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Comment on: Research projects in human genetics in Switzerland: analysis of research protocols submitted to cantonal ethics committees in 2018

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The article by Driessen and Gervasoni [1] is the last of a series of three papers recently published in the *Swiss Medical Weekly*, which explore the interaction between biomedical research and Research Ethics Committees (RECs) in Switzerland. Previously, the article by Bergstraesser and colleagues [2] analysed several applications for ethics review sent by the University Children's Hospital Zurich to the local REC and suggested strategies to improve the drafting of applications for ethics review in the future. Then, the study by Gloy and colleagzes [3] investigated – by means of document analysis and a questionnaire – how the processing of jurisdictional inquiries to Swiss RECs (i.e., requests by researchers to know whether their projects require ethical oversight) could be improved. The article by Driessen and Gervasoni, on the contrary, focussed only on research in human genetics and provided an overview of the features of research protocols submitted and approved by RECs in 2018. Studies of this kind are important because they help understand how RECs operate on a practical level and can help both researchers who have to interact with RECs in the future, and also REC members and policymakers, in that they show how the ethics review process might be improved.

Since 2014, the interaction between researchers and RECs in Switzerland is governed by Human Research Act (HRA [4]), which has also laid out important rules on how to manage personal health data in the context of research. The contribution by Driessen and Gervasoni is linked to a broader endeavour of evaluation conducted by the Federal Office of Public Health (FOPH) to monitor the implementation of the HRA, which has led to the issuing of several recommendations on how to improve this law [5]. Since it is planned for the Federal Council to soon start revising the HRA [6], we would like to point out two specific findings from the study of Driessen and Gervasoni that could be considered during such revision.

First, the article showed that 97% of the research proposals in human genetics used data in a coded form, i.e., where the identity of participants is reversibly removed from the dataset. At present, the HRA does not compel the use of data in a coded form, but for projects involving data previously collected (so called "further use") it sets different sets of rules depending whether the data are in a coded form (art. 32 para 2 HRA), "identified" (i.e., the identity of participants is NOT protected by a code or pseudonym, art. 32 para. 1 HRA) or whether they are anonymised for further use (art. 32 para. 3 HRA). Moreover, rules change depending on whether the data used in the project are exclusively genetic (art. 32 HRA), or whether they are non-genetic, but still health-related (art. 33 HRA). The fact that the study by Driessen and Gervasoni shows that the overwhelming majority of research projects use data in a coded form suggests: (1) that this is the set of rules of greatest importance during the revision process of the HRA; (2) that the different sets of rules for data in an "identified" form (art. 32 para. 1) or for the anonymisation of data (art. 32 para.3) are *de facto* extremely rarely applied, and it can be considered whether they should be kept in their current form. A simplification of such rules seems to be the preferable option, as also previously recommended by Junod and Elger [7].

Second, the study showed that a substantial proportion of the research projects based on the further use of genetic material exploit the possibility of exemption from regular consent requirements through the procedure laid out in art. 34 HRA. This procedure allows researchers to ask RECs to grant an exemption from the standard consent rules, if a set of conditions (e.g., the interest of conducting the research project surpasses that of the person whose data or genetic material are used) are satisfied. The current wording of the HRA states that RECs should grant such exemptions only *exceptionally*, but this study shows that *de facto* this happens in a substantial number of cases. Thus, as also suggested by a report of the FOPH (recommendation number 8 [5]), the exemption allowed by article 34 should be reformed. It should be recognised that the exemption can be conceded regularly and not only exceptionally, but the conditions upon which it can be granted should be further specified [7], to make sure that they are applied in a har-

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monised way throughout Switzerland and that the privacy of research participants is not compromised.

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Potential competing interests
The author has no conflict of interest to declare.

References
1 Driessen S, Gervasoni P. Research projects in human genetics in Switzerland: analysis of research protocols submitted to cantonal ethics committees in 2018. Swiss Med Wkly. 2021;151:w20403. doi: http://dx.doi.org/10.4414/smw.2021.20403. PubMed.
2 Bergstraesser E, Nadal D, Özgü H, Kleist P. Deficiencies in paediatric research applications delaying ethics committee approval. Swiss Med Wkly. 2020;150:w20267. doi: http://dx.doi.org/10.4414/smw.2020.20267. PubMed.
3 Gloy V, McLennan S, Rinderknecht M, Ley B, Meier B, Driessen S, et al. Uncertainties about the need for ethics approval in Switzerland: a mixed-methods study. Swiss Med Wkly. 2020;150:w20318. doi: http://dx.doi.org/10.4414/smw.2020.20318. PubMed.
4 Federal Act of 30 September 2011 on Research involving Human Beings (Human Research Act, HRA) [Internet]. 810.30 Jan 1, 2014. Available from: https://www.fedlex.admin.ch/eli/cc/2013/617/en [cited 2021 Feb 11]
5 Humanforschungsgesetz (HFG). Ergebnisse der Evaluation und weiteres Vorgehen [Internet]. Bern: Federal Office of Public Health; 2019 Dec [cited 2021 Feb 11]. Available from: https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/forschung-am-menschen/evaluation-humanforschungsgesetz.html. German.
6 Federal Office of Public Health (FOPH). Evaluation of the Human Research Act [Internet]. [cited 2021 Feb 11]. Available from: https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/forschung-am-menschen/evaluation-humanforschungsgesetz.html
7 Junod V, Elger B. Données codées, non-codées ou anonymes. Jusletter. December 10 2018. French.