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**International Prader-Willi Syndrome**

**Diagnostic Testing Initiative**

***Declaration of consent for PWS testing***

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| --- |
| **Patient:** |
| *Surname:*Surname | *Name:*Name | *Date of birth:*DD/MM/YYYY |

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| --- |
| [x]  **Mother /** [ ]  **Legal guardian:** |
| *Surname:*Surname | *Name:*Name | *Date of birth:*DD/MM/YYYY |

|  |
| --- |
| **Father:** |
| *Surname:*Surname | *Name:*Name | *Date of birth:*DD/MM/YYYY |

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| --- |
| **Medical doctor collecting the consent:** |
| *Surname:*Surname | *Name:*Name |
| *Unit / department:*Unit / Department |
| *Institution:*Institution |

*By signing this* *declaration of consent, I acknowledge that I have:*

* *received, read and understood the preceding written explanation of the PWS analysis;*
* *received appropriate explanations (from my doctor) with regard to the syndrome and the genetic basis, purpose, scope, type, significance and achievable results by and limitations of the planned test, importance of the results for the possibilities of treatment of PWS, planned use of the sample (including processed samples) and of the test results. All my questions have been answered and I have had the necessary consideration time.*

*With my signature at the end of this declaration I consent to:*

1. *the genetic analysis for PWS by the laboratory of the B.I.R.D. Foundation (Italy);*
2. *the collection, processing, use and transfer (also electronically and across country borders) of the provided personal data (also partially health related) and sample by and between my doctor and the B.I.R.D. Foundation for the purposes stated in this consent form;*
3. *generation of the necessary sample,*
4. *storage and use of the sample for up to 20 years to be able to verify/check the results,*
5. *inform my doctor about the results of the genetic analysis.*

*I am aware that I can withdraw my consent, fully or partially, at any time without stating reasons. I may request the destruction of all test results not yet known to me.*

*I also* [ ]  *agree /* [ ]  *do not agree to the retention, storage and further usage for a period of at least 20 years of the collected personal data (e.g. name, birthday, address, description and symptoms of the syndrome), and the results of the genetic analysis and examination, as well as the original and processed samples for further advising/testing, verification/checking of results or other requests, quality assurance and the tracking of latest scientific findings as well as for internal and external research, knowing that personal information will not be shared with any third party without my prior explicit consent.*

*All procedures will be conducted in accordance with the General Data Protection Regulation (EU) 2016/679 (GDPR).*

*Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Parent / legal guardian: Medical doctor:*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

***Purpose of the PWS test:***

*The purpose of this genetic test is to study the genetic material (DNA) using a molecular method that has the capability to detect Prader-Willi syndrome (PWS).*

***Biological material and its storage:***

*The sample used for the PWS genetic test is peripheral blood spotted on laboratory grade filter paper. This requires the collection of a small blood sample.*

*The biologic material will be stored at the B.I.R.D. Foundation, in accordance with your consent declaration.*

***Significance of the results:***

*If the test is positive the result is highly conclusive. If no disease-causing mutation is found, genetic changes responsible for the disease may still exist but the probability of a PWS diagnosis is very small.*

***Use of the sample and results:***

*The sample will be used for the analysis and in accordance with your consent declaration. The test results will be used for treatment decisions by your doctors (s).*

***Right of revocation:***

*You can withdraw your consent to the analysis/examination with effect for the future at any time in full or in part without stating reasons.*

***Privacy:***

*The biological material will be conserved anonymously, the collected data will be secured in a room with limited access, and the ability to link the samples with the personal data will be limited to authorized personnel only.*