


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

<b>Study number WeCie HAIG</b>	W2020.048	
<b>Principal investigator</b>	Natasha Appelman-Dijkstra	
<b>Research title</b>	The Core Registry	
<b>Sponsor</b>	LUMC	
<b>Reviewed</b>	Document	Version no. & date
	<input checked="" type="checkbox"/> Protocol <input checked="" type="checkbox"/> ICF <input type="checkbox"/> Other:	V3, 09-09-2020 V4
<i>It concerns 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 study is feasible and practicable in a practical sense</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 covered by 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</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 according to the applicable laws and regulations.</li> <li>Personal data collected as part of the research should be handled correctly and carefully and in accordance with applicable laws and regulations.</li> </ul>		
<b>Possible explanation:</b>		
<b>Positive ruling</b>	<input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No	
The science committee of the HAIG in its role as Institutional Review Board 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>Chairperson:</b>  Prof.dr. O.M. Dekkers	Signature: 	Date: 19-10-2020