

Forschungsbezogene Verwendung klinischer Daten: Was wollen die Patienten?

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Broad Consent and no-consent policy: Studies assessing acceptance and motivation

	Study 1	Study 2
Who?	Patients at the Comprehensive Center for Inflammation Medicine (CCIM), UKSH, Campus Kiel	
When?	2015/2016	03/2018 (shortly before GDPR came into force)
Aim	Understanding & acceptance of broad consent , motivation to give broad consent	Acceptance of broad consent , motivation, Acceptance of a no-consent policy , motivation
How?	760 delivered questionnaires, 550 completed questionnaires (73,4%)	700 delivered questionnaires 503 completed questionnaires (72%)
	Richter G, Krawczak M, Lieb W, Wolff L, Schreiber S, Buyx A, Genetics in Medicine 2018.	Richter G, Borzikowsky C, Lieb W, Schreiber S, Krawczak M, Buyx A, European Journal of Human Genetics 2019

Broad Consent and no-consent policy: Studies assessing acceptance and motivation

—————> Motivation to give broad consent

		Study 1	Study 2	
Acceptance to give broad consent		86,9%	93%	
Motivation to give broad consent				
<u>Altruism</u>	Support of research in general	188 (77.1%)	48 (20.5%)	403 (86.1%)
	<u>Helping all future patients</u>	120 (49.2%)	131 (56.0%)	315 (67.3%)
<u>Solidarity</u>	Helping future patients with same disease	157 (64.3%)	89 (38.0%)	328 (70.1%)
	Feeling connected with future patients	55 (22.5%)	32 (13.7%)	189 (40.4%)
<u>Reciprocity</u>	Returning own benefit from research	118 (48.4%)	92 (39.3%)	339 (72.4%)
<u>Gratitude</u>	<u>Gratitude toward doctors</u>	115 (47.1%)	126 (53.9%)	214 (45.7%)
Other	Hope for <u>personal benefit</u> , Acting as a role model, Worry about disadvantages if not consenting, Knowing of others who consented, <u>No specific reasons</u>			

Broad Consent and no-consent policy: Studies assessing acceptance and motivation

→ Motivation not to give broad consent

	Study 1	Study 2
Acceptance to give broad consent	86,9%	93%
Motivation not to give broad consent		

<u>Worries about data security</u>		14 (40.0%)
Wanting to know type of research		13 (37.1%)
Wanting to know who does research		12 (34.3%)
Denial of research on other than own disease		5 (14.3%)
No personal benefit expected from consenting		4 (11.4%)
Insufficient personal benefit from research so far		3 (8.6%)
<u>No specific reasons</u>		7 (20.0%)

No-consent policy: Study assessing acceptance and motivation

→ Attitude towards no-consent policy

	Study 1	Study 2
Acceptance to give broad consent	86,9%	93%
Attitude towards research without consent		76 % (n = 381)
Refusal of new regulation		24% (n=122)



Positive correlation between acceptance to give broad consent and non-consent policy

Acceptance to give broad consent	93% (n=468)	▶	Acceptance of no-consent-policy	79 % (n=371)
Refusal to give broad consent	7% (n=35)	▶	Refusal of no-consent-policy	71% (n=25)

No-consent policy: Study assessing acceptance and motivation

→ Reasons for acceptance of no-consent policy

	Study 2
Attitude towards research without consent	76 % (n = 381)

How would you find a regulation in which patients would no longer have to consent separately to the use of their data and biomaterials for scientific research purposes under the conditions mentioned?

regulation is **good**, because **we all benefit** from the results of the research and that will only work if we all participate 61% (n=233)

regulation is **good**, but a **special commission should decide** on the use of data and biomaterials 25% (n=95)

regulation is **good**, but it should **apply only to certain areas of research** 23 % (n=89)

No-consent policy: Study assessing acceptance and motivation

→ Reasons for refusal of no-consent policy

	Study 2
Refusal of no-consent policy	24% (n=122)

How would you find a regulation in which patients would no longer have to consent separately to the use of their data and biomaterials for scientific research purposes under the conditions mentioned?

regulation is **not good**, because I can no longer decide on the use of data and biomaterials 73% (n=89)

regulation is **not good**, because I do not see who controls the use of data and biomaterials 59% (n=72)

regulation is **not good**, because I fear disadvantages for myself 7 % (n=9)

Conclusion and Discussion

- 1. Willingness to give broad consent** was very high in our study
main motivations to give broad consent were altruism, reciprocity, and solidarity
- 2. High approval (n=381, 76%) of no-consent policy**
that allows research with clinical data without patient consent
under certain conditions
- 3. Moderately positive correlation between the willingness to give broad consent and the approval of a no-consent-policy**
- 4. Demand for transparent infrastructure to regulate access to data.**
- 5. Offer the dissenting group a choice that allows preserving their autonomy and self-determination, e.g. by the introduction of opt-out mechanisms**

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