Response of the German Society of Neuroradiology to the Guideline

"Ethically Appropriate Reaction to Incidental Imaging Findings in Brain Research",

suggested by Thomas Heinemann, Institut für Wissenschaft und Ethik, and
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The article "Incidental imaging findings in brain research. Ethical considerations and suggestions for problem solutions", published in *Deutsches Ärzteblatt* [1], has provoked reactions mainly by members of the German Society of Neuroradiology (Dtsch Ärztebl 2007;104:A3184–6). In reaction to the criticism, the authors of this article invited neuroscientists to discuss a revised version of the originally suggested guideline in a closed session. The current version of the guideline as the result of this discussion was sent to the German Society of Neuroradiology and other societies being involved in brain research and the problems associated with incidental findings on brain imaging.

The response of the German Society of Neuroradiology (DGNR) is as follows:

(1) This text has the ambition to formulate a general guideline for imaging in brain research. Without restrictions to specific methods and techniques, the reader can expect that all juridical aspects, laws, and guidelines for human brain research are respected.

(2) The suggested guideline points exclusively in the direction of brain research with magnetic resonance imaging (MRI) by "researchers". The "researcher" is defined as "the responsible project leader of the research". Qualifying features are missing like medical license, qualification according to the German "Medizin-Produkte-Gesetz", or certification in radiation protection. With this background, the rights and responsibilities of the "researcher" in this guideline need to be critically investigated. When seeking informed consent, test persons should be fully informed about the qualification of the researcher, in particular about his or her certification to read and interpret brain MR images.

(3) The guideline gives informed consent special emphasis and states not to irritate test persons with incidental findings as top priority. The guideline does not discuss standardized conditions that allow or may not allow the detection of incidental findings by unexperienced "researchers" and the problems being raised by the misinterpretation of incidental imaging findings. The guideline does not discuss the opportunity that the detection of brain disease may provide advantages for the test person, like treatment in time.

(4) The guideline does not discuss the implications of incidental brain findings for the research results and thus for the scientific basis of the research and its ethical justification.

(5) In consequence, this guideline does not fulfill published and realized standards [2–5], because it ignores the competence of certified specialists for Neuroradiology or Nuclear Medicine in interpreting medical brain images and thus does not fulfill scientific and ethical requirements of brain research.

The German Society of Neuroradiology recommends the following essential points and considerations for guidelines describing ethical aspects of incidental imaging findings in brain research:

(1) Independent of the project leader's qualification, it should be guaranteed that certified specialists identify incidental imaging findings, assess its clinical relevance, the relevance for the test person, and for the

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scientific background of the study [6, 7]. When applying for approval by the institutional review board, the project leader is supposed to provide a concept that safely allows to detect, identify, and interpret incidental imaging findings and its communication to the test person. Special certification is required if radiation is involved.

(2) The test person agrees that his or her brain images will be used for study purposes. This should not exclude image evaluation by certified specialists [8]. The test person should be informed that his or her brain images will be reviewed by certified specialists and should decide whether he or she will be informed about the results of this review or not. The test person agrees to the extent of personal data being passed on. The discussion of pseudo-named study data is not affected by the right of informed self-determination. If a certified specialist detects a finding that bias study results, the test person can be excluded from the study.

(3) The juridical view is, that the rights of the test person are not violated by the communication of incidental findings, because these findings are generated by the test person, but not by the study (§ 823 BGB, German right). Damage to the test person cannot be prevented by ignoring or hiding incidental imaging findings, but exclusively by detection and valid interpretation of these findings. The missing of incidental findings or its misinterpretation may cause severe irritation of the test person and unnecessary and sometimes invasive examinations [9]. Irritation of the test person should be weighed against the expectations [10] and the right of informed self-determination. Special problems should be taken into account when including patients with mental diseases [11], in particular the problems of getting informed consent from these patients [12, 13].

(4) When informing the test person about the ethical aspects of incidental imaging findings, the test person should be informed about the qualification of the persons that are going to evaluate his or her brain images, because the test person expects that incidental findings will be diagnosed irrespectively of the text of the informed consent [10]. The test person should be aware, that, e.g., brain images will be obtained by basic scientists (e.g., physicists) with the aim to improve MR sequences, and should know which concept the researchers follow in order to identify and manage incidental findings.

(5) The term "Patientenprobanden" as used by the authors of the guideline mentioned in the title has to be avoided [14]. Patients and healthy test persons differ in many aspects, like purpose of study, personal rights, and potential benefit from brain imaging. Patients with other illnesses are somtimes participating in special studies as control persons. The term "Patientenprobanden" is confusing.

(6) After receiving appropriate informed consent, the researcher is primarily responsible for the scientific validity of the study [8]. Scientific validity is an indispensable precondition of research that meets ethical requirements [4, 15]. If the scientific basis of a study is invalid – including the identification of incidental findings that could affect study results –, the study is ethically unjustified with view to its scientific value and – last not least – to its responsibility for the test person who voluntarily gave his or her brain images for study purposes.

(7) A researcher without special qualification should principally not exceed his or her authority. If the researcher has no experience in and certification for brain image interpretation, he or she should leave the detection and diagnostic interpretation of incidental imaging findings to a certified physician. If the researcher decides to involve a certified physician, who may see the necessity of further examinations or special treatment, the juridical status of the test person converts into the status of a patient with special rights and duties.

(8) A guideline on "Ethically correct reaction to incidental imaging findings in brain research" does not relieve a physician from his or her professional duties even when he or she is acting as researcher.

Regarding scientific neuroimaging, we have currently an ethically doubtful situation in Germany, because no standards are available for incidental imaging findings. Each researcher can deal with incidental imaging findings at his or her own discretion without any transparency and remote from standards [9]. Like Synofzik, the German Society of Neuroradiology demands ethically justified standards when brain research is dealing with structurally and functionally abnormal brain images. This is true for the rights of test persons as for the scientific validity of research. The suggested guideline is unacceptable in this regard [16].

The German Society of Neuroradiology criticizes, that the suggested guideline does not care about a standard that guarantees a reliable detection and interpre-

tation of intracranial abnormalities. The detection of incidental imaging findings by chance does not require guidelines. Such guidelines are counterproductive for the attempt to develop ethical standards for brain research with MRI. Brain research based on guidelines that do not describe standards for the identification and interpretation of incidental imaging findings does not meet basic standards of science and standards of good clinical practice with its responsibility for the test persons. Both aspects are involved if research is irrelevant, repetitive, obsolete, or invalid and, thus, ethically unacceptable. Poor research is unethical with view to the test persons even if the test persons do not bear risks or any burden worth mentioning [17]. In conclusion, guidelines for the ethically correct reaction to incidental imaging findings in brain research should contain far more than just standardization of informed consent.

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