

1. General

- 1.1. FINPEDMED services ("Services") are provided by the members of FINPEDMED, Finnish Investigators Network for Pediatric Medicines, FINPEDMED, office located at University of Tampere, School of Medicine, Tampere Center for Child Health Research, Biokatu 10, FM 3, 3rd floor, FIN-33014 University of Tampere, Finland ("FINPEDMED Office"). The purpose of such Services is to offer centrally administered high quality tasks of the experts of pediatric clinical trials, under the harmonized conditions of contracts, by standardized procedures.
- 1.2. The Services are administrated by FINPEDMED's legal entity ("FPM Host") Clinical Research Institute Helsinki University Central Hospital Ltd., CRI-HUCH Ltd, a corporation organized and existing under the laws of Finland, located at P. O. Box 700 (Haartmaninkatu 8), Biomedicum Helsinki I, FIN-00029 HUS, Finland.
- 1.3. The Services, as defined later more in detail in Clause 2, provided under the laws of Finland, include expertise, basic feasibility assessment and consulting in issues related to pediatric clinical trials for defining feasibilities (patient recruitment potentials, potential trial sites, and investigators) in Finland, including investigator recruitment, protocol design, and conduct of final protocols. These Services are targeted to both pharmaceutical industry sponsored as well as academic clinical trials. The Services are to be delivered on valid FINMEDMED Service Fees set by the FINPEDMED Steering Committee (See Clause 8. *Payments*).
- 1.4. The user of the Services ("Requester") is a legal entity such as a pharmaceutical, biotechnological or other type of biomedical company, or research organization, institution or network engaged in the business of the research, development and commercialization of human medicines, willing to use the Services in order to receive advice and assistance in the area of pediatric clinical trials.
- 1.5. A FINPEDMED member ("Expert") is an individual person registered in the FPM Registry (as later defined in Clause 1.6) as a recognized expert in his or her field of science in Finland, having a certified degree, competence and scientific qualification and expertise in field of pediatrics, pediatric pharmacology, pharmacy or other relevant specialty required for giving a statement or opinion on specified pediatric clinical trials or drug development. The Expert may perform basic feasibility assessments and provide consulting services for the Requester in the field of pediatric medicine and development of pediatric medicines. The Experts will act as independent contractors. The FPM Host shall have no authority to bind or obligate the Experts and shall not be liable for any obligations or liabilities of the Experts or for any of Experts' actions while performing the Services. Some of the Experts are also members of the 14 FINPEDMED Expert Boards (as later defined in Clause 2.3. *Consultations and Expert Board Services*).
- 1.6. The FINPEDMED Investigators Registry ("FPM Registry") is a private registry administrated by the FPM Host where all Experts are registered by the specialty or subspecialty of pediatrics or by other specialty in medicine, pharmacy or other relevant field of science. The FPM Registry includes information such as names, titles, contact details, education background, training and work / research experience of the Experts. Such information in the FPM Registry is not publicly available but is released to the Requester concerning the Expert who has expressed her/his interest in the Service Request by an electronic reply with a positive answer to the FINPEDMED Office. However, the names and titles of the Experts in the FINPEDMED Expert Boards (as later defined in Clause 2.3) are publicly available on FINPEDMED website.
- 1.7. The Services are provided based on the FINPEDMED Service Request ("Service Request"), an electronic web-based FINPEDMED questionnaire form to be completed by the Requester and to be sent to the FINPEDMED Office. The forms of the Service Request are part of the FINPEDMED IT-structure ("FPM System") including the e-questionnaire for the Requester, the Expert's e-response system integrated to the FPM Registry, and the database for Service Requests and related statistics. Service Requests are processed using the FPM Registry. All proprietary rights related to the forms of the Service Request and the FPM System are reserved by the FPM Host / FINPEDMED.
- 1.8. The FINPEDMED Executive Secretary working at the FINPEDMED office answers the Service Request to the Requester ("Reply") providing information collected of the Experts' e-responses to the FINPEDMED Office. These include both positive (i.e. YES interested) and negative (NOT interested) responses. Negative responses also contain the reasons behind the answers. All responses will be entered into the FPM System according to the rules defined in Clauses 6. *Public Information* and 7. *Privacy*.

2. Service Request

2.1. Service Request Categories and Service Hours

The Service Request form covers two request categories 1) Basic feasibility assessment: New pediatric clinical trial (final protocol); investigators, trial sites, patients, including a possible feasibility evaluation for a pediatric clinical trial in Finland and 2) Consultation: Consultation on pediatric medicinal product development (early phase, PIP's –Pediatric Investigation Plans). One Service Request may include only one of these categories (i.e. one clinical study or one consultation per Service Request). All Services are provided during FINPEDMED's office hours. All holiday seasons when the FINPEDMED Office is closed will be announced publicly on FINPEDMED web pages and through Out-of-Office e-mail responses.

2.2. Service Request Process

- 2.2.1 After receiving a Service Request, the FINPEDMED Office reserves the right to assess the nature of the request. The FINPEDMED Office will contact the Requester by e-mail to confirm the receipt of the request. If the request can be processed without the involvement of the Expert Board as a basic feasibility assessment, the FINPEDMED Office will confirm the request and start the process upon the acceptance of the Terms of FINPEDMED Services by the Requester confirming all such terms by clicking the "I Agree" – button on the FINPEDMED Service Request website (see Clause 18. *Acceptance of the terms of FINPEDMED Services*).
- 2.2.2 After the Requester's acceptance and confirmation, the Service Request is delivered to the Experts of the particular subspecialty by using the FPM System. The timeframe for processing basic feasibility assessments, such as measuring preliminary expressions of interest shown by the Experts (YES-Interested and NO - not interested responses received at the FINPEDMED Office), will be normally targeted to approx. 48 hours starting from the point of confirmation received from the Requester. In case of no response from the Experts to the initial request (day 1; working day) are received at the FINPEDMED Office, an electronic notification will be automatically repeated several times during the following two weeks (until day 10; working day). With this repeated automatic notification to the Experts, the process time may exceed 10 working days. In case of no response from the designated Experts after repeated notifications, the response will be classified as "NOT interested". All responses and Replies will be compiled as statistics to the FPM System database.
- 2.2.3 Basic feasibility assessments and consultations with demanding questionnaires included as part of a Service Request need more time for processing, depending on the scope of the feasibility questionnaire that is included in the Service Request. Such feasibility may be evaluated within 7 working days, but if it includes complex questions, it will take more time. The timelines of Expert Board opinions / statements and consultation tasks vary, depending on the nature of the request (see Clause 2.3.).
- 2.2.4 The FINPEDMED Executive Secretary will send a Reply to the Requester by e-mail. The Reply contains the final answers to the Service Request depending naturally on the Service Request category and the extent of the assignment. Service Request replies may also include negative results, indicating that none of the Experts are interested in basic feasibility assessments or consultations concerning the new clinical trial proposed via the Service Request, or the Experts have turned down the electronic notification.

2.3. Consultations and Expert Board Services

All Category 2 Service Requests are processed as consultations. Additionally, if a Category 1 Service Request seems to be more suitable for Expert Board evaluation (i.e. including specified feasibilities or protocol details of a certain subspecialty/-ies concerning the whole of Finland), the FINPEDMED Office will suggest that the Requester uses Expert Board Services. All consultations are processed as follows;

- 2.3.1 After receiving a Service Request, the FINPEDMED Office will contact the Requester to confirm their acceptance for obtaining an Expert Board opinion / statement on the Service Request. FINPEDMED has a total of 14 Expert Boards representing 14 subspecialties of pediatrics, psychiatry, and clinical pharmacology. Each Expert Board has 4 to 6 designated Experts as members. FINPEDMED Expert Board Experts must have the qualifications and competence set by the FINPEDMED Steering Committee. Like other FINPEDMED Experts, Expert Board members also act as independent experts representing their

specialties/sub-specialties within the field of Pediatrics; provide independent views; take part in discussions as group members; and promote joint proposals for Expert Board decision-making. (See the list of Expert Boards and the description of FINPEDMED Expert Board Services). A member of the Expert Board may act as a Principal Investigator or Sub-investigator in a prospective clinical trial that may have been previously evaluated by any of FINPEDMED's Expert Boards.

- 2.3.2 The FINPEDMED Office prepares a proposal including information about the Experts available and about the suggested actions for processing the Service Request, including also information about the expected expenses according to the current FINPEDMED Service Fees. Based on that information, the Requester decides how many Experts they need, and how many subspecialties need to be represented for the assignment. After receipt of acceptance, the designated (by subspecialty/-ies) Expert Board/s will be called for the assignment. The processing time and service charge depends on the extent of the assignment (definitions of FINPEDMED Service Fees.) The final outcome of the assignment may be presented as a statement or equivalent written document expected or preferred by the Requester.
- 2.3.3 If the Requester accepts the use of an Expert Board/-s and wants to have an Expert Board opinion on the Service Request, the assignment, adhering to the Service Request, 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 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.
- 2.3.4 Upon the Requester's decision, consultation provided by the Experts may also be executed by separately concluded written consultation agreements. After a Service Request process proposal has been approved by the Requester, the Requester may offer the first version of a consultation agreement, on defined consultation that is to be performed by the designated Experts, to the FINPEDMED Office for comments. Payments for consultations are listed in FINPEDMED Service Fees.

3. Confidentiality

All FINPEDMED Experts are obliged to comply with confidentiality and data protection requirements pursuant to Finnish law, and as mandated by the Experts' primary work organizations (Finnish Hospitals and/or Universities). The FINPEDMED 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.

The Experts of the FINPEDMED Expert Boards have each given an individual Confidentiality Undertaking that applies to all Expert Board consultations the content of which is publicly available on the FINPEDMED website under the Expert Board.

While the Experts are acting as independent individual contractors providing 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. If separately requested by the Requester, the FPM Host may also conclude a CDA with the Requester in order to receive information relating to the Service Request. If signed CDAs shall also be obtained from the Experts before being granted access to detailed Service Request information, the Requester shall inform about their preferred practice in managing CDA documents.

4. Declaration of Interests

The FINPEDMED Experts have no obligation to declare interests to the FPM Host or to the Requester except the Experts of the Expert Boards who shall declare any direct or indirect interests but only according to the Requester's requirements. If the Requester needs the Declaration of Interests, it needs to be requested separately.

5. FPM System and database protection

All Service Requests, including any related attachments (such as protocol synopses, feasibility questionnaires, and other attached documents) are saved into the FPM System database. Database information is handled as highly confidential information. Only the FINPEDMED Executive Secretary has access to the database.

Only the FINPEDMED Executive Secretary and the FINPEDMED Experts are entitled to view the Service Request including any related documents, one at the time, and during the active process, in the protected e-system view, using unique passwords, and with limited user rights. Passwords are generated and granted per Service Request and per Expert. Access to view Service Request related documents is limited to the designated Experts selected based on the nature and specialty or subspecialty of the Service Request. The Experts are not allowed to view these documents retrospectively after the Service Request process has ended.

6. Public information

To increase public awareness about the important progress in increasing pediatric drug development and pediatric clinical trials in Finland (and in Europe), some data of the Service Request information will be made publicly available on FINPEDMED websites (www.finpedmed.fi and www.finpedmed.com) in the form of Public Notifications of Service Requests.

6.1 This public information contains the following five (5) fields of data from the Service Request:

6.1.1 Date of publication

6.1.2 Title of notification; Disease or Medical Condition

6.1.3 Request category

6.1.4 Specialty; Pediatric therapeutic area OR specialty / subspecialty (-ies)

6.1.5 Age group / groups

6.1.6 PIP Trial; Trial protocol as part of the accepted PIP (Pediatric Investigation Plan) by the EMA PDCO (European Medicines Agency, Pediatric Committee): Yes or No

6.1.7 Estimated Start date; Estimated time schedule of trial conduct, and;

6.1.8. Estimated Completion date; Estimated time schedule of trial completion.

6.2 FINPEDMED will regularly update the Status of Public Notifications of Service Requests for three (3) additional data fields:

6.2.1 Trial request or consultation; ongoing in Finland

6.2.2 Trial request or consultation; completed in Finland, and;

6.2.3 Trial request or consultation; cancelled in Finland

7. Privacy

The FPM Host / FINPEDMED compile statistics on all Service Requests to its own database. The FPM Host/FINPEDMED is committed to protect the privacy of all Requesters. All data generated from Service Requests are stored electronically on the FPM System secured database. The data are used only for FINPEDMED's operational and statistical purposes and will not be released to any third parties. The FPM Host/FINPEDMED will never collect any sensitive information about Requesters without their explicit consent.

The FPM Host / FINPEDMED operate according to the international, national and European legislation, regulations, guidelines and declarations in order to ensure that trial related information and documentation are treated respecting strict data protection, basic rights, human rights, and good clinical practice GCP.

The FPM Host / FINPEDMED will keep all personal information confidential except to the extent that it needs to be disclosed by law (for example, where fraud or other crime is involved) or to comply with an instruction of a regulatory body of competent jurisdiction. In case of any complaint regarding any breach of this privacy policy, contact the FINPEDMED Office at the address shown in Clause 1.

7.1 This privacy policy relates only to the information that the FPM Host / FINPEDMED obtain from the Requester. The information that the Requester provides to the FPM Host / FINPEDMED when using this Service will be processed for the following reasons:

- 7.1.1. to process the Service Request for advice or information supplied by FINPEDMED;
- 7.1.2. to notify of our services;
- 7.1.3. to respond to any comments, suggestions or questions the Requester may have about us, experience of us, or any complaints the Requester may have;
- 7.1.4. to customise the Service Request website according to the interests of various Requesters;
- 7.1.5. to comply with our statutory and regulatory obligations; and
- 7.1.6. to monitor the use of FINPEDMED Services.

7.2 The type of information the FPM Host / FINPEDMED will collect about the Requester includes:

- 7.2.1. name and address of the Requester;
- 7.2.2. phone number and e-mail address;
- 7.2.3. name and field of the organization / company;
- 7.2.4. invoicing details, VAT number or Tax ID;
- 7.2.5. information completed in relation to our client surveys – if surveys are carried out; and
- 7.2.6. pages and the resources used of FINPEDMED Services.

8. Payments

The charges of the Services are defined in the FINPEDMED Service Fees. The Service Request charge will be invoiced by the FPM Host / FINPEDMED from the Requester based on the invoicing information contained in the initial request. Corresponding compensation to the Experts (both Category 1 and 2 Service Requests include remuneration) is paid by the FPM Host further to the designated Experts after such Service is provided and accepted by the FPM Host and the Requester.

The Service Fee of regular Service Requests (Category 1) is not refundable to the Requester. In case of a possibly negative outcome (negative Experts responses towards to the Service Request), the payment is considered as a compensation to cover the expenses of the Service provided by FINPEDMED and as a basic compensation to the Experts. For academic projects, academic institutions, research networks, and research groups, and for requests from the European Network (Enpr-EMA), Services are provided free of charge. The consultation fees (Category 2 Service Requests) are negotiated separately according the FINPEDMED Service Fees.

8.1 Invoicing information

The Service Request requires that the actual contact and invoicing information of the Requester be provided. FINPEDMED / FPM Host will provide Services only to natural persons or legal entities. The Requester needs to provide their contact and invoicing information, including VAT or TAX ID information, with the initial Service Request. The invoicing information must be correct. Any false names or attempts to act behalf of another person, or company, without permission are forbidden.

The Service Request can only be made for one study protocol (i.e. one clinical study) at a time. If there are several trials with the same investigational medicinal product but with different protocols, the Service Request needs to be filled and submitted separately for each trial.

8.2 Taxes

If the Requester and the FPM Host are organized and located in the same European Union member state, the FPM Host is entitled to collect Value Added Tax (VAT) on the payments. FINPEDMED Service Fees are represented as total sums, including any applicable VAT or similar taxes. An invoicing fee will be added to the invoices. The rate and amount of such VAT shall appear on any invoices that are be paid by the Requester.

The payment to be paid to CRI HUCH Ltd. for a Service Request includes all taxes, excises, tax assessments, and other similar charges levied by the Finnish government on the Services performed and on any materials, equipment, services or supplies furnished or used in the performance of the Service Request.

9. Term

The Service Request starts after the Requester sends a Service Request and the FINPEDMED Office receives and confirms the process to be started. The term expires after the defined assignment for the said Service Request (for example, request for opinion) ends with the Experts. The Service Request (1 request) ends after the Requester has received a Reply for the Service Request from the FINPEDMED Office and the Requester notifies that the Reply has been received. This terminates the process term of one Service Request. The time used for one Service Request process may vary from approx. 48 hours to 1-2 weeks depending on the nature of the Service Request. In case of consultations, the Service Request process can be longer (e.g. weeks or months) depending on the specified consultation task.

10. Termination

This Service may be terminated by the Requester, with or without cause, upon a written notice to the FINPEDMED Office (by e-mail). Without accepted payments in due time the Service Request automatically terminates without any obligation to send a Reply to the Requester. Consultation agreements may have separate terms for termination.

11. Force Majeure

Any event occurring after the initiation of the Service Request, which a party could not reasonably have taken into account prior to the Service Request and which prevents or delays the affected party from fulfilling its obligations under the Services or makes the fulfillment thereof unreasonably difficult and which cannot be overcome without unreasonable loss of time or cost, shall constitute an event of force majeure. An event of force majeure shall include: strike, war, revolt, import or export prohibition, acts of God, interruption of public traffic or distribution of energy, legal labor dispute, fire or any other reason having as severe and unusual effects beyond the control of the FPM Host / FINPEDMED.

12. Amendments to the Service

The FPM Host / FINPEDMED reserve the right to amend these terms of FINPEDMED Services or the up keep of the Services. Any amendments affecting the Service Request under the agreed process will be informed to the Requester. The Requester is entitled to either accept or reject these amendments. In case of rejection, the assignment will be

terminated and negotiated to fulfill the Services performed until the amendments or until appropriate ending for a one Service.

13. Disclaimer and limitation of liabilities

The Requester and the FPM Host / FINPEDMED are obliged to notify the other party immediately in writing of all errors, omissions, and deficiencies detected during the Service Request process. Thereafter, the defaulting party has a duty to correct the reported error, omission, or deficiency in reasonable efforts and time.

The Services are provided only when the Requester is complying with the Terms of FINPEDMED Services and all due payments are paid by the Requester according to these Terms of FINPEDMED Services and FINPEDMED Service Fees.

All Services are provided impartially, independently, and transparently but without any official validity (no official decisions). The statements, recommendations or other opinions while providing the Services are not official decisions and not binding in any respect. The Experts 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. The basic feasibility assessment and/or consultations provided within the Services have no direct or indirect binding effect or any relation to solutions resulting either to the conduct or dismiss of the clinical trial by the Requester or any third party. The Services are not considered in any way official decisions or approvals comparable to the ones made by the regulatory and competent authorities or research ethics committees. Within the Services, the basic feasibility assessments and consultations provided on the basis of respective Service Requests are independent evaluations made by the Experts concerned.

The FPM Host / FINPEDMED, and the Experts providing the Services disclaim any express or implied warranties related to the Services or arising out of any basic feasibility assessments and/or consultations provided within the Services, any suitability, success or fitness for a particular purpose.

In no case the FPM Host / FINPEDMED, or the Experts providing the Services shall be liable for any direct, indirect, incidental, special or consequential damages, costs or expenses including without limitation damages for lost profits or business, depletion of goodwill arising from the Services or from any use of the outcome of the basic feasibility assessments or consultations within the Services. The FPM Host / FINPEDMED, or the Experts have no responsibilities or any liabilities resulting directly or indirectly to the Requester or any third party due to the interruption of operations of the FPM System or FINPEDMED website, or any direct or indirect loss, costs, expenses or loss of data whatsoever arising out of the Requester's use of FINPEDMED website or the Requester's use of the Service Request services on FINPEDMED website.

The liability of the Experts providing the Services and that of the FPM Host /FINPEDMED shall in no case exceed the Service Fees already paid to the Experts by the Requester based on the Service concerned.

14. Reclamations

Any reclamations resulting from the use of the Service Request, such as broken web page links or incorrect data fields, or related defects, must be reported to the FINPEDMED Office. The FPM Host / FINPEDMED have no responsibility for any defective services resulting from technical or electronic network problems caused by a third party.

15. Intellectual property rights

The FPM Host/FINPEDMED is the owner or the licensee of all intellectual property rights on the FINPEDMED website, in the FPM System and in the material published on it. All such rights are reserved.

The website user may print off one copy, and may download extracts, of any page(s) from the FINPEDMED website for personal reference and for the attention of others in the user organization. The content of any materials related to the Service Request may not be modified or used separately from any accompanying text. The status of the FPM Host / FINPEDMED as the author of any material on the FINPEDMED website must always be acknowledged. No part of the material on the FINPEDMED website can be used for commercial purposes without obtaining a license for this from the FPM Host / FINPEDMED.

16. Cookies

When using the FINPEDMED Service Request website, the FPM Host / FINPEDMED would like to use tracking technologies which automatically record and store information about the Requesters' visits to the FINPEDMED Service Request website. The Service Request therefore requires the use of a "cookie" which will be stored on the browser of the Requester. For these purposes FINPEDMED needs the Requester's permission in the form of accepted Terms of FINPEDMED Services. To give this permission, the Requester is requested to tick the box set out next to the "I Agree" button on the FINPEDMED Service Request website. Please note that if the Requester withholds consent to use such technology, it disables the functionality of the FINPEDMED Service Request website and the Requester will be unable to proceed with this service.

16.1 The FPM Host / FINPEDMED automatically collect and store only the following information about Requesters' visits:

- 16.1.1. the internet domain and IP address from where the Requester accesses the FINPEDMED website;
- 16.1.2. the type of browser software and operating system used to access the FINPEDMED website;
- 16.1.3. the date and time of access to the FINPEDMED website;
- 16.1.4. the pages that the Requester enters, visits and exits the FINPEDMED website from;
- 16.1.5. if the Requester is linked to the FINPEDMED website from another website, the address of that website;
- 16.1.6. the Requester's user identity if the Requester is logged in; and
- 16.1.7. the version of the Terms of FINPEDMED Services the Requester has agreed to.

The FPM Host / FINPEDMED use this information to identify click stream patterns, to improve the website and to learn about the number of visitors to the Services and the types of technology the webpage visitors use. The FPM Host / FINPEDMED only use this information to ensure that the webpages stay compatible with a selection of browsers and systems and thereby ensure that the pages appeal to a wide audience.

17. Governing law and dispute solution

All FINPEDMED Services and Service Requests shall be governed by the Laws of Finland without regard to its conflict of law principles. All disputes arising out or in connection with this agreement or the Services shall be finally resolved in arbitration by one (1) arbitrator according to the Rules of Arbitration of the Central Chamber of Commerce of Finland in Helsinki, Finland.

18. Acceptance of the terms of FINPEDMED Services

By clicking the "I Agree" button on the FINPEDMED Service Request website, you agree on your own behalf and on behalf of the legal entity acquiring FINPEDMED Services that you have read the Terms of FINPEDMED Services and FINPEDMED Service Fees and consent to all such terms and agree to be bound by these terms and conditions, and the use of cookies by this FINPEDMED web service.