TASK GROUP 126
Radiological Protection in Human Biomedical Research

ICRP 2023
6-9 NOVEMBER 2023 • TOKYO, JAPAN

Members

Isabelle Thierry-Chef **(Chair)**, Spain
Hanne Waltenburg **(Vice-Chair)**, Denmark
Cameron Jeffries, Australia
Seok Ho Lee, Korea
Anja Almén, Sweden
Kimberly Applegate, USA
Monica Bernardo, Brazil
Yi Du, China
Catrin Baureus Koch, Sweden
Chieko Kurihara-Saio, Japan
M. Mahesh, USA
Loredana Gabriela Marcu, Romania
Deborah Oughton, Norway
Christian Helmut Pfob, Germany
Camille Pacher **(Technical Secretary)**, Canada

Mandate

Participation of patients and volunteers in medical research exposing them to ionizing radiation requires specific recommendations.

ICRP Task Group 126 mandate is to provide updated guidance since ICRP Publication 62 to follow significant advances in social norms, ethical frameworks, scientific RP evidence, and medical practice leading to new complexity in biomedical research involving ionizing radiation.

The scope is limited to human subjects and data. The report is intended to be of use to individuals, regulatory bodies and ethical committees concerned with the design, assessment (justification), evaluation and oversight of such research.

Progress to Date

Task group members are currently working within subgroups to review and update each chapter, after agreement have been reached on the main chapters to be considered (still subject to potential revision):

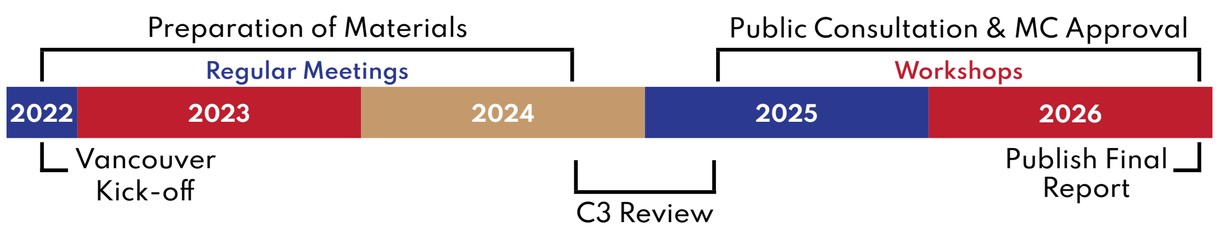
Content of the Report

1. Introduction
2. Ethical Aspects
3. Nature, Types and Magnitude of Radiation Risks
4. Methodology of Risk Assessment – Required Info
5. Principles of Research Design Involving Use of IR
6. Factors and Procedures Related to Project
7. Education and Training

Specific points currently under discussions are:

- How to address justification/benefit and dose constraint for volunteers
- Provide guidance to limit participation in multiple trials
- Role of ethical committees and feasibilitty to request an evaluation of doses

Timeline



Mentorship Programme

Mentees

Abraham Adewale Aremu, Nigeria
Isabel Adorio Elona, Philippines
Altay Myssayev, Spain
Venkatraman Pitchaikannu, India
Benjamin Puzantian, Canada
Kirti Tyagi, India
Mohammed sani Umar, Nigeria

Selection of candidates from Latin America in progress (call closed 27/10)

Role of Mentees

Assist in the organization of an international survey on national/regional practices of Radiation Protection in Research involving Humans

Investigate the principles and implementation of human biomedical research involving ionising radiation considering the ethical and data protection aspects together with design, assessment (justification), evaluation and oversight of human biomedical research

The mentees will contribute to:

- update literature searches,
- develop a questionnaire to survey current practices on the use of IR in biomedical research worldwide,
- establish contact with relevant authorities,
- distribute questionnaires and
- analyze results of the survey to be used by the wider Radiation Protection Community

A few questions (subjet to modifications)

Legislative / Regulatory Issues

4. What, if any, limits on the radiation doses allowed in biomedical research exist in your country for each category of human volunteer subjects? [Please mark one in each column]

	For patient volunteers	For healthy volunteers	For children
No limits	☐	☐	☐
Limit on the dose to the human volunteer in each individual study	☐	☐	☐
Limit on the combined dose to the human volunteer from all studies over certain time period, e.g. during one year	☐	☐	☐
Other	☐	☐	☐

If other, please elaborate_____

Management Issues

7. Is involvement of a **medical physicist/radiation protection expert** in the review and approval of research proposals that involve ionizing radiation required by regulations/guidelines?

a. ☐No
b. ☐Always
c. ☐Depends on exposure type

Human Volunteer-related Issues

9. Are volunteers in biomedical research paid?

a. ☐Yes
b. ☐No
c. ☐In certain studies
d. ☐I do not know

Please contact us to participate in the survey!

Isabelle Thierry-Chef
isabelle.thierrychef@isglobal.org
Hanne Waltenburg
hwa@sis.dk