**THIRD PARTY CONTRACT**

**WHEREAS**

The **ISTITUTO GIANNINA GASLINI,** Via Gerolamo Gaslini, 5, 16147 Genova , VAT registration number: 00577500101, Contact person: Simona Angioloni, [simonaangioloni@gaslini.org](mailto:simonaangioloni@gaslini.org)

**(hereinafter IGG)** has entered into a Grant Agreement with Innovative Medicines Initiative (IMI), a public-private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA), as Beneficiary for the implementation of the project entitled “Anti-Biopharmaceutical immunization: Prediction and analysis of clinical relevance to minimize the risk” (ABIRISK), Grant Agreement number 115303 (CUP: G31J12000350006);

The global coordinator of the ABIRISK project is GlaxoSmithKline Research & Development Limited (Middlesex, UK);

This contract is entered into by and between **IGG** and

**Všeobecná fakultní nemocnice v Praze,** seated at U Nemocnice 499/2, 128 08 Praha 2 – Nové Město, Czech Republic, Identification number (IČ): 00064165 TAX ID (DIČ): CZ00064165, represented by Mgr. Dana Jurásková, Ph.D. MBA, director (the third party)

indicated in the signature page;

NOW THEREFORE the parties agree as follows:

1. **Description and scope of the project**

This project is a multi-centre prospective cohort study that aims to collect biological samples from paediatric patients with Juvenile Idiopathic Arthritis (JIA) in order to detect early biomarkers able to predict immunization against biopharmaceuticals (adalimumab, etanercept, and tocilizumab) within the first year after initiation of treatment with the same.

The collaboration of the [Unit](http://Unit) of Pediatric Rheumatology of IGG in this study regards paediatric patients, with the aim to include the paediatric population with JIA in the ABIRISK project.

Among its current ongoing initiatives, the Pediatric Rheumatology Unit of IGG is implementing a study whose goal is to establish a pharmacovigilance registry of patients treated with biopharmaceuticals. Because the ABIRISK project shares complementary objectives with the IGG initiative, centres affiliated with the network coordinated by the Pediatric Rheumatology Unit of IGG will be invited to collect biological samples (serum and RNA) for the specific purposes of the ABIRISK project, and will provide the related clinical information collected for the pharmacovigilance registry of patients treated with biopharmaceuticals.

The afore-mentioned samples will be gathered and stored in the Paediatric Rheumatic Immunology Laboratory located in IGG and will be shared with laboratories participating in the ABIRISK project.

There will be 6 fixed study visits: baseline at month 0 and follow-up visits at month 1, month 3, month 6, month 12 and a final visit between month 15 and month 18. The visits will be conducted according to standard clinical practice, with additional blood sampling that will be used for investigations on the development of anti-drug antibodies patients treated with biopharmaceuticals. During each study visit, the doctor will examine the child and will draw samples of serum and RNA in relation with child’s age and weight as foreseen by international guidelines. 5 mL of Serum should be collected at each visit, while RNA (min 2,5 – max 5 mL) will be collected if the patient’s age/weight allow additional blood sampling.

1. **Payment**

A maximum of €200 per visit (indirect costs) for a total of 6 visits (maximum 1,200 € total per patient), for every patient enrolled, evaluable and completed, will be allocated to the Third Party. Enrollment will be competitive until a total of 200 patients are enrolled (100 newly treated with adalimumab, 50 newly treated with etanercept and 50 newly treated with tocilizumab).

**IMPORTANT:** The amount allocated to the Third Party is inclusive of all related costs (e.g., bank commission fees/charges) and taxes (e.g., except VAT, if due, or other). The Third Party should make all necessary arrangements with its appropriate authorities in connection with the taxation (other taxes except VAT, if applicable) and shall deal directly with such authorities in respect of any liability for tax and/or national insurance contributions incurred as a result of entering into this agreement.

Payment will be transferred to the bank details reported in **Attachment A** of this agreement upon receipt by IGG of an invoice issued by the third party for the amount due.

IGG will transfer the money to the third party as per the current agreement.

1. **Provisions for Invoicing**

The invoice must contain the following information (sample draft **Attachment B**):

- Name of the project (ABIRISK) and grant N.: 115303;

- Invoices must be addressed to:

ISTITUTO GIANNINA GASLINI

Via Gerolamo Gaslini, 5

16147 Genova

VAT registration number: 00577500101

1. The VAT registration number of the Third Party should be included, if available;
2. The name “PRINTO” **MUST NOT** appear on the invoice: PRINTO is not a legal entity, but an academic research network whose coordination centre is hosted c/o the Istituto Giannina Gaslini;
3. Scanned draft versions of invoices should first be sent by e-mail to the attention of Simona Angioloni, e-mail: [simonaangioloni@ospedale-gaslini.ge.it](mailto:simonaangioloni@ospedale-gaslini.ge.it)
4. Once electronic versions of invoices have been approved by, originals must be sent by surface mail.

**SIGNATURES PAGE IGG**

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| Signed on behalf of the:  **ISTITUTO GIANNINA GASLINI**  Via Gerolamo Gaslini 5, 16147 Genova (Italy**),**  VAT number 00577500101  Dr. Pietro Pongiglione  President, Istituto Giannina Gaslini  Date:\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_\_  **Signature (and stamp if available):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

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| Signed on behalf of:  **ISTITUTO GIANNINA GASLINI**  Via Gerolamo Gaslini 5, 16147 Genova (Italy**),**  VAT number 00577500101  Prof. Alberto Martini  Scientific Director, Istituto Giannina Gaslini  Date:\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_\_  **Signature (and stamp if available):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

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| Signed on behalf of:  **ISTITUTO GIANNINA GASLINI**  Via Gerolamo Gaslini 5, 16147 Genova (Italy**),**  VAT number 00577500101  Dr. Nicolino Ruperto  MD, MPH at Unit of Pediatria II-Reumatologia  Date:\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_\_  **Signature (and stamp if available):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**SIGNATURE PAGE THIRD PARTY**

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| Signed on behalf of:  **THIRD PARTY**  Organisation/hospital Všeobecná fakultní nemocnice v Praze  Address with town and country Nemocnice 499/2, 12808 Praha 2  VAT number (if available):CZ00064165  Name and title of the legal representative of the organisation/hospital Mgr. Dana Jurásková, Ph.D., MBA, ředitelka  Date: \_\_\_/\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_  **Signature (and stamp if available):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **The THIRD PARTY authorises the payment to the entity indicated below (please choose one option):**   * Individual health professional (preferred) please indicate the name …………. * Organisation/hospital (legal representative) * Family association (legal representative) * Other (please specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   **BENEFICIARY ENTITY DETAILS**  ***(The beneficiary entity must correspond to the bank information on page 5 of this compensation agreement)***  Individual health professional name or Legal name of the organisation/hospital *or* Family association  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address with town and country\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| Signed on behalf of:  **LOCAL SCIENTIFIC COORDINATOR OF THE STUDY**  Name and Title of local scientific coordinator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Organisation/hospital\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address with town and country\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_  **Signature (and stamp if available):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

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| Signed on behalf of:  **INDIVIDUAL HEALTH PROFESSIONAL RESPONSIBLE FOR DATA COLLECTION** Name and Title of study coordinator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Organisation/hospital\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address with town and country\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_  **Signature (and stamp if available):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Attachment A**

(Banking details of beneficiary entity)

**THE FIRST 5 FIELDS MUST BE COMPLETED, OTHERWISE OUR HOSPITAL ADMINISTRATION WILL BE UNABLE TO PROCESS YOUR PAYMENT.**

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| **ACCOUNT HOLDER** | **Všeobecná fakultní nemocnice v Praze** |
| **NAME OF THE BANK** | Komerční banka a.s. |
| **Bank account CODE/number** | 27-3567080287 EUR |
| **IBAN code** | CZ19 0100 0000 2735 6708 0287 |
| **Swift code** | KOMBCZPPXXX |
| Bank code | 0100 |
| Branch number |  |
| Street | Náměstí Míru, Italská 2 |
| Postal code | 120 02 |
| Town | Praha 2 |
| Country | Česká republika |
| Telephone of the bank |  |
| Fax of the bank |  |
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Specific symbol: 5204516216

**ATTACHMENT B**

**Template of invoice**

TO BE PRINTED ON THE LETTERHEAD OF YOUR INSTITUTE/ORGANISATION

**To the attention of:**

Istituto Giannina Gaslini

Via Gerolamo Gaslini 5

16147 Genova

Italia

Partita IVA=00577500101

**Object:** Request of payment for Abirisk project-Grant Nr. 115303

With the present we ask for the payment for the participation to the Abirisk project

Below the details for payment.

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| **Fee per visit** | **N. of visit** | **Patient ID** | **Subtotal €** |
| €200,00 | xxx |  | 1200,- |
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| --- | --- | --- | --- |
|  |  | **TOTAL AMOUNT TO BE PAID IN EUROS1** | **€xxx1** |

1 Please pay attention that this amount is inclusive of any cost or tax except VAT. You will make all necessary arrangements with the appropriate authorities in connection with your tax affairs and shall deal directly with such authorities in respect of any liability for tax and/or national insurance contributions which you incur as a result of entering into this Agreement.

The money should be transferred to the following bank account:

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| Account holder | **Všeobecná fakultní nemocnice v Praze** |
| Bank name | Komerční banka a.s., |
| Account number | 27-3567080287 EUR |
| IBAN | CZ19 0100 0000 2735 6708 0287 |
| SWIFT | KOMBCZPPXXX |
| Bank address | Náměstí Míru, Italská 2, 120 02 Praha 2, Česká republika |