FINPEDMED Expert Board Service Description – valid for the year 2018

02January2018

1. POSITION IDENTIFICATION

Title	FINPEDMED Member, Investigator / Specialist (M.D.)
Functional Area	Pediatric Clinical Trials / Study Design / Drug Development
Sub-Specialty	e.g. *Pediatric Endocrinology*
Payment*	e.g. *400,-€* per one Expert Board member, invoiced by the CRI-HUCH Ltd ("Institution").
Employment Status	Member of the FINPEDMED Expert Board

2. POSITION OBJECTIVE

Expert Board assignments are provided by FINPEDMED based on Service Requests filed by a Requester; i.e. pharmaceutical companies/CROs, competent authorities, or other parties related to pediatric drug development or pediatric clinical trials. An Expert of the FINPEDMED Expert Board is a member of FINPEDMED and acts as an independent contractor (consultant) representing his/her specialty / sub-specialty within the field of Pediatrics; provides independent views; takes part in discussions as a group member; and promotes joint proposals for expert board decision-making.

The FINPEDMED Services are financially administred by the Clinical Research Institute HUCH Ltd., which has a collaboration agreement with the FINPEDMED Legal Host, Hospital District of Helsinki and Uusimaa (HUS). During the Expert assignment, the Expert acts as a temporary employee of CRI HUCH Ltd. Expert Board members are paid for their services by the CRI HUCH Ltd., based on respective consultant services, in accordance with the applicable policies and procedures of the CRI HUCH Ltd. While the Experts are acting as independent individual contractors who provide the Services, the Requester may ask for the designated Expert/-s to conclude a separate confidentiality agreement (CDA) with the Requester. If such a CDA is needed and asked by the Requester prior to generating a Service Request, a draft of the CDA needs to be sent to the FINPEDMED Office. The FINPEDMED Office evaluates and negotiates the terms and conditions of the proposed CDA on behalf of the Experts.

The Requester decides how many Experts they need, and how many subspecialties need to be represented for the assignment. After the receipt of Requester´s acceptance, the designated (by subspecialty/-ies) Expert Board/s will be called for the assignment. The assignments, will be offered primarily to two (2) Experts of a designated Expert Board/-s by the FINPEDMED Office. These two Experts give a preliminary opinion whether the assignment is suitable for more detailed processing. If yes, the assignment will also be sent to other Experts of the Expert Board for information. Only those Experts within the Expert Board who express their interest in the assignment will perform a Reply to the Service Request. These Experts may suggest other FINPEDMED Experts, also from outside the designated Expert Boards, whom they judge to be more suitable for the assignment.

Upon the Requester´s decision, consultation provided by the Experts may also be executed by separately concluded written Consultation Agreements (CA). The Requester may offer the first version of a CA, on defined consultation that is to be performed by the designated Experts, to the FINPEDMED Office for comments. The final CA will be signed by the Requester and the Expert, but also by the CRI HUCH Ltd. By signing, the CRI HUCH Ltd. confirms to take care of the administrative obligations of the Services and agrees to be bound by the terms and conditions contained in the CA. The processing time (e.g. hours / days) and service charge depends on the extent of the assignment (the definitions of FINPEDMED Service Fees.) or consultation. The final outcome of the assignment is a Reply, presented as a statement, report, feasibility questionnaire or equivalent written document expected or preferred by the Requester. The assignment ends once the Reply has been given to a particular Service Request.

Experts are responsible and accountable for:

- Making statements (i.e. expert opinions) in compliance with European and Finnish Laws and regulations, ethical principles of medical research involving human subjects, GCP and safety procedures for risk identification, assessment and control, all related to clinical trials in the pediatric population.
- Active participation in the field of clinical trials on pediatric medicinal products.
- Identification and reporting of health and safety risks and possible scientific faults arising from the tasks and assignments.

3. COMPETENCIES, QUALIFICATIONS, KNOWLEDGE, and EXPERIENCE REQUIRED

Expertise in a sub-specialty	Expertise in pediatrics, pediatric neurology, or in other relevant specialties that the Expert Board requires for giving a statement or opinion on specified pediatric clinical trials.
Medical and scientific qualifications	A medical doctor or dentist with clinical experience and scientific expertise, of a Ph.D. level, minimum.
Expertise in clinical trials and pediatric pharmacology	Proven established experience in conducting pediatric clinical trials on medicinal products, and/or experience and knowledge of pediatric pharmacology (as defined in the Expert Board assignment).

4. KEY PERFORMANCE OBJECTIVES

- A Reply: Statement, report, or other similar documented answer is compiled using the best available expertise and knowledge and with the available information and documentation.
- A Reply: Statement, report, or other similar documented answer is given in the name of FINPEDMED as a general opinion of the FINPEDMED network Experts in the field concerned.
- The scope of the assignment depends on the original Service Request, and may vary.
- The charge incurring the Requester (i.e. the requesting company) will be invoiced by the CRI-HUCH Ltd. pursuant to FINPEDMED Service Fees for sponsors.
- Academic Service Requests as well as requests from the Enpr-EMA are free of charge.

5. ORGANIZATIONAL RELATIONSHIP/AUTHORITY

ORGANIZATIONAL RELATIONSHIP

Reports to: FINPEDMED Office
Fees and payments: CRI HUCH Ltd. as a contracted consultant, Expert as a temporary employee of the CRI HUCH Ltd.
External Contacts: Expert´s own work organization (i.e. employer; hospital, or other organization)

ORGANIZATIONAL AUTHORITY

Decisions made in the position: Independent Expert opinions and group decisions
Possession of the Service Request Reply: The FINPEDMED Service Request database (HUS)
Right to use Replies: The Requester (A Reply in a form of a written document).

6. DECLARATION OF INTERESTS AND CONFIDENTIALITY

Expert Board members have signed individual FINPEDMED CONFIDENTIALITY UNDERTAKING document, publicly available on FINPEDMED web-site. Experts shall declare any direct or indirect interests in the pharmaceutical industry but only according to the Requester´s requirements. If the Requester needs the Declaration of Interests, it needs to be requested separately. All assessments are made impartially, independently, and transparently but without official validity. Expert Board statements are not official decisions and they are not binding in any respect. Expert Board members are not bound by the Administrative Procedure Act (434/2003) or considered incompetent due to the likelihood of bias with regard to their Expert Board activities. Expert Board members act as independent individuals and receive their fees directly. Expert Board members may act as Principal Investigators or Sub-investigators in prospective clinical trials which may have been previously evaluated by any of FINPEDMED's Expert Boards. All members are obliged to comply with strict confidentiality requirements pursuant to Finnish law, and as mandated by experts' work organizations and defined in the Terms of FINPEDMED Services by HUS / FINPEDMED.

ACKNOWLEDGEMENT

This position description has been designed to describe the general nature and level of work performed by Experts within this classification. It is not designed to contain or to be interpreted as a comprehensive inventory of all duties, responsibilities, and qualifications required of Experts assigned to the role.