

Ethical, Legal and Social Implications in a Nursing Field Study in Bavaria

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Abstract. The Institute DigiHealth of the University of Applied Sciences Neu-Ulm is planning ELSI guidelines and legal policies on data protection and making ethics requests for the CARE REGIO project, founded by the Bavarian State Ministry for Health and Care. CARE REGIO's joint project aims at reforming the care system with digital solutions.

Keywords. Digital solutions, ELSI guidelines, field study, Nursing

1. Introduction

In research, social, legal, and ethical issues are frequently encountered. The majority of the concerns revolve around data protection and research ethics. The latter refers to issues with ethics committee approval, reporting results, protecting patients' rights, and consent/assent procedures [1]. The professional code of physicians regulates obtaining a positive ethical vote for clinical medical research. Apart from individual activities of professional associations, this is not the case for medical-nursing research projects. Institute DigiHealth of the University of Applied Sciences relies on ethical review by the relevant ethics committees, legal requirements and data protection in CARE REGIO's collaborative project. The main tasks in the CARE REGIO project are the support of all project partners in data protection and ethics, process optimization, evaluation frameworks, statistical evaluation and analysis of results. The project's primary goal is to provide noticeable relief for caregivers, family caregivers, and those needing care through the use of technical-digital systems.

2. Methods

In elaborating the ELSI conditions (ethical, social and legal implications), we used a model of basic medical ethics. According to Beauchamp and Childress, the model's base is on the principles of biomedical ethics. These are respect autonomy, nonmaleficence, beneficence and justice [2]. Guidelines from ethics committees were reviewed in a literature search and incorporated into the ELSI conditions to meet ethical requirements in science. The ELSI requirements are applied individually to the subprojects. Regular audits of all subprojects with a specially created checklist ensure strict compliance and

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control of the ethical aspects. These audits also include data protection aspects. Institute DigiHealth prepared necessary ethics applications for the relevant ethics committees.

3. Results

In case of vulnerability of study participants, appropriate measures are required to avoid risks and harms from the planned study. Not every research project should be evaluated in the same way. In Europe is a special protection of personal data. On a legal basis, there are no ethical requirements. In the literature, it was found that this is necessary and must also be examined by independent ethics committees. The Declaration of Helsinki provides a basis for these studies as well. A framework for the planning, conduct and review by an Ethics Committee of non-medical studies is recommended. Institute DigiHealth created an individual data protection concept for each subproject. The concept also consists of a submission to the data protection officers of the respective institutions. The subprojects can only collect and process data with a positive vote from the data protection officers and the ethics committee. The Institute established a trust center. It is responsible for the pseudonymization and storage of all data collected in the project.

4. Discussion

Awareness of ethical issues is critical throughout the planning, conduct, and follow-up of research to ensure that the results are of maximum benefit and that ethics committees and institutional review boards provide an appropriate and informative review [3]. When research ethics committees evaluate data-driven medicine projects, the question of assessing the risk-benefit ratio and scientific, societal benefit arises. The amount of knowledge needed, the purpose of the study, and the challenges are essential factors in preparing the study. The ELSI requirements will be continuously reviewed and adjusted until the end of the project.

5. Conclusion

Institute DigiHealth ensures compliance with ELSI guidelines, assists with ethics applications, constantly monitors compliance with data protection laws and is available as a service provider to project partners.

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