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STRENGTHENING THE PROTECTION OF HUMAN RESEARCH SUBJECTS: NEW SWISS ACT REGARDING RESEARCH ON HUMANS

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On 1 January 2014, a new Act regarding research on humans will enter into force in Switzerland. The Act will be accompanied by three Regulations, regarding clinical trials, regarding research on humans other than in clinical trials and an organisational regulation. This new body of law will replace the existing collection of federal and cantonal laws and regulations, national and international guidelines and self-regulation, and will fill a number of gaps and inadequacies.

The new Act is broader in scope than comparable EU-level regulation. It covers not only clinical trials, but all research on human disease and the structure and function of the human body that is carried out on living or deceased individuals, embryos and foetuses, with biological material or with health related personal data. On the other hand, it does not apply to research on in vitro embryos according to the Act on Stem Cell Research of 19 December 2003, nor to research with anonymised biological material or with anonymously collected and anonymised health-related personal data.

Key to the approach taken in the new Act is the protection of the dignity, personality and health of the individual. This is laid down in Article 1 paragraph 1 of the Act. The interests, health and comfort of the individual must be given priority over the interests of science and society. The rights of individuals participating or being asked to participate in research projects are strengthened. Special provisions are laid down for all research on children, minors and adults lacking legal capacity, not just in the context of clinical trials as presently. The Act also contains provisions on concrete measures for protecting individuals involved in research, for example through:

- the principle that research may only be conducted on humans if there is no alternative means of achieving the same results,
- the requirements for information to be provided to the individual,
- the requirements for informed consent, to be given in writing after an appropriate period of reflection,
- the permissible relationship between risk and benefit in a research project,
- the restrictions on use of placebos in research projects,
- the prohibition on paying individuals for participation in research with an expected direct benefit for the individual, and on having individuals pay to participate in research, and
- the requirements of ethics committee review.

The entity instigating a research project is liable for the damage caused in connection with the project. This liability must be secured through insurance or other means. Claims by individuals involved in the research are subject to a three year limitation period from the time of knowledge of the damage, at the most ten years from completion of the research project or thirty years from completion for damage caused by the use of ionising radiation or genetically modified organisms. This compares to a standard limitation period under Swiss law of one year from discovery of the damage, at most ten years from the date of the event that causes the damage. The injured research participant may bring a claim for compensation directly against the insurer, and the insurance contract may not be terminated after the date of occurrence of the damage.

The Act and accompanying regulations take a risk based approach to reduce the burden of securing potential claims in some circumstances, namely when the research involves:

- the administration of an approved pharmaceutical product in accordance with the approved instructions

for use or in a standard way in line with internationally recognised quality criteria guidance, or
- the use of a medical product that bears a conformity mark in accordance with the instructions for use, or
- the use of another health-related intervention that is considered standard in line with internationally recognised quality criteria guidance, or
- the collection of biological materials or health related data in clinical trials in a way that carries only minimal risks and imposes only minimal inconvenience on the research subjects.

For clinical trial sponsors and researchers, the new rules will bring some other welcome changes too. In particular, the harmonisation of laws and procedures under the new Act represents a major benefit. For example, for multi-centre research in Switzerland the approval of just one ethics commission at the place where the lead researcher is active will be required, rather than the current need for separate approvals from ethics commissions in each canton where a multi-centre research project is to be conducted. The lead ethics commission will however be required to collect opinions from the ethics commissions in all of the cantons where research is to be conducted on the material and operative conditions in those cantons, and these opinions will be binding on the lead commission.

Finally, there are a number of additions to data protection laws relating to health related personal data. In particular in the following situations consent of the affected person, their statutory representative or closest relatives will be required prior to collection of data:
- for collection and use of biological and genetic material in unencrypted form for use in a research project,
- for collection and use of biological and genetic material in encrypted form for research purposes,
- for further use of non-genetic health-related personal data in unencrypted form for research purposes.

By contrast in the following situations consent is not required, but the affected person, statutory representative or closest relatives must be informed and have a right to object:
- for anonymisation of biological and genetic material, as this will take further research on such material outside the scope of the Act,
- for further use of non-genetic health-related personal data in encrypted form for research purposes.

Where it is impossible or disproportionately difficult to obtain consent or to inform of the right to object or this cannot be expected of the affected person, there is no documented refusal and the interests of the research outweigh the interests of the affected person, then failure to observe the requirements of consent or information will not prevent the use of the relevant data for research purposes, provided ethics commission approval is obtained.

The new Act imposes criminal penalties for certain violations. Intentional failure to observe the following rules may result in a prison sentence of up to three years or a monetary penalty of up to CHF 1.08 million:
- failure to obtain ethics commission approval,
- failure to obtain informed consent,
- sale or purchase of human body parts,
- carrying out a research project with the aim of changing the characteristics of a human embryo or foetus without reference to any disease, or
- use of embryos or foetuses from abortions or miscarriages before death is established.

Where the crime is in a business context, the prison sentence is to be combined with a monetary penalty. If the failure is negligent rather than intentional, the primary punishment is a fine. Further, fines of up to CHF 10,000 may be imposed for wilful or negligent behaviour in the following cases:
- if the above crimes are committed without the health of the participating person being affected,
- if an individual receives payment or other valuable benefit for participation in research with an expected direct benefit for the individual or pays or gives a valuable benefit for participation in a research project, or
- if biological material or health related personal data are used without the required consent or information.

In conclusion, from the beginning of 2014, Switzerland will have a nationally applicable set of rules reflecting current best practice in ethical and research standards internationally. The Act strikes a balance between the interests of the individual, which are rightly given first priority, and the interests of researchers in a harmonisation of the applicable rules and minimisation of the regulatory burden where the research is of low risk.

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