

## CHECKLIST ADVICE RESEARCH PROPOSAL with use of routine care data from ELAN for the LUMC-PHEG SCIENCE COMMITTEE

We ask the ELAN research team to give advice to the PHEG-science committee on the points listed below. Please type your advice below under each point. The applicants will receive a copy of your comments. If applicable, you can also provide feedback on the protocol.

Ticket nr:

Title:

### METHODOLOGIC QUALITY

1. Which format is chosen for the protocol?  
 LUMC-template 'onderzoek met bestaande (patiënt)gegevens'  
 other, namely: .....
2. Is the research of sufficient scientific quality (and why)?
3. Is clearly stated which data will be used and which variables will be generated from the data? Is it clear what analyses will be done?

### FEASIBILITY AND GRP (Good Research Practice)

4. Was the protocol discussed in the ELAN-GRP steering committee? If so, fill in date when the ticket was approved (and turned 'green').
5. Is clearly stated where the data will be stored and processed?  
 ELAN-data on I-drive PHEG  
 CBS-RA environment  
 other environment, namely .....
6. Is clearly stated who will process the data (see protocol item 4.12)?
7. Scientific output: is the goal a scientific paper? One or more papers?
8. Does the study comply with applicable law and regulations (GRP, WMO, GDPR, WGBO, MDR)?  
The following 4 criteria must all be positive for approval.  
 The study is exempt from the Medical Research Involving Human Subjects Act (WMO), and does not include any prospective data collection;  
 It is clear that the study is of public interest;  
 The necessity for the requested data ('proportionality and subsidiarity') is clear;  
 Description of the TTP and 'informed opt-out' (explaining why explicit consent cannot be obtained) is stated clearly in the protocol and the nWMO-questionnaire (B2).

## **OVERALL CONCLUSION**

**What advice do you give based on points above to the PHEG science committee?**

- A. Positive.
- B. Positive, with suggestions for improvement (re-submission not necessary).
- C. Large suggestions for improvement(re-submission of the revised protocol necessary).

Date advice:

Name of reviewers:

Explanatory notes about the provided advice: