



FPM-G-001-EN v11.0 01.01.2024

FINPEDMED Terms of FINPEDMED-NORDICPEDMED Services - valid for the year 2024

1. General

1.1. FINPEDMED-NORDICPEDMED (FPM-NPM) services ("Services") are provided by the registered members of FINPEDMED, Finnish Investigators Network for Pediatric Medicines, FINPEDMED ("FPM"), and members of NORDICPEDMED ("NPM"), Nordic Investigators Network of Pediatric Medicines across five Nordic countries; Finland, Norway, Sweden, Denmark and Iceland. All these five Nordic countries have national network represented as a common NORDICPEDMED network.

1.2. The services are targeted to the user of the Services ("Requester") who is a natural person or a legal entity, such as a pharmaceutical, biotechnological or other type of biomedical company, Contract Research Organization or academic 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.

1.3. FINPEDMED Headquarters are located at Helsinki University Hospital, Department of Children and Adolescents, P.O. Box 281 (Stenbäckinkatu 11), FI-00029 HUS, Helsinki, Finland ("FPM-NPM Office). The purpose of network Services is to offer centrally administered high quality tasks of the experts of pediatric clinical trials. Harmonized conditions of consultation contracts and standardized procedures are currently available only in Finland via national FINPEDMED network.

1.4. The legal entity of FPM ("FPM Host") is HUS Group, the Joint Authority of Helsinki and Uusimaa ("HUS"), Services for Women, Children and Adolescents, New Children's Hospital, located at Stenbäckinkatu 9, P.O. Box. 100, FI-00029 HUS, Helsinki, Finland, acting as the governing host organization for the FPM through Department of Children and Adolescents. HUS is the governing organization of the FPM centralized services in Finland; Expert services (consultations), uniform service concept, harmonized terms of agreements and administration of the Services and Experts' service fees for consultations. Additionally, HUS is the governing organization of the NPM management services and the General Secretariat in FPM-NPM Office is located at Department of Children and Adolescents. NPM is a non-legal entity, a collaborative network of national Nordic networks and managed by FPM. Additionally, HUS is the governing organization of the NPM management services and the General Secretariat of FPM-NPM Office. NPM is not a legal entity, but a collaborative network of national Nordic networks and managed by FPM.

1.5. The FPM Host HUS follows the Privacy and Data Protection rules with all Contracting Parties (i.e. all the Requesters) according to the specific *General Information Security Annex (v1.22. in English)*. This Annex document is available on FINPEDMED website at page; Services/Data Protection.

1.6. The FPM host HUS holds the following ownerships and intellectual property rights: The FPM system with ownership, right of access and intellectual property rights; Materials and Trademarks applied and granted to the network, which include, the FINPEDMED name, and the FINPEDMED logo, and the FINPEDMED figure Filperi, and related pictures thereof; copyrights of Filperi picture cards; and rights to all the applied domains/domain names. Granted domains/domain names include FINPEDMED.fi, FINPEDMED.com and NORDICPEDMED.com and applied domains/domain names include norpedmed.com, swedpedmed.com, danpedmed.com and icpedmed.com.

1.7. The Services are provided based on the FPM-NPM Service Request ("Service Request"), an electronic web-based questionnaire form to be completed by the Requester and to be sent to the FPM-NPM Office. The forms of the Service Request are part of the FPM IT-structure ("FPM System").



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The FPM system includes a collaborative FPM-NPM investigators register, a trial register and a site management and maintenance system ("FPM-NPM Registry"). In FPM-NPM Registry, a member can be an Expert via the NPM network in any of the five Nordic Countries. The Service Request includes the e-questionnaire for the Requester, the Expert's e-response system integrated to the FPM-NPM Registry, and the database for Service Requests and related statistics. Service Requests are processed using the FPM-NPM Registry. All proprietary rights related to the forms of the Service Request and the FPM System, are reserved by the FPM Host HUS. The abovementioned FPM system refers to the FPM-NPM websites and the connected online service, where pharmaceutical companies can make service requests to the researchers of the network.

1.8. The Services are financially administered by HUS' affiliated company (HUS ownership 100 %) Clinical Research Institute Helsinki University Central Hospital Ltd., CRI-HUCH Ltd. ("Institution"), a corporation organized and existing under the laws of Finland, located at (Mannerheimintie 105, 00280 Helsinki), Helsinki, PO Box 710, 00029 HUS, Finland, which is a separate legal entity of HUS. The Institution has a collaboration agreement with HUS. Under this Collaboration Agreement, Institution shall manage the Clinical Trial Agreements and other study contracts for HUS and implement the Services provided by Consultant specified in this Agreement, including invoicing, transactions and other administration of finances involved.

1.9. The Services, as defined in detail in Clause 3. *Service Request*, 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 five Nordic countries covered by NPM, including investigator recruitment, protocol design, and conduct of final protocols. These Services are targeted to both the company sponsored pharmaceutical-, biotechnology and medical device industry and academic clinical trials. The Services in Finland are delivered on annually confirmed valid FPM Service Fees set by the FPM Steering Committee (See Clause 9. *Payments*).

1.10. FPM-NPM Member ("Expert") is an individual investigator or medical or scientific expert, and a member of the national network registered in the FPM-NPM Registry (as defined in Clause 1.6), acting as a recognized specialist in his or her field of science, in any of the NPM countries. Experts have a certified degree, competence and scientific qualification and expertise in the field of pediatrics, pediatric pharmacology, pharmacy or other relevant specialty, in order to perform basic feasibility assessments. However, currently only the FPM Experts in Finland can provide consulting services for the Requester in the field of pediatric medicine and development of pediatric medicines under Consultation Agreement. The Experts that fulfill abovementioned requirements, are able to give a statement, recommendation or opinion on specified pediatric clinical trials or drug development. Experts act as independent contractors in Finland. 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 any actions taken by the Experts in the performance of the Services (See Clause: 14. *Disclaimer and limitation of liabilities*)

On separate Service Request by the Requester, FPM/NPM Office can coordinate and create an *ad hoc* Scientific Board and call in Experts of the specific field of science / pediatrics in Finland and perform Expert service as a group under Consultation Agreements (CA) for one specific Consultation assignment. The PFM/NPM Office will first propose suitable Experts to the Requester. The requester confirms their acceptance for Scientific Board opinion and the process. After acceptance, the CAs are signed by each individual Expert (as later defined in Clause 3.4 *Consultations, Consultation Agreements (CA) and Expert Services in Finland*).



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1.11. The FPM-NPM Registry is 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-NPM Registry includes information such as names, titles, contact details, education background, training and work/research experience of the Experts.

No information of the registry is disclosed to external parties and it is not publicly available, but the information of the Expert (name and affiliation) who has replied with a positive answer "YES" (i.e. expressed her/his interest in the Service Request) by an electronic reply to the FPM-NPM Office can be disclosed to the Requester if consented so by the Expert.

1.12. The FPM-NPM Office personnel replies to the Service Request to the Requester ("Reply") providing information collected of the Experts' e-responses to the FPM-NPM Office. These include both positive (i.e. YES interested) and negative (NOT interested) responses. Negative responses contain justification. All responses will be entered into the FPM System according to the rules defined in Clauses 7. *Public Information* and 8. *Privacy and Data Protection*.

2. Materials and use of the materials

2.1 FINPEDMED has created various materials ("FPM Materials") to help support and serve pediatric clinical trials. Part of the FPM materials are publicly available on FPM website only in secured pdf-format together with integrated user guidance within the templates. These are general document templates for informed consent and patient information for all age groups and the notification to legal guardians (parents). These templates cannot be modified by the users as such; however, they can be modified for the purposes of each clinical trial in a way that the text is written again by the user, to the user's own document templates. However, when using copied text, it shall always include reference to the original template information in the following form; "Registered trademark FINPEDMED®".

The following materials are available for pediatric clinical trials. All materials (excluding guidelines) are available in English, Swedish, and Finnish:

1. Guidelines and Table of important facts for investigators and sponsors to be used in Informed Consent process design (available only in Finnish)
2. Document templates for Informed Consent and Patient Information for children and adolescents (available in Finnish, Swedish and English). Part of the documents have been updated between years 2021 and 2023.;
 - a. Under 15 years old: Informed Consent – template for a clinical trial_2021
 - b. Under 15 years old: Additional sections for Informed Consent_2021
 - c. 15-17 years old: Trial Information Sheet –Table of Contents_2021
 - d. 15-17 years old: Informed Consent – template for Clinical trial_2021
 - e. 15-17 years old: Information on the Processing of Personal Data_2021
 - f. 15-17 years old: Notification to Guardians of Trial Participation_2021
 - g. Under 15 years old: Informed Consent – template for a Guardian_2021
 - h. Maternal ICF for pregnant women for clinical drug trial or medical device trial



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3. Picture Cards for pediatric clinical trials and clinical practice; support material

2.2 FINPEDMED Picture Cards (hereinafter “Picture Cards”) in all formats (electronic and printed) are subject to the following conditions:

2.2.1 Picture Cards can be licensed for the use by signing a separate Licensing Agreement (LA) between the FPM/FM Host (as “Licensor”) and the user (natural person or legal entity). The LA includes separate budget of all expenses, compensations, taxes and a possible VAT. The detailed user conditions are described in the LA and its attachments. In general, the use of licensed picture cards is subject to the following conditions:

2.2.2 User shall not modify, adapt or transform the Picture Cards and the name translations in any manner or form, including but not limited to any minor or significant change in wording, graphic illustrations, concept of idea, topics, objects or situations, represented clinical examinations or procedures, drug formulations or administration methods, or format of the Picture Card and the name translations without prior written permission from FPM/HUS. For name translations, user shall inform and ask permission from FPM/HUS before any translation procedures, for additional guidance of the internationally accepted standards for translation of medicinal products, equipment, methods and clinical procedures. User shall provide FPM/HUS with documentation of the name translation process including a back-translation of the Picture Card names to English prior to pilot-testing in patients, as well as final foreign language versions. All rights, title, and any intellectual property rights in and to the translations and any changes or modifications made by the Licensee shall be owned by HUS which shall have the sole right for any renewals and extensions thereof.

2.2.3 User shall not reproduce the Picture Cards and the name translations except for the limited purpose of generating certain number of copies for its own uses as described in LA and its attachments. User shall in no event distribute copies of the Picture Cards and the name translations to third parties by sale, rental, lease, lending, or any other means. Any authorized copies of the Picture Cards and the name translations must include the copyright notice. For material used in the Europe and in the United States (U.S.), the following text must be included: “Copyright © 2017 HUS/FINPEDMED. All rights reserved”. And for the illustrations, as follows: “Kuvitus / Illustration Mari Oksanen” (name in handwriting by the graphic designer). In case of publication, user shall cite the following in reference section of its paper: Lepola P., Oksanen M., Kaartinen M., Kiiski-Mäki H., Qvist E. Picture Cards for Paediatric Clinical trials / FINPEDMED (Finnish Investigators Network for Pediatric Medicines), 2010. Also, user shall not reproduce in full all the Picture Cards (n=36) or the name translations as part of a published article.

2.2.4 Upon the Requester’s decision to license and use the Picture Cards, the LA will be negotiated separately. The FPM-NPM Office will provide the standard LA template for the Requester’s review and comments. That includes definitions of the licensing that is to be planned to execute, and the negotiated price. All LA comments will be reviewed and negotiated with the FPM-NPM Office. Payments for licensing are administrated by the Institution.



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3. Service Request

3.1. Service Request definition

The FPM-NPM Office receives the e-Service Request from the requester. The Office can search for Experts, interested trial sites and preliminary information of the available patient groups suitable for the new trial in case. For this, FPM-NPM Office uses the FPM-NPM Registry.

The FPM-NPM members are committed to work and perform in accordance with the common operational principles and to quickly respond to FPM-NPM Service Requests received through the national networks.

All FPM-NPM Members are obliged to comply with confidentiality and data protection requirements pursuant to National and European laws and regulations, and as mandated by the investigators' primary work organizations (Hospitals and/or Universities).

The service is intended for requests related to new pediatric clinical trials for defining feasibilities, including investigator recruitment, protocol design, and conduct of final protocols. In addition, the service includes specific consultation regarding clinical trial design, product and protocol development.

3.2. Service Request Categories and Service Hours

Service Request is made in 3 steps:

1. If needed, send blanc CDA (SA) via CDA link prior to Service Request
2. Select country/countries you want to cover with the Service Request
3. Fill-in the e-Service Request form and send it.

The Service Request categories:

1. Basic feasibility assessment (R): New pediatric clinical trial (final or draft protocol); searching for investigators, trial sites and patients, including possible feasibility evaluation for the trial conduction in Finland and other Nordic countries.
2. Consultation (C): Consultation on pediatric medicinal product development (early phase, PIPs – Pediatric Investigation Plans; draft protocols; drug development, drug markets / reimbursements).

One Service Request may include only one of these categories at the time. (i.e. one basic feasibility assessment of a trial or one consultation). 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.

The FPM Service fees covers the consultation (2.) requests subjected only to FPM services in Finland. These service fees are confirmed annually by the FPM Steering Committee. The basic service request (1.) for all Nordic countries is free of charge.



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3.3. Service Request Process including Confidentiality Agreement (CDA) or Secrecy Agreement (SA)

All Services are provided during the FPM-NPM Office hours. All holiday seasons when the office is closed will be informed on FPM website and through Out-of-Office e-mail responses.

Prior submitting Service Request, the Requester may decide, whether they need signed CDA before starting the request process. If CDA is needed, the requester can send blank CDA (SA) via CDA link located in the Service Request website and define.

The FPM/NPM Office will review and comment only CDAs targeted to HUS employees (i.e. experts) and negotiates the changes if needed with the requester (sponsor) on behalf of HUS Group. For other FINPEDMED-NORDICPEDMED linked sites and experts from other legal entities must review the CDA on behalf of the organization and its employees in case, as all terms need to be accepted by Expert's own organizations where they are employed, usually these are public or private hospitals.

To submit the e-Service Request needs the acceptance of the current Terms of FPM-NPM Services by the Requester, confirming it by clicking the "*I have READ and AGREED with the terms of FINPEDMED/NORDICPEDMED Services*" –button on the Service Request website (see Clause 19. *Acceptance of the terms of FINPEDMED-NORDICPEDMED Services (FPM-NPM Services)*).

3.3.1 After receiving a Service Request, FPM-NPM Office makes initial assessment of the nature of the request. If the request can be processed as a basic assessment without CA, the Office will confirm the request by an e-mail to the requester and start the process. The requester may select those Experts they find most suitable for the service, if they know these experts by name already.

3.3.2 After the Requester's acceptance and confirmation, the Service Request is delivered to the Experts of the targeted 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 by the FPM-NPM Office), will be normally assessed and answered to within approx. 14 working days, starting from the point of confirmation received from the Requester. In case the FPM-NPM Office receives no response to the initial request from an individual Expert (day 1; working day), an electronic notification will be automatically repeated every three (3) days during the following two weeks (14 calendar days), or until the Expert sends a response. In case of no response from the designated Experts after repeated notifications, the request can be re-submitted to second round with the same timelines. In case of no response, the FPM-NPM Request will be classified as "NOT interested". All responses and Replies will be compiled as statistics to the FPM System database.

3.3.3 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 3.2).



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3.3.4 The FPM-NPM Office will send a Reply to the Requester by e-mail. The Reply contains the final answers to the Service Request, depending 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.

3.4. Consultations, Consultation Agreements (CA) and Expert Services in Finland

All **Category 2** Service Requests are processed as consultations. All consultations are done under separate Consultation Agreements (CA). Additionally, if a Category 1 Service Request seems to be more suitable for more extensive *ad hoc* Scientific Board evaluation (i.e. including specified / long / demanding feasibilities or protocol details of a certain subspecialty/-ies concerning the whole of Finland, and or other Nordic countries), the FPM-NPM Office may suggest that the Requester uses Expert services under CA. All consultations are processed as follows:

3.4.1 After receiving a Service Request, the FPM-NPM Office will contact the Requester to confirm their acceptance for obtaining an Expert opinion/statement on the Service Request. FPM represents a total of 23 specialties, including Rare Diseases, in Finland. In addition, upon a request, FPM-NPM Office is able to establish an *ad hoc* Scientific Board for a certain specific task. This type of Scientific Board can include other Experts identified outside the FPM registered members (these can present other specialties, such as adult medical specialists or other fields of science / expertise).

These external members have similar individual expert position as FPM Experts per assignment. Scientific Board Experts must have the qualifications and competence set by the FPM Steering Committee. Like other FPM Experts, Scientific Experts 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 decision-making.

3.4.2 The FPM-NPM Office prepares a proposal, including information about the Experts available and the suggested actions for processing the Service Request, including information on the expected expenses according to the current FPM Service Fees. Based on the 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(-s) will be called for the assignment. The processing time and service charge depends on the extent of the assignment (definitions of FPM Service Fees.) The outcome of the assignment may be presented as a statement or equivalent written document as preferred by the Requester. These can be compiled into form of Expert Report.

3.4.3 Only those Experts who express their interest in the assignment will reply to the Service Request. These Experts may suggest other experts, also from outside the designated Expert Boards, whom they judge to be more suitable for the assignment.

3.4.4 After the FPM-NPM Service Request process and after the proposal has been approved by the Requester, the FPM-NPM Office will provide the first CA template version of a consultation agreement for the Requester's review and comments. That includes definition of the consultation that



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is to be performed by the designated Experts, and the negotiated price. All CA comments will be reviewed and negotiated with the FPM-NPM Office. Payments for consultations conducted in Finland are listed in FPM Service Fees and are administered by the Institution.

4. Confidentiality

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. Each Expert of the FPM in Finland have committed to act according to high confidentiality level and that applies to all consultations the content of which is publicly available on the FPM website.

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 FPM-NPM Office. The 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-NPM Office personnel 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.

5. Declaration of Affiliations (and Interests)

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

6. 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 FPM-NPM Office personnel has access to the database.



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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.

The Experts are not allowed to view these documents retrospectively after the Service Request process has ended, and neither they cannot have technical access or view to other Service Requests or other Expert's documents due to closed database and restricted administrative rights hold by General Secretariat in FPM-NPM Office (See Clause: 1. *General*; 1.4-1.7).

7. Public information

To increase public awareness about the important progress in increasing pediatric drug development and pediatric clinical trials in Finland and in other Nordic countries some data of the Service Request information will be made publicly available on FPM-NPM website (www.NORDICPEDMED.com) in the form of Public Notifications of Service Requests.

7.1 This public information contains the following eight (8) fields of data from the Service Request:

- 7.1.1 Date of publication
- 7.1.2 Title of notification; Disease or Medical Condition
- 7.1.3 Request category
- 7.1.4 Specialty; Pediatric therapeutic area OR specialty/subspecialty(-ies)
- 7.1.5 Age group/groups
- 7.1.6 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
- 7.1.7 Estimated Start date; Estimated time schedule of trial conduct, and;
- 7.1.8. Estimated Completion date; Estimated time schedule of trial completion.

7.2 FPM-NPM Office will regularly update the Status of Public Notifications of Service Requests for three (3) additional data fields:

- 7.2.1 Trial request or consultation; ongoing
- 7.2.2 Trial request or consultation; completed, and;
- 7.2.3 Trial request or consultation; cancelled

8. Privacy and Data Protection

The FPM/FPM Host compiles statistics on all Service Requests to its own database. The FPM/FPM Host 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 FPM-NPM's operational and statistical purposes and will not be released to any third parties.



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The FPM/FPM Host will never collect any sensitive or personal information about Requesters without their explicit consent.

The FPM/FPM Host operates 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). All authorized personal data is treated in compliance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons, with regard to the processing of personal data and on the free movement of such data, and repealing Directive

95/46/EC (EU General Data Protection Regulation, GDPR), to be used for the specific purpose they are collected (any communication of personal data to private or public subject will be allowed only for the specific purpose they are collected); to create, update and use of the FPM-NPM Investigator's Registry and the FPM System and database. The FPM/FPM Host is the Responsible Data Controller (the registrar). See Clause 1. *General*; 1.5.

The FPM/FPM Host will keep all personal information confidential except to the extent that it needs to be disclosed by any rule, law or regulation or in order to comply with an instruction of a regulatory body of competent jurisdiction or act of any governmental authority or agency. In case of any complaint regarding any breach of this privacy policy, contact the FPM-NPM Office at the address shown in Clause 1. *General*.

Any person whose personal data has been processed by FPM-NPM Office, has the right to ask which personal data is stored by the Responsible Data Controller, which can provide the stored personal data for modification, correction and verification, or deletion. Request for such review can be done by using the FPM-NPM Office contact information seen at FPM an NPM websites, or using the postal address defined in Clause 1. *General*.

All personal data of Service Requests will remain in the FPM-NPM Registry and FPM System and database until the agreed timelines are valid, according to the signed Confidentiality Agreements / Secrecy

Agreements / Clinical Trial Agreements, and during the clinical trials conducted via FPM-NPM Services are conducted, for the regulatory and legal purposes (audits, monitoring etc.) or as long as required by mandatory law or regulation

Each registered Expert of the FPM-NPM Registry can store, modify, correct and delete all their personal data at any time by using their direct access to the database without a need of any additional request from the Data Controller. The FPM-NPM Registry is closed and secured, and the access is possible only with personal username and passwords. All registered experts have such unique personal usernames and passwords for the access.

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

- 8.1.1. to process the Service Request for advice or information supplied by FPM-NPM Experts;
- 8.1.2. to notify of our services;



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- 8.1.3. to respond to any comments, suggestions or questions the Requester may have about us, experience of us, or any complaints the Requester may have;
- 8.1.4. to customise the Service Request website according to the interests of various Requesters;
- 8.1.5. to comply with our statutory and regulatory obligations; and
- 8.1.6. to monitor the use of FPM-NPM Services.

8.2 The type of information the FPM/FPM Host and Institution will collect about the Requester includes:

- 8.2.1. name and address of the Requester;
- 8.2.2. phone number and e-mail address;
- 8.2.3. name and field of the organization/company;
- 8.2.4. invoicing details, VAT number or Tax ID;
- 8.2.5. information completed in relation to our client surveys – if surveys are carried out; and
- 8.2.6. pages and the resources used of FPM-NPM Services.

9. Payments

The charges of the Services in Finland are defined in the annually confirmed FPM Service Fees. The Services requiring payments will be invoiced by the Institution from the Requester based on the invoicing information contained in the initial request. Corresponding compensation to the Experts (Category 2 Service Requests include remuneration) is paid by the Institution after such Service is provided by the

designated Expert/-s, and after it has been accepted by the FPM-NPM Office, Institution and the Requester.

The Service Fees for the Category 2 Service Requests (consultations) are negotiated separately in the corresponding Consultation Agreement (CA), and are not refundable to the Requester, unless cancelled according to the terms of the CA, which terms include possibility of refunds.

Of materials, only FPM Picture Cards are offered against payment and can be ordered in a format of folders (including 31 cards) via FPM website. These orders are administrated by the FPM-NPM Office, and the payments by the Institution.

In case of licensing the separate Picture Cards in other formats (electronic, PDF), it needs a separate Licensing Agreement (LA) between FPM/FPM Host ("Licensor") and the user. These payments are also administrated by the Institution.

9.1 Invoicing information

The Service Request requires that the actual contact and invoicing information of the Requester are provided. FPM/FPM Host/Institution will provide Services only to natural persons or legal entities. The Requester shall provide their contact and invoicing information to Institution, including VAT or TAX ID information, with the initial Service Request, when including the service for the Consultation Agreement and/or Licensing Agreement. The invoicing information must be correct.



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Any false names or attempts to act on behalf of another person, or company, without permission are forbidden and reported to the relevant authorities. It is the Requester's responsibility to ensure correct invoicing information. More detailed invoicing information can be provided by the Institution.

Picture Card orders are invoiced also by the Institution with similar invoicing information as for the Consultation Agreements or Licensing Agreements.

9.2 Taxes

If the Requester and the Institution are organized and located in the same European Union member state, the Institution is entitled to collect Value Added Tax (VAT) on the payments. FPM Service Fees are represented as total sums. Any applicable VAT or similar taxes will be added to the invoices. The rate and amount of such VAT is informed on the invoice.

10. Term

The Service Request process starts when the FPM-NPM Office, after receiving the Service Request from the Requester, sends a written acceptance confirmation (by e-mail) to the Requester. The term expires after the defined assignment for the said Service Request (for example, request for opinion) is completed by the Experts.

The Service Request (1 request) process terminates after the Requester has received a Reply for the Service Request from the FPM-NPM Office and the Requester acknowledges the receipt of the Reply. This terminates the process term of one Service Request. The time used for one Service Request process may vary from approx. 2 to 14 working days depending on the nature of the Service Request and the number of repeated searches. The Service Request process can be longer in consultations (e.g. weeks or months) depending on the specified scope of consultation.

11. Termination

This Service may be terminated by the Requester, with or without cause, upon a written notice to the FPM-NPM Office (by e-mail). The Service Request expires automatically if payments are not received in due time. In such case, FPM-NPM Office is no longer under any obligation to send a Reply to the Requester. Separate terms of termination may be negotiated in Consultation Agreements.

12. 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 contractual obligations or 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-NPM/FPM Host, the Institution or the Requester.



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13. Amendments to the Service

The FPM-NPM/FPM Host reserves the right to amend these terms of FPM-NPM Services or the maintenance 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 the Requester is liable to pay any incurred payments, costs and expenses of work performed before termination. The Parties may also negotiate a new agreement to fulfill the Service Request.

14. Disclaimer and limitation of liabilities

The Requester and the FPM-NPM/FPM Host 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 a reasonable time.

The Services are provided on condition that the Requester is complying with the Terms of FPM-NPM Services and all due payments are paid by the Requester. All Services are provided impartially, independently, and transparently but without any official legal validity defined by national laws and are not comparable to the ones made by the regulatory and competent authorities or research ethics committees. The recommendations or other opinions while providing the Services are not binding in any respect. The basic feasibility assessments and consultations are made by the Experts concerned. The Experts are not bound by the Administrative Procedure Act (434/2003) by Finnish Law or considered disqualified due to the likelihood of bias regarding their Expert Board activities.

The FPM-NPM/FPM Host 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-NPM/FPM Host, or the Experts providing the Services shall be liable for any direct, indirect, incidental, special or consequential damages, costs or expenses including, but not limited to, 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-NPM/FPM Host, 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 FPM-NPM website, or any direct or indirect loss, costs, expenses or loss of data whatsoever arising out of the Requester's use of the FPM-NPM website or the Requester's use of the Service Request services on FPM-NPM website.

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

The Requester is solely liable for the uses of statements, recommendations and/or other opinions and/or actions and decisions it makes as a result of such statements, recommendations and/or other opinions.



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15. Reclamations

Any reclamations resulting from the use of the Service Request, such as broken website links or incorrect data fields, or related defects, must be reported to the FPM-NPM Office.

16. Intellectual property rights

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

The website user may print one copy, and may download extracts, of any page(s) from the FPM-NPM websites for personal use 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 without accompanying text. The status of the FPM-NPM/FPM Host as the author of any material on the FPM-NPM websites must always be acknowledged. No part of the material on the FPM-NPM websites shall be used for commercial purposes without obtaining a license for such use from the FPM-NPM/FPM Host.

17. Cookies

When using the FPM-NPM Service Request website, the FPM-NPM/FPM Host would like to use tracking technologies which automatically record and store information about the Requesters' visits to the FPM-NPM 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, FPM-NPM Office needs the Requester's permission, which is given by accepting the use on the website during the website visit. To give this permission, the Requester is requested to tick the box set out next to the "I Agree" button on the FPM-NPM Service Request website. Please note that if the Requester withholds consent to use such technology, it disables the functionality of the FPM-NPM Service Request website, and the Requester will be unable to proceed with this service.

17.1 The FPM-NPM/FPM Host automatically collects and stores only the following information about Requesters' visits:

- 17.1.1. the internet domain and IP address from where the Requester accesses the FPM-NPM website;
- 17.1.2. the type of browser software and operating system used to access the FPM-NPM website;
- 17.1.3. the date and time of access to the FPM-NPM website;
- 17.1.4. the pages that the Requester enters, visits and exits the FPM-NPM website from;
- 17.1.5. if the Requester is linked to the FPM-NPM website from another website, the address of that website;
- 17.1.6. the Requester's user identity if the Requester is logged in; and
- 17.1.7. the version of the Terms of FPM-NPM Services the Requester has agreed to.



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The FPM-NPM/FPM Host uses 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-NPM/FPM Host only uses this information to ensure that the websites stay compatible with a selection of browsers and systems and thereby ensure that the pages appeal to a wide audience.

18. Governing law and dispute resolution

All FPM-NPM Services and Service Requests administered in Finland shall be governed by the Laws of Finland without regard to its conflict of law principles. Any dispute, controversy or claim arising out of or relating to this contract, or the breach, termination or validity thereof, shall be finally settled by arbitration in accordance with the Rules for Expedited Arbitration of the Finland Chamber of Commerce by one (1) arbitrator. The seat of arbitration shall be Helsinki, Finland and the language of arbitration shall be Finnish or English.

19. Acceptance of the terms of FINPEDMED-NORDICPEDMED Services (FPM-NPM Services)

By clicking the "I have READ and AGREED with the terms of FINPEDMED/NORDICPEDMED Services " button on the FPM-NPM Service Request at NORDICPEDMED website, you agree on your own behalf and on behalf of the legal entity acquiring FPM-NPM Services, that you have read the Terms of FPM-NPM Services and for the Finland, 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.