NCRP Issues Radiation Research Risk Guidance

The National Council on Radiation Protection and Measurements (NCRP) in May issued a new report on *Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects: Guidance for Researchers and Institutional Review Boards* (Report No. 185). The report was developed by an NCRP scientific committee chaired by Julie Timins, MD, an experienced diagnostic radiologist board certified in general radiology and nuclear medicine, who is also chair of the New Jersey Commission on Radiation Protection. In an executive summary, the report's authors noted that the extent of knowledge about ionizing radiation in medical procedures and potential adverse effects varies substantially among members of the public and within the medical community. This variation is also seen in guidelines used across academic and other institutions for the conduct of human research involving radiation. The report is intended to address the need for "comprehensive, consistent, and accurate guidance on radiation risks of research protocols that involve the use of ionizing radiation to those who develop protocols and conduct research involving human subjects and to institutional review boards (IRBs) that review these protocols." In a release accompanying the publication, NCRP said that the report seeks to fill existing guidance gaps by: (1) providing basic information about ionizing radiation and radiation biology, including medical imaging and treatments that involve radiation; (2) identifying the governmental agencies that oversee research and radiation; (3) citing the relevant regulatory requirements; (4) providing guidance regarding the estimation of radiation dose and risk in research protocols; (5) discussing ethical considerations involved in human studies research; and (6) presenting in detail the requirements for ensuring and obtaining truly informed consent.

The comprehensive document has specific value for research staff, IRBs, and other research review entities that involve personnel who may have limited backgrounds in radiation science. For these individuals, the report is intended "to help researchers optimize radiation use in research protocols, IRBs to perform due diligence in review of those protocols, and to promote understanding of the potential short- and long-term health effects" by providing historical and regulatory background, definitions, descriptions of medical imaging studies and procedures, and more than 500 reference sources. The report covers information needed for research protocol development and evaluation, including basic information on radiobiology, radiation protection, and metrics pertinent to radiation; regulatory requirements for the conduct and supervision of research; in-depth discussions on estimation of radiation dose and risk and the appropriate use of effective and absorbed dose; ethical principles relevant to human studies research involving radiation exposure, including those unique to vulnerable populations, including children; and the informed consent process and examples of language to assist in developing informed consent documents. These examples include "plain language" suggestions to simplify and clarify protocols for participants.

The report is available for purchase from NCRP at https://ncrponline.org/shop/reports/report-no-185-evaluating-and-communicating-radiation-risks-for-studies-involving-human-subjects-guidance-for-researchers-and-institutional-review-boards-2020/. Members of the American Association of Physicists in Medicine may download the document at no charge at https://www.aapm.org/pubs/ncrp/detail.asp?docid=185.

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These and other questions will be considered and discussed at a National Institute of Biomedical Imaging and Bioengineering (NIBIB) workshop on "Engineering New Instrumentation for Imaging Unsealed Source Radiotherapy Agents," to be held August 17 and 18 at the Natcher Center on the main National Institutes of Health (NIH) campus in Bethesda, MD. We believe that such discussions are timely for moving hand-in-hand into the testing and use of α-emitting therapy trials.The mission of NIH's NIBIB is to improve health by leading the development and accelerating the application of biomedical technologies. Among the many technologies supported, NIBIB researchers believe the challenge of considering cameras that would deliver improved dosimetry measurements for optimizing the outcome of α-emitting radiotherapy ligands is one that merits a serious look. For more information on the workshop, see https://www.imagingtherapy.nibib.nih.gov/.

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