

## Response to comment on: Research projects in human genetics in Switzerland: analysis of research protocols submitted to Cantonal Ethics Commissions in 2018

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The authors thank Andrea Martani for highlighting the importance of the published work on research projects in human genetics in his comment [1, 2]. In his view, the publication not only elucidates the work of the ethics committees in evaluating this type of research project, but also provides useful information for future political and regulatory decisions on clinical genetics and genetic research, including insights that are central for the ongoing revision of the ordinances of the Human Research Act (HRA) and, later, the HRA itself.

Martani addresses in his comment two aspects that, in the legal and ethical context, need to be developed further: firstly, the level of coding and anonymisation and secondly, the scope of article 34 of the HRA. The analysis of genetic research projects revealed that almost all research data are used in a coded form. Striving for simplification between uncoded, coded and anonymous data, as previously proposed [3], might therefore be an interesting approach. However, the latest revision of the Swiss data protection law of September 2020, albeit not yet in force, also distinguishes between anonymised data and “reasonable measures to prevent the identification of the data subjects”, suggesting that data shall be “coded” or “pseudonymised” if anonymisation is impossible or requires a disproportionate effort [4]. In addition, international standards use these definitions as well. Therefore, it appears reasonable to stick to these definitions. Furthermore, the current development of genetics, big data, digitalisation and the future challenges created by a widespread use of artificial intelligence in research suggest that the potential risk or harm for individuals is not merely associated with the level of coding or anonymisation, but rather with the general risk of re-identification in the research context.

If the distinction between research with coded data and research with anonymised data is maintained in the revised ordinances of the HRA, researchers and hospitals will be confronted with the challenge of standardising the process of data handling and data coding, or rather data anonymisation in the context of genetics and big data. As such, the requirements for anonymisation should be redefined in the

revision of the ordinances of the HRA. Additionally, core competences in bioinformatics in this evolving field are required, both on the researcher’s site and within ethics committees, to protect participant’s privacy.

The second point raised by Martani is the exception from obtaining the participant’s informed or general consent when research projects are approved by ethics committees under article 34 HRA. As the statistics of swissethics and the evaluation of further-use projects show, the conduct of such studies without an informed consent or general consent is, from a quantitative perspective, not by a long way an “exception”, as is the wording in the law. swissethics was mandated by the Federal Office of Public Health (FOPH) to characterise in depth the research projects that are approved by the ethics committees under the provisions of article 34 HRA. A comprehensive overview of the results of this study was published recently in Jusletter [5]. In addition to a quantitative analysis of the research projects conducted under the provisions of article 34 HRA, several other aspects were addressed in this study, such as: (a) an evaluation of the efforts undertaken by the researchers to obtain study-specific informed consent or a general consent of the contactable participants – these research projects are called “mixed” projects, meaning that the participants’ consent is available for some, but not all data; (b) the handling of missing crucial information in the study protocols; and (c) an evaluation of the review and approval process by the ethics committees. While this analysis does not support the notion that the Article 34 criteria are inappropriate and should be changed, or that new ones should be defined, research on this question remains open.

The current practice reflects the fact that article 34 HRA is a qualitative exception from the general requirement for getting consent, although this does not reflect its quantitative use. This is in line with the argument that giving exemption is possible regardless of quantitative limitations, provided that the objective qualitative criteria are fulfilled [6].

In conclusion, it is crucial and of absolute priority that ethics committees fulfil their task of protecting research

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participants and respecting fundamental ethical principles such as participants' autonomy. Therefore, participants' consent should be obtained whenever possible, even including situations where researchers request the application of article 34 HRA. swissethics also clearly underlined this principle during the COVID-19 pandemic with the publication of a statement [7], in line with similar statements of regulatory authorities and ethics committees abroad. The provisions of article 34 HRA remain crucial for future research on human beings. Ongoing discussions between legal and ethical experts on one hand and researchers on the other remain important to ensure that its use adequately balances research expectations with individual rights and ethical principles.

#### Disclosure statement

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