Criteria for the assessment of studies and projects from a patient's perspective

Name research application:
Name assessor:
Date:

Note:
Are you involved in this research application in any way? yes / no
If you have answered 'yes', you should **not** fill in this assessment for reasons of objectivity.

This research application should be treated confidentially at all times.

	Type of study	Which criteria
	Registration	1, 5, 6, 7 + additional criteria
	Biobank	1, 5, 6, 7 + additional criteria
	Scientific research CURE with people	1, 4, 5, 6, 7 + additional criteria
	Scientific lab research	1, 6, 7
	Scientific research CARE with people (quality of life/care)	1, 2, 3, 5, 6, 7 + additional criteria
	Other / non-scientific grant applications	1, 2, 3, 5, 6, 7

1	Relevant for people with ALS/PLS/PSMA	Opinion agree/ disagree/ n/a	Suggestions for researchers
a	Is the study relevant for the entire patient group? (Or a minor part of the group)		
b	Does it improve the patient's health and wellbeing and/or the health care provision of patients?		
c	Is the study based on needs and questions of (a part of) the patients?		
d	Does the result have applications in daily life? And is it part of a plan?		
e	Is the study current? (check research agenda as well)		
f	Is similar research done elsewhere which can be included?		
g	May the result possibly have a negative effect on patients? E.g., think of compensation that could become jeopardized?		
h	Does it improve health and wellbeing and/or health care provision of patients and/or caregivers?		
i	Will the research lead to new insights?		
j	Are the most relevant end points included for both patients and caregivers? (Please report here: possible suggestions for end points or measuring tools.)		
Any further doubts or questions:			**PARTIAL CONCLUSION:**

2	**The research improves quality of life**		
a	Does it improve patients' quality of life? (E.g., influence upon physical limitations in the day-to-day implementation?)		
b	Does it improve participation in society?		
c	Does it provide the patient with a practical and useful result?		
Any further doubts or questions:			**PARTIAL CONCLUSION:**

3	**The research improves quality of care**		
a	Does it improve the care (provision) for patients?		
Any further doubts or questions:			**PARTIAL CONCLUSION:**

4	**Ethical aspects and security** [If the research design has been approved by MEC/METC, please omit these questions.]		
a	Is this the least problematic treatment to achieve the set objective?		
b	Does the study ensure the safety of patients and research participants?		
c	Have participants insurance coverage?		
d	Is insight into side effects and risks feasible and are they being monitored?		
e	Have patients an explicit freedom of choice? Do they receive comprehensive information, are they aware that they can quit any time and that participation has no consequences for their existing care provision?		
f	Are values and standards made with due respect for human dignity? And (how) is privacy ensured?		
g	Do professionals act with due care and responsibility and according to the prevailing rules, codes of conduct and guidelines? Are you familiar with the complaint procedure? Are standards of professional conduct followed, such as the Act on Medical Research with People (Wwmo in Dutch), codes of professional conduct, the code of conduct for researchers according to the Personal Data Protection Act (Wbp in Dutch), CCMO, and METC?		
h	Have the risks for participants been clearly described?		
i	Do you think that the risks for participants are acceptable?		
j	Has the personal burden for participants been clearly described?		
k	Do you think the personal burden for participants is acceptable?		

Any further doubts or questions:	PARTIAL CONCLUSION:

5	**Information and communication [**If the research design has been approved by MEC/METC, please omit these questions.]		
a	Has the citizen's summary of the research application been clearly written?		
b	Are patients able to understand the information provided? (patient information letter and informed consent)		
c	Is the information complete (nature, goal, duration, risks, complications, pros and cons of the research, and the possibility to quite at all times)? (patient information letter and informed consent)		
d	Do patients and their organizations receive (sufficient) information on progress and results of the research?		
e	Have patients, who have been provided with full and complete information, the possibility to explicitly give their consent yes/no? (informed consent)		
Any further doubts or questions:			**PARTIAL CONCLUSION:**

6	**Feasibility and planning** [If the research design has been approved by MEC/METC, please omit the grayed out questions.]		
a	The study as described is feasible.		
b	Is the preferred number of respondents in relation to the prevalence?		
c	Is there sufficient knowledge to conduct the study well?		
d	The study has relevant endpoints.		
e	Do the endpoints match with the target group and are they able to display the consequences both positive and negative?		
f	Are the endpoints SMART*?		
g	The research must result from or should be done in collaboration with professional researchers associated with a trusted institution for scientific research or a commercial research institute.		
h	Technical and organizational measures have been taken to secure the collected data against unlawful use.		
i	No more data is collected than is necessary for conducting the study.		
j	Do you expect that sufficient people from the target group are willing to participate?		
Any further doubts or questions:			**PARTIAL CONCLUSION:**

7	Costs		
a	Is a specified budget available?		
b	What is your appreciation of the budget? Is it realistic, too high or too low?		
c	Do you think there is a right balance between costs/effort/use of resources and (expected) results and revenues?		
d	Are other funds/subsidy programs, e.g., ZonMw, Revalidatiefonds, HeldCare, VGZ, VWS available for this research/project? See http://www.zorgsubsidiekalender.nl/)		
e	Has an application for this research/project been submitted at other funds/subsidy programs as well?		
Any further doubts or questions:			**PARTIAL CONCLUSION:**

+	Additional criteria for a registration / biobank from a patient's perspective		
a	It is known who manages the data. Preferably, the patient organization has partly a voice what is being done with the data.		
b	The objective of the registration has been clearly described and is transparent for the participants.		
c	Preferably, also natural course data is collected.		
d	It is known whether there is a registration/biobank for the specific muscular disease on (inter) national level (preferably with a link to treat nmd) and affiliated if possible.		
e	At the registry/biobank it is preferred that a Dutch UMC with a NMA neurologist or other NMA doctor is the main contact person.		
Any further doubts or questions:			**PARTIAL CONCLUSION:**

+	Additional criteria for scientific research CARE and CURE with people from a patient's perspective		
a	Have technical and organizational measures been taken to secure the collected data against unlawful use?		
b	Have the inclusion and exclusion criteria been reasoned well?		
c	Are the results of the research translated to the daily practice?		
d	Do the pros and cons counterbalance?		
e	Is the personal load sufficiently transparent? Think: does it concern a questionnaire or a research in a hospital?		
f	How much time does it take for both patient and family?		

g	Are there alternatives? E.g., a home visit.		
h	What is the physical load? (in case of biopsies ask for an alternative)		
i	Does the study group refund possible cost of travel and accommodation of the participating patients?		
j	Have patients (or patient representatives) sufficiently been involved in the design of the study?		
k	Are clients (or client representatives) included during the conduct of the study?		

Any further doubts or questions:	**PARTIAL CONCLUSION:**

FINAL CONCLUSION:**

* The letters SMART stand for:
- Specific: What do you want to achieve?
- Measurable: Under which conditions (measurable/observable) or form has the goal been achieved?
- Achievable: Is it acceptable for the target group and/or management? Instead of Acceptable Ambitious is often used (Will the objective really achieve a true change?)
- Relevant: Is the goal feasible?
- Time-oriented: When (in time) must the goal be achieved?

**** Excellent, good, adequate, mediocre, bad → positive, positive if, negative**

Criteria for the assessment of patient recruitment from a patient's perspective: clear communication

	Communication patient recruitment		
a	Information on the study is understandable.		
b	Information on the study consists of the goal, pros and cons, risks, treatment, frequency, duration, and location.		

Any further doubts or questions:	**PARTIAL CONCLUSION:**

With thanks to NPCF, SGF and Spierziekten Nederland for the criteria.