Ethics in action: Approving and improving medical research with human subjects

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PROLOGUE

An elderly man, for confidentiality reasons I will call him Jan, went to see his general practitioner with mild urinary tract symptoms. Jan was sent for a biopsy, which confirmed he had prostate cancer. After consulting a surgeon, Jan decided that he wanted to have ‘nerve-sparing’ surgery, mainly because it provided a better chance of preserving his erectile function compared to a more radical removal.

However, the surgeon also asked Jan whether he would be willing to participate in a scientific study to collect and store tissue and patient data for use in future research. In addition to storing blood samples and tumor tissue, the study involved additional imaging of the prostate with MRI, a diagnostic technique that was not part of regular clinical care for prostate cancer. The main risks of participating in this study were the potential side-effects of the contrast agent used for the MRI. The informed consent form also mentioned that the results of the MRI could, in individual cases, be used to adapt the therapeutic approach and the choice for a particular surgical procedure. After reading the consent form, Jan decided to participate since he thought the risks were small and he wanted to help improve the treatment of future patients.

Unfortunately, Jan’s MRI indicated that nerve-sparing surgery would not result in a removal of all tumor tissue, so the surgeon performed a more radical operation, including a removal of the nerves. Jan recovered well after the operation, but suffered from permanent impotency. Pathological analysis after the operation showed that the MRI had given misleading information and that nerve-sparing surgery would have been possible after all. The surgeon told Jan that, within the context of regular clinical care, he would indeed have chosen to perform a nerve-sparing procedure. So, in effect, participating in the scientific study had been a major causal factor for Jan’s impotency.
Although Jan appreciated that unfortunate events happen in scientific research, and he did not feel that the surgeon or the investigative team was culpable for his impotency, he was left with many questions. Had it been a good idea to allow an alteration of his treatment based on the MRI? Was he informed properly about the risks or could additional information have changed his mind? Was the knowledge gained by this study worth the risks to him and other patients? And he also started wondering: Who decides about all of these issues? Who ensures that these things are in order? And how do they do that?