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FINPEDMED Expert Service Description – valid for the year 2026

1. Expert service position specification

Title	FINPEDMED Member, Investigator / Specialist (M.D.) / Expert in the field of XX
Specialty	Pediatric Clinical Trials / Study Design / Drug Development / Other
Payment	According to Annually confirmed Service Fees, invoiced by the CRI-HUCH Ltd ("Institution")
Employment Status	Independent Expert, member of the FINPEDMED network, employed by "Institution"

2. Expert service position objective and the service model

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, MedTech companies, CROs, competent authorities, or other legal entities, related to pediatric drug development, medical device development for treating pediatric patients or clinical trials on pediatric population.

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 / Medicines / Other specialty; provides independent views as an expert or as a member of larger expert group promoting joint proposals for 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, HUS Group, the joint authority for Helsinki and Uusimaa (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 Consultation Agreement (CA) and in accordance with the applicable laws, policies and procedures of the Institution and according to the FINPEDMED-NORDICPEDMED (FPM-NPM) Terms. The Requester may ask for the designated Expert/-s to conclude a separate Confidentiality Agreement (CDA) with the Requester prior the Consultation Agreement. If such CDA is needed and asked by the Requester, a draft of the CDA needs to be reviewed by FPM-NPM Office and HUS to evaluate the terms and conditions.

The Requester decides the number of Experts needed, and which subspecialty/-ies need to be represented for the assignment. The 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. If the Requester accepts the Experts, the FPM-NPM Office will then prepare a draft CA for the Requester. The Requester may also 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. 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.

After the expert has performed the assignment, the FPM-NPM Office will create a summary report for the sponsor and organizes payments for the experts. In addition, upon a request, FPM-NPM Office can establish ad hoc Scientific Board including several experts for a certain specific task. This type of board may include other Experts representing several specialties. These Board members have similar individual expert position as FINPEDMED experts per assignment.

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 assignment, presented as a statement, report or equivalent written document, or specified activity 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 statement (i.e. giving expert opinion) in compliance with European and Finnish laws and regulations, ethical principles, good clinical practice (GCP) and safety procedures for risk identification, assessment and control, all related to clinical trials in the pediatric population;
- Participating actively in the field of expertise (clinical trials / other expertise);
- Identifying and reporting potential 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 or pharmacologist or pharmacist or other expert with clinical experience and/or scientific expertise, of a Ph.D. level, minimum.
Expertise in a sub-specialty	Expertise in pediatrics or in other relevant specialty that the assignment requires for giving a statement or opinion on specified questions related to pediatric medicines.
Expertise in clinical trials and/or pediatric pharmacology	Proven established experience in conducting pediatric clinical trials on medicinal products or medical devices, and/or experience and knowledge of pediatric pharmacology, or other type of expertise according to the assignment in case.

4. Expert service key performance objective and nature of the assignment

The expert´s opinion, in the form of oral statement (via teleconference or equivalent), written report, or other similar documented, or other agreed activity (i.e. presentations or other live statements, meetings etc.) answer which is compiled using the best available expertise and knowledge together with the available information and documentation. This is given in the name of FINPEDMED as a general opinion of the FINPEDMED network expert in the field concerned. The scope of the assignment depends on the original Service Request and may vary.

Expert opinions are not official decisions, and they are not binding in any respect. Experts 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.

Expert may act as an investigator in the clinical trials which may have been previously evaluated by any of the FINPEDMED experts.

5. Expert service´s organizational relationship / authority

- The expert(-s) reports to FPM-NPM Office, but fees and payments are managed via the "Institution"
- The expert(-s) acts as a temporary employee of the "Institution" during the assignment and the related CA.
- The expert(-s) works as an independent Consultant for given opinions and group decisions
- The charge incurring the Requester (i.e. the requesting company) will be invoiced by the "Institution"
- The FPM-NPM Office has the responsibility of the negotiating the CA with the "institution" and report the result for the Requester

6. Declaration of interests and confidentiality of the experts

All Experts are obliged to comply with confidentiality and data protection requirements pursuant to Finnish and EU laws (General Data Protection Regulation, GDPR), and as mandated by the experts' primary work organizations (Hospital and/or University/Other Legal Entity). 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 investigators or research related staff.

All confidential data and information related to the Service Requests is saved into the FPM System database. Database information is handled as highly confidential information. Password is generated and granted per Service Request and per Expert. 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. (See more: Terms of FPM-NPM Services; https://www.nordicpedmed.com/service-requests/terms/). 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 (DoI), it needs to be requested separately. All assignments are made impartially, independently, and transparently but without official validity.

7. Acknowledgements

This position description has been designed to describe the general nature and level of work performed by FINPEDMED 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.