

TG 126 - Radiological Protection in Human Biomedical Research

Chair Isabelle Thierry-Chef, Vice Chair Hanne Waltenburg (acting Benjamin Puzantian)


BACKGROUND

- Report 62 on Biomedical Research was published in 1991, since then
- Publication 138 on ethical foundations of the System of Radiological Protection
- TG 109 Ethics in Radiological Protection for Medical Diagnosis and Treatment
- TG 114 on Reasonableness and Tolerability

Journal of Radiological Protection

OPINION ARTICLE

Radiological protection in human research ethics using a case study: toward update of the ICRP Publication 62

Chieko Kurihara^{7,1} , Kimberly E Applegate^{6,2}, Jee Hyang Jeong³, Keiichi Akahane⁴ and Keon Wook Kang⁵

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[Journal of Radiological Protection, Volume 43, Number 4](#)

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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 based on 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. 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

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CONTENT

Task group members are working within subgroups to review and update each chapter with focus on

- Ethical concept
- Knowledge on radiation health effects and risk assessment

1 Introduction

2 Ethical Aspects

3 Nature, Types and Magnitude of Radiation Risks

4 Methodology of Risk Assessment – Required Info

5 Principles, factors and procedures for execution and evaluation of research projects

6 Education and training ([new chapter](#))

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TOPICS UNDER DISCUSSION

- How to address justification/benefit and dose constraint for volunteers
- Role of ethical committees and feasibility to request an evaluation of doses
- Importance of radiation experts/radiologists in review boards
- Evaluation of the net risk associated with the exposure performed specifically for research
- Provide guidance to limit participation in multiple trials
- Guidance on vulnerable populations (such as pregnant women, children)



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MENTORSHIP PROGRAMME

9 mentees for around the world with objective to

- 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 contributed to update literature, developed the **questionnaire** (survey chair Hanne / Benjamin), established contact with relevant authorities, distributed questionnaires and will **analyze results** of the survey to be used by the wider Radiation Protection Community
- **NEXT STEP: ACCESS AND ANALYSE REGULATORY DOCUMENTS FROM DIFFERENT COUNTRIES**



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SURVEY QUESTIONNAIRE



- 13 questions on the following **main topics**:
 - Regulatory issues (such as availability of guidelines or regulations?)
 - Level of doses for healthy volunteers vs patients?
 - Participation of medical physicists or radiation safety specialist in review boards?
 - Requirements to perform imaging or therapy on volunteers ? Financial reward?
 - How doses are evaluated?
 - What information on dose and risk is provided in informed consent?

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FEW QUESTIONS



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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Limit on the dose to the human volunteer in each Individual study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Limit on the combined dose to the human volunteer from all studies over certain time period, e.g. during one year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If other, please elaborate _____

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FEW QUESTIONS



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

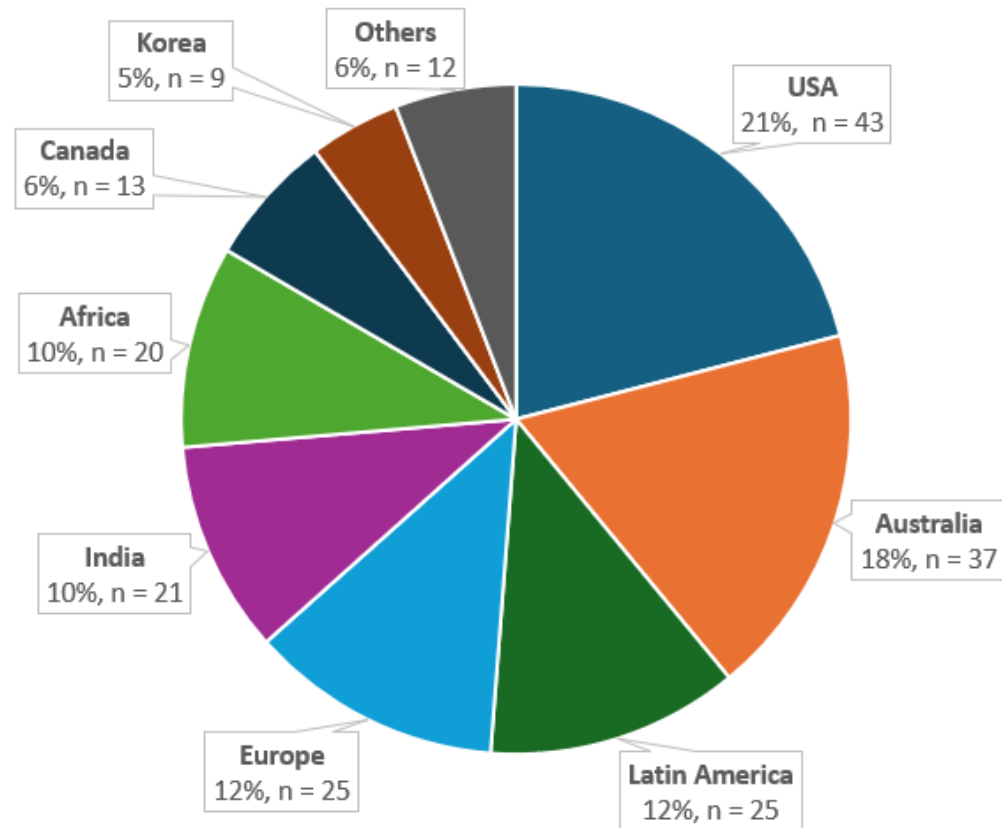
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PRELIMINARY ANALYSES - PARTICIPATION



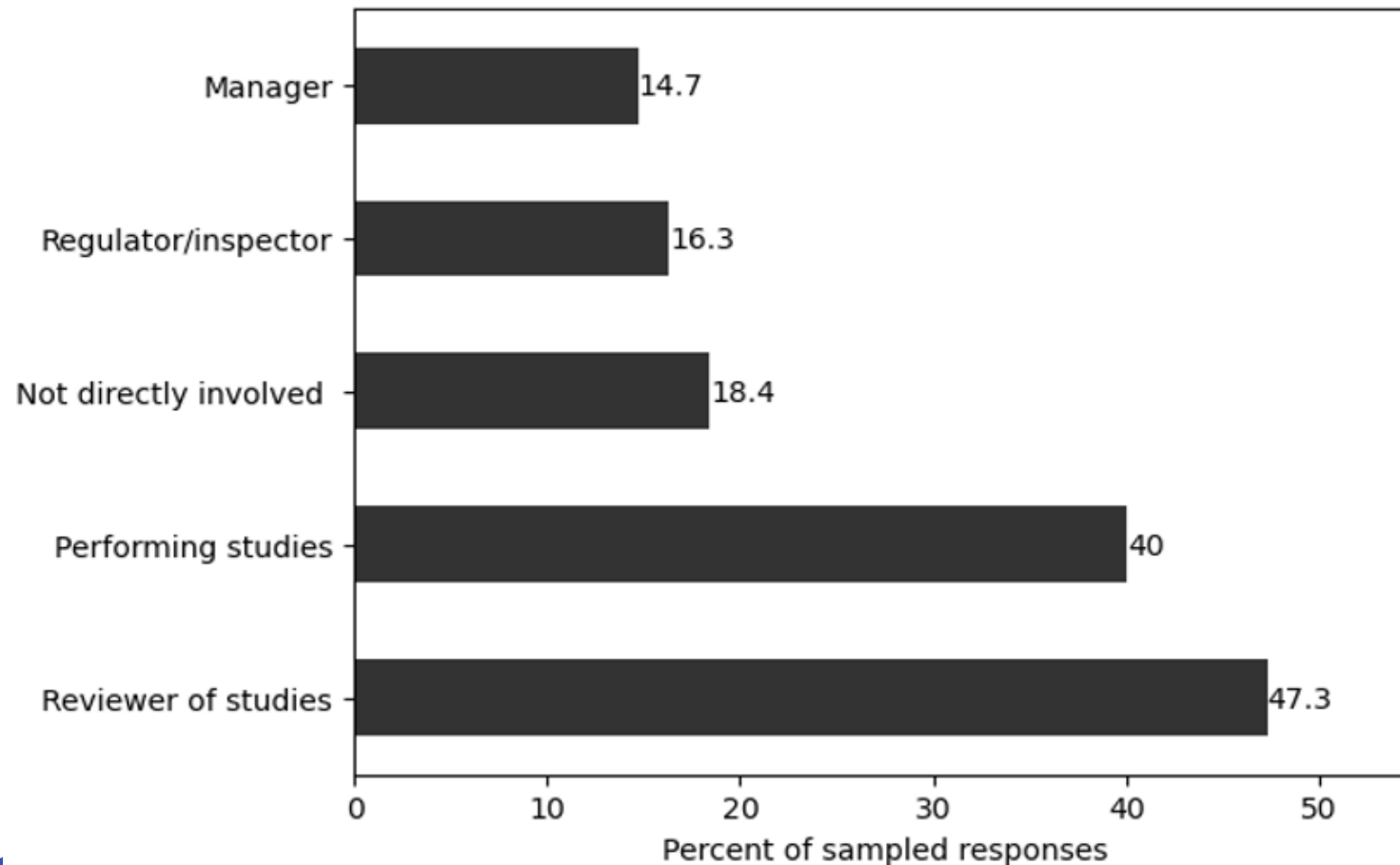
206 responses
43 countries
13 weeks

Completion rate:
62% (206/333)



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PRELIMINARY ANALYSES – SAMPLED GROUPS

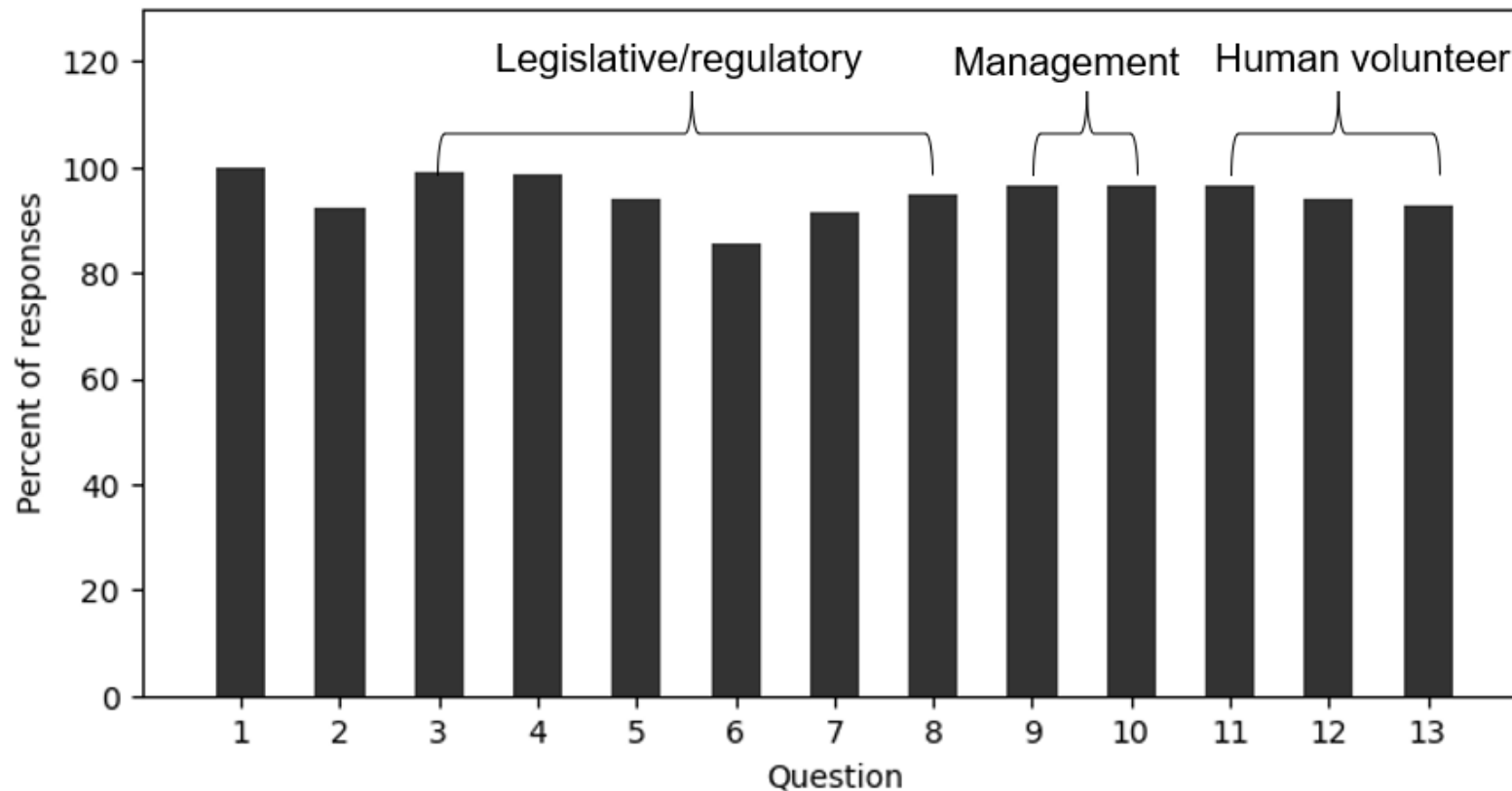


Mostly reviewer and performer of studies (87.4%)



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PRELIMINARY ANALYSES – RESPONSE BY QUESTION



Legislative:

Average 93.8%

Min: 85.4% (Q6)

Max: 99% (Q3)

Management:

96.6% (Q9, Q10)

Human volunteer:

Average 94.5%

Min: 92.7% (Q13)

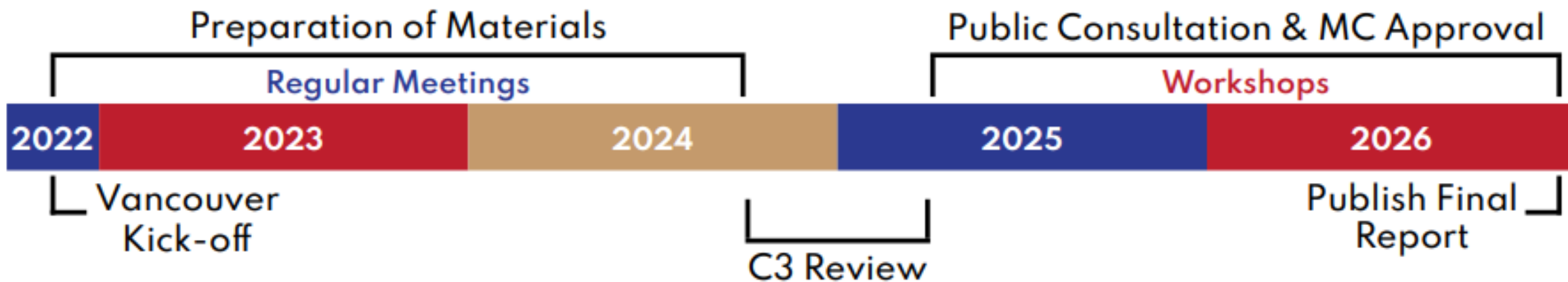
Follow-up information:

145 responses (70.7%)



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TIMELINE



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MEMBERS

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

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
- **Beatriz Bühler de Araújo**, Brazil
- **Luz Eliana Franco Olarte**, Colombia