**SPECIFIC AND TECHNICAL CONDITIONS FOR**

**A Contract Research Organization to analyse urine samples from the third trimester of pregnancy for more than 100 steroid metabolites by targeted liquid chromatography coupled to mass spectrometry at IGRO project ( PI21/01269)

(File 14-2022)**
**I. OBJECT**

The present document (the "Pliego") to contract a Laboratory to analyse 1200 urine samples from the third trimester of pregnancy for more than 100 steroid metabolites by targeted liquid chromatography coupled to mass spectrometry on the project : PI21/01269 “THE IMPACT OF PRENATAL EXPOSURE TO ENDOCRINE DISRUPTORS ON NEURODEVELOPMENT: THE MEDIATION ROLE OF THE PLACENTA-BRAIN AXIS (IGRO)” funded by Instituto de Salud Carlos III and cofounded by Fondos FEDER.

All the technical specifications contained in this document are considered to be part of the minimum requirements and do not exclude any other needs for compliance with the purpose of the service contracted.

**II. CONTENT OF THE WORK**

PROJECT TITLE: THE IMPACT OF PRENATAL EXPOSURE TO ENDOCRINE DISRUPTORS ON NEURODEVELOPMENT: THE MEDIATION ROLE OF THE PLACENTA-BRAIN AXIS (IGRO) PI21/01269

The overarching aim of IGRO is to evaluate the effects of the maternal steroid milieu during pregnancy on fetal and child growth and brain development in 1200 pregnant women and their children. IGRO, nested in two established longitudinal birth cohorts, will benefit from available data on comprehensively characterized growth and neurodevelopment at different life stages up to adolescence (age 14-16 years).

IGRO capitalizes on the large amount of available data in two existing large longitudinal birth cohort studies with extensive outcome assessments, exposure biomonitoring measurements and multi-omics data available: the INMA Sabadell cohort with health trajectories up to 14-16 years, and the BiSC cohort with cutting edge data on brain development at early ages (up to 18 months). BiSC project is an ongoing population-based birth cohort (Barcelona Life Study Cohort, http://www.projectebisc.org/en/home/). INMA project: The INMA Sabadell birth cohort is a prospective study that selected 657 pregnant women during the first trimester of pregnancy, between 2004 and 2006 (Guxens et al., 2011).

**Scope of work**

ISGlobal approach is multidisciplinary, ranging from the molecular to the population level and including disciplines across health sciences, life sciences, environmental, social, economic and climate sciences. The Institute’s research on lifestyle and environmental risk factors in terms of conditions with long latency period and expertise in simultaneous assessment of multiple exposures has enabled a systematic approach to unravel the complex pathways affecting the health topics targeted in this project. The project will directly benefit from ISGlobal’s leading role in the European Human Exposome Network (https://www.humanexposome.eu/), the world’s largest network of projects studying the impact of environmental exposure on human health.

ISGlobal is looking for a Laboratory who are experienced in steroid determination in different scenarios (including prenatal diagnosis). The laboratory needs the state-of-the art equipment (LC-MS/MS instruments with triple quadrupole analyzers) for performing the determinations. The methods employed in the analysis of samples should have been already developed and validated by the group for progesterone and oestrogens metabolites (at least 80 different metabolites) in pregnant woman urine samples.

The key deliverables are:

1. The analysis of a total of 1200 urine samples from the third trimester of pregnancy will be analyzed for more than 100 steroid metabolites by targeted liquid chromatography coupled to mass spectrometry.
2. The preparation of a report of the results of these analyses with the levels of the steroid hormones in all the samples and quality control

**III. REQUIRED QUALIFICATIONS**

The Laboratory should have the following qualifications:

* state-of-the art equipment (LC-MS/MS instruments with triple quadrupole analyzers) required for performing the determinations
* at least 3 relevant publications justifying their expertise to measure the urine steroid metabolome

**IV. PERIOD OF EXECUTION AND DELIVERY OF THE REPORT**

The execution of the work will be carried out through the 30 months of the project trial periods.

**V. ESSENTIAL CONTRACTUAL OBLIGATIONS**

The following will be considered as essential obligations of the successful bidder:

a) The Service Provider will use the Material only for the use specified: To analyze by targeted liquid chromatography coupled to mass spectrometry

b) The Service Provider acknowledges that the supply of the Material is conditional upon

the Service Provider obtaining approval for the use of the Materials from an appropriately constituted research ethics committee.

c) The Service Provider will not sell, gift, charge, pledge, transfer, or otherwise supply the Material.

d) The Service Provider shall not provide the Material to a third party. Furthermore, the

Service Provider declares and warrants that it will fulfill the material’s storage and use

requirements, as instructed by ISGlobal.

e) The Service Provider agree to use the Material in compliance with all applicable statutes and regulations, including public health service and Good Clinical Practices and

guidelines.

f) The Service Provider shall respect the privacy rights of the donors and thus refrain from tracing or identifying the identity of any donors who provided the simples.

g) The Service Provider will discontinue its use of the Material and will, upon direction of ISGlobal, return or destroy any remaining Material:

a. On termination of this Agreement.

b. If the Service Provider is in breach of any term of this Agreement; or,

c. At any other time on the reasonable request by ISGlobal.

**VI. CONTRACT PERIOD**

The duration of the contract will be of 30 months
The estimated start date of the contract is May 15, 2022.

**VII. BUDGET, PRICE AND ESTIMATED VALUE OF THE CONTRACT**

The contract budget amounts to the maximum amount of

**€ 88.105 excluding tax**

The award amount will not exceed this budget in any case. The price of the contract, consequently, will be that to which it rises plus the corresponding Value Added Tax, in the case of non-exempt bidders, which must be included in the separate item.

**VIII. ADVERTISING**

The present contract will be published by announcement in the Contracting Profile of the entity on the website: [www.isglobal.org](http://www.isglobal.org)

**IX. PLACE AND DATE OF SUBMISSION OF PROPOSALS**

The economic proposals must be submitted by email to the address licitaciones@isglobal.org
The deadline for submitting proposals will end on 9th of May 2022, 13:00 hs.

**X. LEGAL SYSTEM OF THE CONTRACT**

The contract is considered a private contract and is subject to private law, ruling by this Schedule, by the contract and documentation attached, and in everything not provided by the applicable civil and commercial legislation.

**XIII. EXPENDIENT OF RECRUITMENT, AWARD PROCEDURE OF THE CONTRACT AND DOCUMENTATION TO BE PROVIDED TENDERS**

The contracting of the reference services will be awarded by the procedure envisaged in Section IX of the Internal Contracting Instructions of the entity. From the day of publication of the tender notice, interested companies can obtain the necessary documentation to prepare their proposals through the contractor's profile on the website www.isglobal.org.

**XI. PAYMENT METHOD**

Payment will always be made under invoice and 30 days invoice date by bank transfer:

ISGlobal shall pay according to the following calendar:

- 60% upon signature of the present Agreement.

- 40% upon termination of the present Agreement.

Barcelona, April 28th, 2022