

Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents





Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents



Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents.

ISBN 978-92-4-150841-4

© World Health Organization 2018

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Designed by Inís Communication Printed in Switzerland

Contents

	Acknowledgements Abbreviations	
	About this guidance document	
1	Defining the study population	
	1.1 Introduction	
	1.2 Pertinent information necessary to resolve Case scenario 1	
	1.3 Case scenario 1 resolution	
	1.4 Conclusions	
2	Autonomy, consent and assent	
	2.1 Introduction	
	2.2 Pertinent information necessary to resolve Case scenario 2	12
	2.3 Case scenario 2 resolution	
	2.4 Conclusions	
3	Reconciling conflicting ethical and legal obligations	
	with regard to adolescent research participants	
	3.1 Introduction	
	3.2 Pertinent information necessary to resolve Case scenario 3	
	3.3 Case scenario 3 resolution	
	3.4 Pertinent information necessary to resolve Case scenario 4	25
	3.5 Case scenario 4 resolution	
	3.6 Conclusions.	
4	Information-sharing	
	4.1 Introduction	
	4.2 Pertinent information to resolve Case scenario 5	
	4.3 Case scenario 5 resolution	
	4.4 Conclusions	
5	Conclusion	
	Glossary of terms	
	References	

Acknowledgements

We gratefully acknowledge the contributions of many individuals to the development of this document.

A technical consultation hosted by the World Health Organization (WHO) Department of Reproductive Health and Research on the sexual and reproductive health of young adolescents in low- and middle-income countries identified a pressing need for guidance on the ethical and safety issues to consider when conducting research with adolescents.

As follow-up to this meeting, a mapping of the available documents related to ethical considerations for sexual and reproductive health research with adolescents was conducted. Next, researchers and programme planners from high-, middle- and low-income countries were identified to define the key content to be included in the guidance document. Deepa Leah Persad solicited and collated feedback from this group, which included Rajib Acharya, Akin Bankole, Carmen Barroso, Linda-Gail Bekker, Marissa Billowitz, Claire Brindis, Fabian Cataldo, Marinella Della Negra, Jessica Dietrich, Annabel Erulkar, Adesgun Fatusi, Sarah Flicker, Janet Frohlich, Loretta Gavin, Marianne Haslegrave, Shireen Jejeebhoy, Rachel Jones, Susan Kasedde, Sabrina Kitaka, Sonal Mehta, AJ Melnikas, Ramiro Molina Cartes, Busiswe Nkala, Friday Okonofua, Helen Rees, Michael Resnick, John Santelli, Katie Schenk, Vinit Sharma, Renee Sieving, Susheela Singh, Catherine Slack, Ann Strode, Cynthia Summers, Johanne Sundby and Melissa Wallace. Based on the input received, a concept note was prepared.

In consultation with the WHO Ethics Review Committee, Jerome Amir Singh (Centre for the AIDS Programme of Research in South Africa, University of KwaZulu-Natal, Durban, South Africa, and Dalla Lana School of Public Health, University of Toronto, Toronto, Canada) was engaged to draft the document. The first draft was reviewed by a subgroup of the stakeholders consulted earlier, including Akin Bankole, Marinella Della Negra, Lee Fairlie, Lawrence Finer, Loretta Gavin, Shireen Jejeebhoy, Rachel Jones, Sabrina Kitaka, AJ Melnikas, Busiswe Nkala, John Santelli, Vinit Sharma, Susheela Singh, Catherine Slack, Ann Strode, Cynthia Summers and Melissa Wallace. Abha Saxena, Secretary of the WHO Ethics Review Committee, also reviewed the document and obtained inputs from researchers within and outside WHO.

The second draft received comments from researchers involved in the Global Early Adolescent Study, including Omaima El-Gibaly, Eleanor Faur, Caroline Kabiru, Chaohua Lou and Kristien Michielsen, who provided valuable inputs informed by their experiences in the field.

Drawing upon the feedback of these groups, a revised third version of the document was developed. Following a field test in South Africa by Jane Ferguson, the guidance was strengthened further. Pooja Parameshwar and Manahil Siddiqi, two young researchers, reviewed the document and provided input and feedback on the third draft.

Venkatraman Chandra-Mouli from the WHO Department of Reproductive Health and Research led the development of the document.

Abbreviations

CIOMS	Council for International Organizations of Medical Sciences
CRC	Convention on the Rights of the Child
EMA	European Medicines Agency
ICH	International Council for Harmonisation
ILO	International Labour Organization
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNFPA	United Nations Population Fund
UNHCR	Office of the United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund
WHO	World Health Organization

预览已结束, 完整报告链接和二维码如下:



https://www.yunbaogao.cn/report/index/report?reportId=5_25818