Institute has adopted and implemented an Information Security Policy, compliance with which guarantees activities in accordance with the law and the highest standards of information security, including personal data. The Institute has appointed a data protection officer. Only authorized persons who have been instructed to process personal data have access to it. Agreements on entrusting the processing of personal data or on co-management of data are concluded with partners and subcontractors, respectively.  Data backups are made in accordance with the adopted intra-organizational rules, which guarantee their reproducibility in case of an incident. The security of sensitive data stored at separated account will be physically protected with a lock and virtually secured against any unsecured attempt (hackers, viruses. e.c.t.) by the software implemented by the IT Department. |
| 1. **Wymogi prawne, kodeks postępowania** |
| **Sposób zapewnienia zgodności z przepisami dotyczącymi danych osobowych I bezpieczeństwa danych w przypadku przetwarzania danych osobowych** |
| **WSKAZÓWKA:** Tu należy odwołać się do RODO (z ang. GDPR): “Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation” oraz ponownie do Polityki Bezpieczeństwa Danych Osobowych.  **PRZYKŁAD1:** Personal data management will be performed in accordance with applicable regulations concerning personal data protection in Poland (Dz.U. 2018 poz. 1000).  **PRZYKŁAD2:** Personal data in the Project are processed only to the extent necessary - in accordance with Article 5(1)(c) of the GDPR. In any other cases, the data are anonymized. During the implementation of the Project, if at any given stage or within the framework of cooperation with a subcontractor, personal data are not necessary – they are subject to pseudonymization. All processing is carried out in accordance with the GDPR. The participants have the opportunity to read the information clause, and if the basis for processing personal data is the participant's consent, it is always voluntary and can be withdrawn at any time. |
| **Sposób zarządzania innymi kwestiami prawnymi, np. prawami własności intelektualnej lub własnością. Obowiązujące przepisy** |
| **PRZYKŁAD1:** Rules concerning the intellectual property at MMRI are listed in “Regulations on the use of intellectual work results”.  In brief, researchers produce creative results based on the contract. Creators' copyright is the authorship, signing with their name, immunity of the work, and first publication.  **PRZYKŁAD2:** At Mossakowski Medical Research Center intellectual property regulations are listed in "Regulations on the use of intellectual work results", available at: http://www.imdik.pan.pl/images/radanaukowa/regulamin\_korzystania\_z\_wynikow\_pracy\_intelektualnej\_zalaczniki.pdf.  Before the results will be published, every person who would help in any task to obtain the data during the project realization will be  asked for permission to use those data according to the internal intellectual property rights agreement.  All of the experiments will be performed only during the period of Local Bioethics/Ethics Committees consents validity. |
| 1. **Udostępnianie i długotrwałe przechowywanie danych** |
| **Sposób i termin udostępnienia danych. Ewentualne ograniczenia w udostępnianiu danych lub przyczyny embarga** |
| **WSKAZÓWKA:** Tu należy doprecyzować jak długo dane będą przechowywane I jakie będą zasady dostępu do nich.  **PRZYKŁAD1:** Data will be made available through various means, including publication in peer-reviewed journals and presentations at professional meetings. Data will be deposited during award but may be embargoed until the publication of research based on the data or until 1 year after the expiration of the award. Users will be required to agree to terms that prohibit unlawful uses and intentional violations of privacy.  Datasets and publications will be provided electronically freely accessible online by the scientific community and the public for educational, research, and non-profit purposes.  The MMRI will administer and provide research resources, tools, and any model organisms derived from this proposed study. Such resources will be freely shared with the research community, pending third parties' rights, via Material Transfer Agreements generated by MMRI. In some cases, MMRI may establish a licensing program to guarantee the availability and quality of a particular tool or reagent instead.  **PRZYKŁAD2:** Data and metadata will be stored on an account configured with Cloud Storage. The backup of collected data will be stored automatically on the Cloud managed by the IT Department at MMRI. Paper hardcopy will be created. PI will be responsible for administering all of the created, processed and collected data during the research project realization. |
| **Sposób wyboru danych przeznaczonych do przechowania oraz miejsce długotrwałego przechowywania danych (np. repozytorium lub archiwum danych)** |
| **PRZYKŁAD1:** Data for preservation in our institution is mandatory for i) Protein, DNA and RNA sequences; ii) macromolecular  structures; iii) crystallographic data for small molecules; iv) microarray, spectroscopy data. For 4 years of the project duration, all data will be stored using Cloud system described above. Upon project completion, the source data for published results will be stored for 3 years. Data will be archived automatically on the Cloud and protected according to the best IT procedures. The hard paper copies will be stored for 5 years.  **PRZYKŁAD2:** For 4 years of the project duration, collected data will be stored using described above IT procedures. After project completion, the source data for published results will be stored for 10 years. Data will be archived automatically on the Cloud and protected according to the best IT procedures. |
| **Metody lub narzędzia programowe umożliwiające dostęp do danych i korzystanie z danych** |
| **PRZYKŁAD1:** Datasets and publications will be provided electronically, and data resources / tools will be provided by shipment,  attending to individual requests. In the case of a dataset, all software selected in Section 1 (“Data description and collection”) formats will be needed.  The data stored on our Cloud Storage will be accessible in the appropriately organized folders (as described in Section 2 (”Documentation and data quality”). The access will be password-protected and managed by the IT Department at MMRI and will be available only to authorized personnel.  **PRZYKŁAD2:** The data stored on Cloud will be accessible in the appropriately organized folders (as described in section “2. Documentation and data quality”). The access will be password-protected set by the IT Department at MMRI and will be available only to authorized persons. |
| **Sposób zapewniający stosowanie unikalnego i trwałego identyfikatora (np. cyfrowego identyfikatora obiektu (DOI)) dla każdego zestawu danych** |
| **PRZYKŁAD1:** A digital object identification (DOI) will be obtained for data publications in open access journals. MMRI ensured and promote publishing with the Open Choice Compact license dedicated for scholars affiliated with Polish academic institutions, free publishing of articles and monographs OA licensed by CC BY in hybrid magazines. More information at: <http://wbn.icm.edu.pl/licencje/#springer>  **PRZYKŁAD2:** A permanently assigned digital object identification (DOI) will be obtained for data publications in open access journals. This is ensured by MMRI with the Open Choice Compact license. Also, data selected for preservation (see this Section) will be registered in an online dataset. |
| 1. **Zadania związane z zarządzaniem danymi oraz zasoby** |
| **Osoba (np. funkcja, stanowisko i instytucja) odpowiedzialna za zarządzanie danymi (np. data steward)** |
| **PRZYKŁAD1:** The Institute (Mossakowski Medical Research Institute) will ensure data storage and management during and after  completion the project duration. The PI is responsible for source data storage and management. The IT department of MMRI is responsible for the security of the data, including all required safety certificates. IT Department is supervised by the Deputy Director for Administration and Development.  **PRZYKŁAD2:** Principal Investigator will be responsible for entire data management during the project realization as well as for the preparation and deposition of the final files into a proper repository. |
| **Środki (np. finansowe i czasowe) przeznaczone do zarządzania danymi i zapewnienia możliwości odnalezienia, dostępu, interoperacyjności i ponownego wykorzystania danych** |
| **PRZYKŁAD1:** The cost of preparing data and documentation will be borne by the project and is already reflected in the personnel  costs included in the current budget. The incremental cost of permanent archiving activities related to data management and safety are approx. 5000 PLN and will be covered from the indirect costs.  **PRZYKŁAD2:**The data will be archived and stored automatically on the Cloud and protected according to the best IT procedures for all project duration and 5 years after its completion. The financial sources related to data management are approx. 5000 PLN and will be paid from indirect costs. |