International Union against TB and Lung Disease
Ethics Advisory Group (EAG)

STANDARD OPERATING PROCEDURE

SOP-EAG 002 vs1 **IMPLEMENTATION DATE:**

SUBJECT:	**Procedure for the Assessing Risk Level of a research proposal on Human Participants by the International Union against TB and Lung Disease Ethics Advisory Group (EAG)**
DIVISION / SCOPE:	**International Union against TB and Lung Disease Ethics Advisory Group (EAG)**
AUTHOR: **REVISION:**	**EAG Chair**
PURPOSE:	This procedure describes the process to be followed by the EAG chair in assessing the risk level for a research proposal and then assigning appropriate reviewers
PREVIOUS VERSIONS / ***(REASON FOR REVISION)***	N/A
CONTENTS:	
APPROVALS:	**Signature of Chairperson** **Date:**

1. DEFINITIONS AND ABBREVIATIONS

FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
CFR	Code of Federal Regulations

2. REFERENCES

Bracken-Roche, D., Bell, E., Macdonald, M.E. and Racine, E. (2017). The concept of 'vulnerability' in research ethics: an in-depth analysis of policies and guidelines. *Health Research Policy and Systems*, 15 (1), 8, doi:10.1186/s12961-016-0164-6.

Horn, L, Sleem, H. and Ndebele, P. (2014). Research vulnerability. In: M. Kruger, P. Ndebele and L. Horn (Eds.), *Research ethics in Africa: A resource for research ethics committees*. Stellenbosch: SUN Press, pp. 81-90.

3. Introduction to Risk Categorisation

It is necessary for the EAG chair to assess the level of risk involved in undertaking research. As the risk level increases, there should be a higher level of scrutiny of the protocol involving more reviewers from the EAG. The risk may be to research participants or patients, to communities, to institutions, or even to the researchers themselves.

Risk refers to

- the likelihood of exposure to a particular negative consequence, and/or
- the magnitude of the possible consequences of exposure, and/or
- the possibility that research could result in harm.

It is essential to consider the individual – not an aggregated group – when assessing risk.

Harm refers to damage incurred (which may include physical, psychological/emotional, social, economic or legal harm) as an outcome of an action, or through emotional distress.

The onus of deciding the level of risk rests with the Chair of the EAG

4. Table of Risk Categorisation

This table identifies broad categories of risk. This is adapted from CFR 45 Part 46

Risk category	Definition	Example	Notes
No risk	No contact with identifiable individuals, *e.g.* when study involves anonymized information	*In vitro* laboratory study using commercially-available cell lines, bacterial cultures, etc Review of anonymized information in the public domain	These studies usually qualify for an ethics waiver
Minimal risk	Where the likelihood and magnitude of possible harm are no greater than those imposed by	Retrospective reviews of existing data, with non-identifiable/ routinely-collected/ aggregate data, and no human contact Questions about participant's everyday lives, activities and opinions, without	These studies can be approved in an expedited manner by the Chair and one other member

	daily life in a stable society, or are to be found in routine clinical testing	detailed identifiable information. No sensitive questions or topics No vulnerable participant categories;	of the EAG
Low risk	Where the only foreseeable risk is that of temporary discomfort, or where there may be some sensitivity involved in terms of the questions asked. This includes much operational research	Questions about participant's everyday lives, activities and opinions, which may include biographical information and some potentially sensitive questions and/or topics Taking of blood samples may cause minor discomfort No vulnerable participant categories	These studies can be approved in an expedited manner by the Chair and one other member of the EAG.
Medium risk	Where there is a possible risk of some harm for participants and/or the researcher, but where appropriate steps can be taken to mitigate or reduce risk	Sensitive topics and/or questions that may have potential for trauma and emotional distress Drug trial, pre-general release to the market May include vulnerable participant categories or marginalized groups. There is a clear justification to undertake the research using this participant group and/or using the proposed instruments, because likely benefit exceeds likely risks	These studies must be sent to the whole EAG. Two assessors must be assigned and a full review to be presented to the EAG
High risk	Where there is a real and foreseeable risk of harm, which may lead to serious adverse consequences if not managed in a responsible manner	Clinical procedures in which a successful outcome cannot be guaranteed, but where non-intervention is likely to result in harm to the individual Highly sensitive topics, Vulnerable or marginalized participant groups, or where multiple vulnerabilities exist Where the participants place themselves at risk of harm if they participate Where the researcher/s may place themselves at risk of harm Where the researcher/s may place themselves at risk of breaking the law, or may be legally required to report what they find, e.g. child abuse or neglect. In such instances, the researcher should consult a competent person or agency, as to whether referral to the Police or Social Welfare is warranted Researchers observing possible illegal activity from a distance, such as vendors selling tobacco to children who may or may not have been above the legal age for tobacco purchase or procurement of the services of a sex worker. Even if researchers are not themselves breaking the law, or are not sure of the illegality of the activity, these are high risk studies and as such should be reviewed by the whole committee/ Where the research may reveal information	These studies must be sent to the whole EAG. Two assessors must be assigned and a full review to be presented to the EAG

		that may place the participant or others at risk (e.g. victims of abuse, violence, crime), requiring intervention from state institutions There is a clear justification to undertake the research using this participant group and/or using the proposed instruments, despite the potential risks	