

FPM-G-002-EN v2 10.07.2020

FINPEDMED Expert Service Description – valid for the year 2020

1. Expert service position identification

Title	FINPEDMED Member, Investigator / Specialist (M.D.)
Functional Area	Pediatric Clinical Trials / Study Design / Drug Development
Sub-Specialty	e.g. <i>Pediatric Endocrinology</i>
Payment	By FINPEDMED Steering Committee's Annually confirmed Service Fees, invoiced by the CRI-HUCH Ltd ("Institution"). See Chapter 5. Organizational Relationship/Authority
Employment Status	Individual Expert, member of the FINPEDMED network or Expert Board

2. Expert service position objective

Expert assignments for Consultations provided by FINPEDMED are only available in Finland. These assignments are based on Consultation Service Requests filed by a Requester; i.e. pharmaceutical companies, Biotech Companies, CROs, competent authorities, or other parties, related to pediatric drug development or pediatric clinical trials. An Expert of the FINPEDMED Expert 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 an individual expert or as a group member and promotes joint proposals for expert board decision-making.

The FINPEDMED Consultation services are financially administered by the Clinical Research Institute HUCH Ltd. ("Institution"), having collaboration agreement with the FINPEDMED Legal Host, Joint Authority of Helsinki and Uusimaa Hospital District (HUS)*. During the Expert assignment, the Expert acts as a temporary employee of the Institution. Experts are paid for their services by the Institution, based on respective consultant services, in accordance with the applicable policies and procedures of the Institution and the FINPEDMED-NORDICPEDMED (FPM-NPM) Terms. 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 CDA is needed and asked by the Requester prior to generating a Service Request, a draft of the CDA needs to be sent first to the FPM-NPM Office. The FPM-NPM Office evaluates and negotiates the terms and conditions of the proposed CDA on behalf of the Experts.

The Requester decides the number of Experts needed, and which subspecialty/-ies need to be represented for the assignment. After the receipt of Requester's acceptance, the designated Experts by subspecialty/-ies will be called for the assignment. The assignments will be offered to a designated Expert Board/-s by the FPM-NPM Office based on the suggestions either of the requester or the FINPEDMED Office. These Experts give a preliminary opinion whether the assignment is suitable for more detailed processing, how long it might take (one assessment in hours) and whether they accept it. The FPM-NPM Office will then prepare a reply with the proposal to the Requester. If the Requester accepts these Experts, they will perform the assignment, and FPM-NPM Office will create a summary report. These Experts may also suggest other FINPEDMED Experts, whom they judge to be more suitable for the assignment. The Requester decides the acceptance of these Experts.

In addition, upon a request, FPM-NPM Office can establish so called ad hoc Scientific Boards for a certain specific task. This type of board may include other Experts outside the FPM registered members (these can present other specialties, such as adult medical specialists or other fields of expertise). These external members have similar individual expert position as FINPEDMED Experts per assignment.

These assignments are done as consultations executed by written Consultation Agreements (CA). The Requester may offer the first version of a CA, to the FPM-NPM Office for comments. The final CA will be signed by the Requester, the Expert, and the Institution, resulting as a tripartite agreement. In case of several Experts agreed to do the same assignment, every Expert will sign own separate CA. By signing, the Institution confirms to take care of the administrative obligations of the FINPEDMED services and agrees to be bound by the terms and conditions contained in the CA.

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The processing time (e.g. hours/days) and the referred fees depend on the extent of the assignment (the definitions of FINPEDMED Service Fees) for the consultation. The assignment ends, once the final outcome of the assignment, presented as a statement, report or equivalent written document, is provided to the Requester, and the related payments have been accepted and finalized by the Institution.

3. Responsibilities, Competencies, Qualifications and Experience of the Expert

The 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, good clinical practices (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;
- Identifying and reporting health and safety risks and possible scientific faults arising from the tasks and assignments.

The required Expert's competence, qualification and experience for the consultation assignments:

Medical and scientific qualifications	A physician or dentist with clinical experience and scientific expertise, of a Ph.D. level, minimum.
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.
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). External experts must have experience according to the assignment in case.

4. Expert service key performance objectives

The key performance objectives are the following:

- 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 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.

5. Expert service's organizational relationship/authority

Organizational relationship

- Reports to: FPM-NPM Office
- Fees and payments: Institution as a contracted consultant, Expert as a temporary employee of the Institution. The charge incurring the Requester (i.e. the requesting company) will be invoiced by the Institution pursuant to FINPEDMED Service Fees for sponsors.
- 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 FPM-NPM Service Request database (HUS)
- Right to use Replies: The Requester (A Reply in a form of a written document).

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FINPEDMED Expert Service Description – valid for the year 2020**6. Declaration of interests and confidentiality of the experts**

All Experts are obliged to comply with confidentiality and data protection requirements pursuant to Finnish law and the General Data Protection Regulation (GDPR), and as mandated by the Experts' primary work organizations (Finnish Hospitals and/or Universities). The FPM-NPM Office or the Experts are not allowed to use the Service Request data for other purposes or disclose it to any third parties other than potential sub-investigators or research staff at the Trial Site/Clinic solely for the purpose of providing the Services.

All confidential data and information related to the Service Requests is processed according to these principles. All Service Requests are saved into the FPM System database. Database information is handled as highly confidential information. Only the FPM-NPM Office personnel and the Experts receiving the Service Request are entitled to view the Service Request including any related documents, one person at the time, and only during the active process, in the protected e-system view, using unique passwords, and with limited user rights. Password is generated and granted per Service Request and per Expert, after the expert's initial registration and signing into the FPM-NPM Registry. Access to view documents related to the Service Request is limited to the designated Experts selected for the assessment task based on the nature and specialty or subspecialty of the Service Request.

All Experts shall declare any direct or indirect interests in the pharmaceutical or other type of industry when required, but only according to the Requester's requirements. If the Requester needs the Declaration of Interests, it needs to be requested separately. All assignments are made impartially, independently, and transparently but without official validity. Expert 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 regards to their Expert activities. Experts act as independent individuals and receive their fees personally directly via Institution. Experts may act as Principal Investigators or Sub-investigators in prospective clinical trials which may have been previously evaluated by any of the FINPEDMED's Experts.

All members are obliged to comply with strict confidentiality requirements pursuant to European and Finnish law, and as mandated by experts' work organizations and defined in the Terms of FPM-NPM Services by HUS / FINPEDMED-NORDICPEDMED*.

7. Acknowledgements

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.

*Terms of FINPEDMED-NORDICPEDMED Services, 2020 (v.8.0).