**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:** EAG Chair

**REVISION:**

**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

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**APPROVALS:**

<table>
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<tr>
<th>Signature of Chairperson</th>
<th>Date:</th>
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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


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

<table>
<thead>
<tr>
<th>Risk category</th>
<th>Definition</th>
<th>Example</th>
<th>Notes</th>
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<tbody>
<tr>
<td>No risk</td>
<td>No contact with identifiable individuals, e.g. when study involves anonymous information</td>
<td><em>In vitro</em> laboratory study using commercially-available cell lines, bacterial cultures, etc</td>
<td>These studies usually qualify for an ethics waiver</td>
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<tr>
<td>Minimal risk</td>
<td>Where the likelihood and magnitude of possible harm are no greater than those imposed by</td>
<td>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</td>
<td>These studies can be approved in an expedited manner by the Chair and one other member</td>
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<tr>
<td>Risk Level</td>
<td>Description</td>
<td>Examples</td>
<td>Approval Procedure</td>
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<tr>
<td>Low risk</td>
<td>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.</td>
<td>These studies can be approved in an expedited manner by the Chair and one other member of the EAG.</td>
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<tr>
<td>Medium risk</td>
<td>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.</td>
<td>These studies must be sent to the whole EAG. Two assessors must be assigned and a full review to be presented to the EAG.</td>
<td></td>
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<tr>
<td>High risk</td>
<td>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.</td>
<td>These studies must be sent to the whole EAG. Two assessors must be assigned and a full review to be presented to the EAG.</td>
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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.
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<th>that may place the participant or others at risk (e.g. victims of abuse, violence, crime), requiring intervention from state institutions</th>
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<td>There is a clear justification to undertake the research using this participant group and/or using the proposed instruments, despite the potential risks</td>
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