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Pioneering Minds

INFORMED CONSENT FOR MINORS – EMPOWERING THE FUTURE OF PAEDIATRIC RESEARCH

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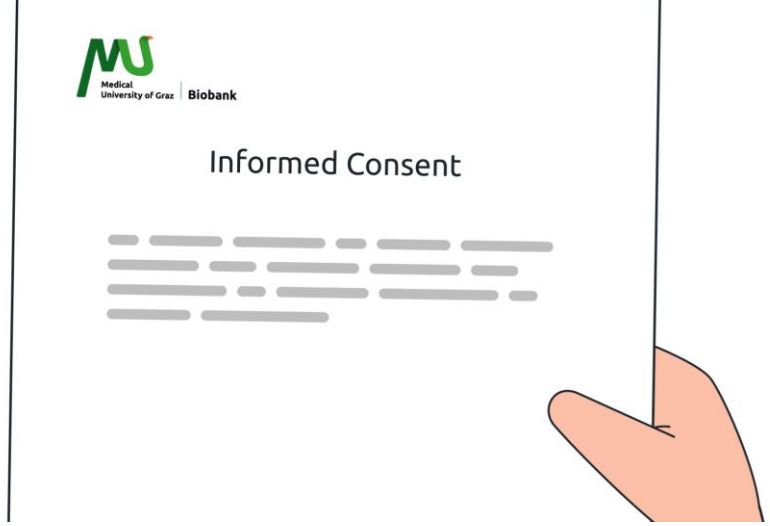
Introduction

- Biobank Graz – **partner of BBMRI.at -** established in 2007 - one of the largest hospital-based biobanks in Europe
- Central service unit of the Medical University of Graz
- Sample collection processes are embedded into the clinical routine system of University Hospital Graz
- Provides logistics and infrastructure for high quality biological material and data:
  - Collection design
  - processing
  - storage

Introduction



- Biobank Graz collects Biobank Informed Consent from adults since 2007
- Biobank Informed Consent allows use of samples in different projects
- There are currently close to 20 million samples stored in the Biobank Graz
- Each individual research project requires approval by the Ethics Committee
- The non-existence of a pediatric IC has been limiting for pediatric research
- Implementation of a consent for patients aged 0 -17 years

Division of Paediatric and Adolescent Haematology/Oncology

- 200 children and adolescents receive an initial consultation (year)
- Around 60 of them have a malignant disease
- The most common types of cancer
  - Cancer of the blood cells
  - Cancer of the lymph nodes
  - Cancer of the central nervous system (CNS)
  - Neuroblastoma
  - soft tissue, kidney and bone tumors
- Studies are coordinated via the study center
- Samples collected in these studies can **now** be used for other research projects

https://paediatrische-haemato-onkologie.medunigraz.at/en/for-patients (22/04/2024)

Timeline

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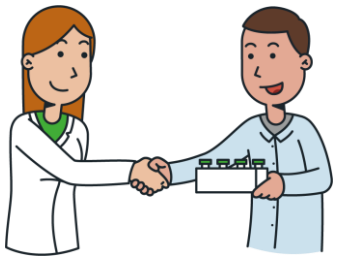
Samples from minors were requested → no Informed Consent no access to samples possible

10/2013

Cover letter to local ethics committee to define access to samples from minors for diagnosis and research purposes

02-06/2014

Cooperation agreement between Biobank Graz and Division of Paediatric and Adolescent Haematology/Oncology
To study specific Informed Consent a information was added → that samples will be stored in the Biobank



10-12/2014

Updated cooperation agreement and new fact sheet

12/2016

Legal Framework – International Level

- United Nations Convention on the Rights of the Child
  - Article 3 (the best interests of the child)
  - Article 16 (privacy)
  - Article 24 (health and healthcare)

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https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-child (22/04/2024)

Legal Framework – European Level

- REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT on clinical trials on medicinal products for human use
  - Article 32 (Clinical trials on minors)
  - Article 10 (Specific considerations for vulnerable populations)
- REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT on the protection of natural persons with regard to the processing of personal data and on the free movement of such data
  - Article 8 (Conditions applicable to child's consent in relation to information society services)
  - Article 9 (Processing of special categories of personal data)
  - Article 12 (Transparent information, communication and modalities for the exercise of the rights of the data subject)

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536
https://eur-lex.europa.eu/eli/reg/2016/679/oj (22/04/2024)

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Legal Framework – National Level

- Austrian data protection law (DSG)
  - Article 2 §4 (4) In the case of an offer of information society services directly to a child, consent to the processing of the personal data of a child pursuant to Article 6 §1 (a) of the General Data Protection Regulation shall be lawful where the child is at least 14 years old.
- Research Organisation Act (FOG)

https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=bundesnormen&Gesetzesnummer=10001597
https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10009514 (22/04/2024)

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Relevant Ethical Guidelines

World Medical Association, Declaration of Helsinki
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

European Medicines Agency, Guideline on the investigation of medicinal products in the term and preterm neonate
ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-medicinal-products-term-and-preterm-neonate-first-version_en.pdf

UNESCO, Universal Declaration on Bioethics and Human Rights
https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights

European Commission, Ethical considerations for clinical trials on medicinal products conducted with minors
https://health.ec.europa.eu/system/files/2018-02/2017_09_18_ethical_consid_ct_with_minors_0.pdf

Council for International Organizations of Medical Sciences, International Ethical Guidelines for Health-related Research Involving Humans

- Guideline 17 → RESEARCH INVOLVING CHILDREN AND ADOLESCENTs

https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

Council of Europe, Recommendation CM/Rec (2016)6 of the Committee of Ministers to member States on research on biological material of human origin

- Article 12: Biological materials from persons not able to consent
- applicable to samples (and associated personal data) used for "future research purposes" (Article 2)

https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff

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Timeline

SOP → sample access for fresh frozen tissue from minors

11/2020 - 03/2021

Information on Rules/statutes for studies/registries accompanying biomaterial banks the Society for Pediatric Oncology and Hematology (GPOH) received

Conversations with Division of Paediatric and Adolescent Haematology/Oncology start

12/2022

Literature research on Informed Consents for minors

01/2023

Timeline – Project execution

02/2023

First draft Biobank Informed Consent for minors content inspired by the Biobank Informed Consent for adults

02-04/2023

Coordination and editing draft with the Division of Paediatric and Adolescent Haematology/ Oncology

04/2023

First meetings for processing the cartoon

Submission to the ethics committee

05/2023

First rough concept and storyboard

Invitation to join ethics committee meeting, to answer questions regarding the submission

07/2023

2.Storyboard and animatic

Approval of the ethics committee for the Biobank Informed Consent for minors

09/2023

Final cartoon

10/2023

Project execution

- Implementation of three informed consents adapted to the age groups (0 -7, 8-13, 14-17 years)

Age group	Signature legal guardian	Signature minors
0 – 7	yes	no
8 – 13	yes	optional
14 - 17	yes	yes

- Reconsenting is only required when patients reach legal age

Cartoon for Kids

https://biobank.medunigraz.at/#c82864

Conclusion

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Informed consent for minors:

- Allows the utilization of valuable samples not only in the scope of the study specific consent but also for future research questions
- Advance the future of health research in the paediatric field

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Thank you!

Biobank Graz

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