

Science Committee approval of research not subject to Medical Research Involving  
Human Subjects Act (WMO) requirements  
Department of Internal Medicine (HAIG)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                      |                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------------------------------|
| <b>ProjectID PaNaMa</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 133036, amendment March 2026                                                                                         |                                |
| <b>Principal investigator</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Natasha Appelman-Dijkstra                                                                                            |                                |
| <b>Research title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | e-Reporting of Rare Conditions (e-REC) in the European Registries for Rare Endocrine and Bone Conditions             |                                |
| <b>Sponsor</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | LUMC                                                                                                                 |                                |
| <b>Reviewed</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Document</b>                                                                                                      | <b>Version no. &amp; date</b>  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input checked="" type="checkbox"/> Protocol<br><input type="checkbox"/> PIF/ICF<br><input type="checkbox"/> overig: | V2, 26-03-2026                 |
| <i>It concern scientific research</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No                                                |                                |
| <i>The research falls within the scope of the HAIG</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No                                                |                                |
| <i>The research is of sufficient scientific quality</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No                                                |                                |
| <i>The research is practically feasible</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No                                                |                                |
| <i>The sample size is sufficiently justified</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No                                                |                                |
| <i>The research is subject to the WMO</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> Yes / <input checked="" type="checkbox"/> No                                                |                                |
| <i>Will a medical device be used? (e.g. Apps)</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <input type="checkbox"/> Yes / <input checked="" type="checkbox"/> No                                                |                                |
| <i>The study should still be assessed by the METC-LDD or central non-WMO-committee</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <input type="checkbox"/> Yes / <input checked="" type="checkbox"/> No                                                |                                |
| <i>The budget is adequate</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <input type="checkbox"/> Yes / <input type="checkbox"/> No / <input checked="" type="checkbox"/> n/a                 |                                |
| <b>The committee draws your attention to the following:</b> <ul style="list-style-type: none"> <li>You and your department are responsible for correctly conducting the research in accordance with the applicable laws and regulations.</li> <li>Any personal data collected as part of the research must be handled properly, carefully, and in compliance with the applicable laws and regulations.</li> <li>Every non-WMO study involving personal data must be registered in the Processing Register: <a href="#">Melding verwerking persoonsgegevens LUMC</a></li> </ul> |                                                                                                                      |                                |
| <b>Remarks: -</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                      |                                |
| <b>Favourable opinion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No                                                |                                |
| The science committee of the HAIG in its role as <i>Institutional Review Board</i> is of the opinion that the subjects will not be subjected to any actions and no behavioural mode will be imposed on them, as referred to in the WMO. The research is therefore not subject to the WMO.                                                                                                                                                                                                                                                                                      |                                                                                                                      |                                |
| <b>On behalf of the Science Committee HAIG:</b><br><br>Dr. H.S. Spijker, chair                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Signature:</b><br>            | <b>Date:</b><br><br>29-05-2026 |