# Post Research Benefits

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# Post Research Benefits

1. First in man studies of drugs/devices to elucidate tolerance/safety
2. A controlled clinical trial to elucidate efficacy

Establish that the tested drug/intervention is

1. unsafe in humans
2. Ineffective in humans

What next?
Sponsors
Research subjects

# Post Research Benefits

1. First in man studies of drugs/devices to elucidate tolerance/safety
2. A controlled clinical trial to elucidate efficacy

Establish that the tested drug/intervention is
1. acceptably safe in humans
2. effective in humans

What next?

Patents, Publication in indexed literature
The drug/intervention is approved by regulators
Large scale production, marketing and sales
Financial & other benefits to sponsors

**What are the benefits to research subjects and/ or the participant community?**

In the developed countries:
The community can access information & understand the new findings.

The newly approved drugs & devices are generally made available via the healthcare system/insurance schemes.

**The risk to research participants is worth the benefits**

## What are the benefits to research subjects and/ or the participant community?

In the **underdeveloped** countries:
The community does not access the information & will not understand the new findings.
The newly approved drugs & devices are NOT made available
via the healthcare system/insurance schemes.

In the absence of access to benefits only the risks are taken.

The participants/community is often unaware of risk-benefit concepts
Generally pleased that they received some extra attention during the study

**NO BENEFIT TO PARTICIPANTS IN THE UNDERDEVELOPED WORLD**
**BENEFITS LIMITED TO SPONSORS FROM THE DEVELOPED COUNTRIES**

Should multinational-sponsored research be conducted in the developing countries?

**NO**

**YES, BUT ?**

**Reasons for conducting research in the underdeveloped world**

1. High prevalence of certain diseases in those areas
2. Easy/less stringent ethics committees
3. Easy recruitment/informed consent
4. Easy large/quick recruitment
5. Low cost
6. Less accountability in case of complications

1,4,5 are probably the only acceptable reasons.

Reasons 2,3,6 should be avoided.

Consider being part of a multicentre study where ethics have
Been approved in a developed country.
Consider indemnifying participants.

# Types of research that are appropriate

Sponsors & ERCs should consider studies which are:

**1. responsive to the healthcare priorities or needs** within the host developing country and be relevant to the short- or long-term needs or priorities of the region(s) or population(s) where the research is to be carried out.
Eg: drugs for TB, HIV, Malaria

or be of

2. **'global public benefit'** and have potential relevance to the health of humans anywhere in the world.

## Research that has a 'global public benefit‘

include basic research into human biology, human genetic variation and the development of research tools (such as genetic maps or databases).
It is usual, in such types of non-therapeutic research, that neither the participants in the research nor anyone of their generation anywhere in the world are likely to directly benefit from the research outcomes.
However, subsequent research, using the information created by these types of studies, could have a potential to benefit the health of anyone globally.

## Post-research access to interventions demonstrated to be effective

**To the community/region/country**

there should be a reasonable expectation that post-research access to interventions will be provided. This is achieved to some extent by ensuring that the research has 'local applicability' (to be locally applicable in this context, the treatment must be or could in the foreseeable future become available to the community in those areas and be deliverable within existing structures (or structures which are to be or could readily be developed).
However, in some cases it may be difficult to estimate with any degree of accuracy how financially or logistically feasible it would be for a successful intervention to become available to patients within the host country.

Principal investigators should indicate in their application forms whether post-research access needs to be addressed and how this might be achieved.
ERCs/funding agencies should encourage grant applicants to consider how post-research access could be ensured.
This may require the instigation of processes, such as discussions, with different stakeholders prior to the research being carried out.

**Post-research access: individual research participants**

Some ERCs/sponsors considers that, in some cases, post-research access to interventions ought to be provided to participants; in these cases, they may not approve /fund the proposed research until it is satisfied that such provision will be made. Such decisions will depend on various factors including:

1.Whether the condition under investigation is chronic or acute.
They may consider it an ethical requirement to guarantee post-research access to treatments to participants involved in research investigating chronic or progressive conditions.

2.The nature of the research question and whether it implies that ongoing care should be provided.
Examples could include research not intended to identify a new effective intervention but seeking to understand a condition, or research investigating how a particular treatment affects the progress of a disease.

# Collateral Benefits

Transient, limited to the study period.

Collateral benefits may arise as a by-product of carrying out research, whether or not they are necessary for the research design.

Examples include the provision of healthcare benefits to communities during a research study, strengthening local research capacity and providing research-related technical or clinical equipment.

Better patient supervision and follow up,

Thus, local clinics associated with a research project may benefit from improved diagnostic, medical and scientific expertise.

Care must be taken that such benefits do not:
1. adversely affect the local research environment
(e.g. by raising expectations that all subsequent research will provide similar benefits)

2. amount to coercive or 'undue' influence to participate in a research study.

Where recompense for participating in research is offered,
either financial or in kind, it should be set at an appropriate level to cover,
for example, reasonable expenses and subsistence costs.

Where it is proposed to offer healthcare unrelated to the specific research question,
It is recommended that this should usually be the standard treatment
that is available locally.

The principal investigator should consider the sustainability of any collateral
benefits once the research is over.

Details of any such proposals should form part of the grant application and be
approved by relevant ethics committees.

Thank you

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