



**University of
Zurich^{UZH}**

Institute of Biomedical Ethics and History of Medicine

Offering Financial Incentives to Participants in Health and Breastfeeding Research

Forum for Global Health Ethics Webinar

Wednesday, 13 April 2022

This Forum for Global Health Ethics Webinar is organised by:

- Institute of Biomedical Ethics and History of Medicine, University of Zurich, a WHO Collaborating Centre for Bioethics
- *Swiss Medical Weekly*
- The Global Health Network, University of Oxford
- LactaHub – A Resource for Evidence-based Breastfeeding Intelligence



**University of
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**Swiss Medical
Weekly**



Moderated by



Nikola Biller-Andorno, Co-creator of EFBRI; Director of the Institute of Biomedical Ethics and History of Medicine, University of Zurich, Switzerland, a WHO Collaborating Centre for Bioethics



Tania Manríquez Roa, Coordinator of the Forum for Global Health Ethics, Institute of Biomedical Ethics and History of Medicine, University of Zurich, Switzerland, a WHO Collaborating Centre for Bioethics

Join us for our expert discussion today with



Mary Ani-Amponsah, Researcher, School of Nursing and Midwifery, College of Health Sciences, University of Ghana; Country Representative for the Council of International Neonatal Nurses, Ghana



Farah Asif, Clinical Research Administrator, Head of the Clinical Research Office, and Secretary of the Scientific Review Committee and the Institutional Review Board, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Pakistan



David Yanagizawa-Drott, Professor of Development and Emerging Markets at the Department of Economics and Managing Director of the LRF Center for Economics of Breastfeeding, University of Zurich, Switzerland



David B. Resnik, Bioethicist at the National Institute of Environmental Health Sciences, National Institutes of Health, USA

Technical information



Questions: If you are joining us on **Zoom**, please ask your question in the public Q&A section that you can find in the bottom bar of your screen. If you are tuning in via The Global Health Network **Facebook** page, please send your question to The Global Health Network via Facebook Messenger. **We will answer as many questions as possible during the webinar Q&A.**



Technical issues: If you cannot hear or see us, please check your computer preferences, close other programmes, and check your sound level. If issues persist, you might need to close and restart the Zoom meeting, or join via Facebook.



Knowledge sharing: In the spirit of open access and knowledge sharing, we are recording this meeting to make it accessible for a wider audience on the Institute of Biomedical Ethic's website and on LactaHub.



Video and audio: Your camera is automatically deactivated and all microphones are muted.

Our agenda for today

- 10 min. Introduction and short update on EFBRI – An Evolving Ethical Framework Informing Breastfeeding Research and Interventions
- 40 min. Experts present their views and share their experiences
- 35 min. Q&A with the audience and the experts
- 5 min. Wrap up and closing remarks

EFBRI - An Evolving Ethical Framework Informing Breastfeeding Research and Interventions

Nikola Biller-Andorno

EFBRI - An Evolving Ethical Framework Informing Breastfeeding Research and Interventions

- Open access compilation of ethical principles to guide research on breastfeeding and lactation
- Lays the groundwork for best practice ethics in healthcare policy, implementation and funding activities
- Based on a review of Swiss and international laws and guidelines
- Bridges research and practice
- Evolving tool: feedback from research community
- Interactive format, easy to find, simple to use
- EFBRI is published on www.LactaHub.org



Today's webinar follows up on the LactaWebinar on EFBRI from 10 March 2022. Recording is accessible here: www.LactaEthics.org

EFBRI and financial incentives

- No person can receive a payment or any other pecuniary benefit for taking part in a research project that has an expected direct benefit
 - Participation in a research projects with no expected direct benefit may be appropriately remunerated
 - Research protocols must include information on incentives for participants and provisions for treating and/or compensating those who are harmed
 - Human body or body parts may not be disposed of or acquired for research purposes in return for payment or other non-cash advantages
-
- What are appropriate incentives in the case of research with no expected direct benefit?
 - What about public health/implementation research?

Swissethics guidelines and open questions

Key points:

- Swiss ethics committees make case-by-case decisions as to whether a financial contribution and its amount are appropriate or not
- Critical assessment of financial contributions with a pure incentive character and uncoupled from effort and burden
- Higher likelihood of individual direct benefit from research as well as higher risk render incentives more problematic
- Offering financial contributions to participants from vulnerable groups is only conceivable in exceptional cases

Questions:

- How can we establish adequate financial incentives in health research that takes place in different contexts?
- How to offer adequate incentives to influence health-related behaviours and outcomes?

Insights viewpoint on financial incentives

International ethics guidelines:

- Helsinki Declaration
- Council for International Organizations of Medical Sciences (CIOMS)

Main ethical concerns:

- Undue inducement
- Exploitation
- Biased enrolment
- Bribery

Potential advantages:

- Removing financial barriers to participation
- Obtaining diverse samples
- Fostering behavioural change

Established in 1871

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Financial incentives for participants in health research: when are they ethical?

Tania Manríquez Roa^{a,b}, Nikola Biller-Andorno^{a,b}

^a Institute of Biomedical Ethics and History of Medicine, University of Zurich, Switzerland
^b Digital Society Initiative, University of Zurich, Switzerland

Offering financial incentives to recruit participants, retain them and promote health-related behaviours is a common practice in health research. The development of health research standards has given rise to a rich and long-standing debate regarding the ethical issues associated with the use of financial incentives. Some researchers argue that financial incentives compromise the integrity of the research process and its outcomes. Since financial incentives can influence decision-making, they may jeopardise the voluntariness of research participants' consent. In particular, they argue that the use of financial incentives may lead to undue inducement, exploitation and biased enrolment of research participants. At the same time, other researchers argue that financial incentives represent a flexible tool that can be designed in ways that do not compromise scientific integrity. They highlight that financial incentives can be fair inducements for participation, a way of acknowledging participants' time and effort, and a means to achieve diverse sample compositions. They also point out that in some situations, these incentives can enable research that would otherwise be unfeasible.

In health research, financial incentives are monetary benefits (e.g., payments, vouchers, gifts) that are used in the recruitment process to get an adequate sample size and composition, to retain participants throughout the course of the study, or to promote health-related behaviours or outcomes. Although the general discussion on these incentives has developed substantially in recent years, different ethical implications may arise depending on the specific nature of the research that is being conducted and the purpose of using financial incentives in each study. An emerging area of health research where this discussion merits further attention is implementation research involving financial incentives to promote health-related behaviours and, more specifically, research of this kind carried out in low-income settings.

International ethics guidelines have advanced in providing more specific recommendations over time. The Helsinki Declaration briefly established the requirement to include information regarding incentives for participants and compensations for harm in study protocols [1], and more recently the Council for International Organizations of Medical Sciences (CIOMS) provided detailed recommendations on how to define reimbursements and compensations [2]. CIOMS also highlighted the danger of

undue inducement, defined what are appropriate and unacceptable compensations, suggested ways to establish adequate monetary compensations, stressed the need to compensate people who are incapable of giving an informed consent in a way that benefits them and stated that participants must receive proportional compensation when they withdraw from a study – owing to either research-related harm or unwillingness of the participant to continue [2]. Although paying study participants is generally accepted in health research, countries have different approaches to establishing when payments are allowed. In Switzerland, for instance, no person can receive a payment or non-cash advantage for taking part in a research project that has an expected direct benefit [3]. Offering financial incentives to promote health-related behaviours is not explicit in this norm, but in principle they could be allowed as long as the behavioural requirements are freely accepted by participants, limited in time, and not excessive, disproportionate or harmful.

The academic literature distinguishes three acceptable rationales for payments to research participants: reimbursement of out-of-pocket expenses, compensation for the time and burdens of participation, and incentives to participate [4]. Although reimbursements and compensations remain relatively uncontroversial, incentives have raised an academic debate. Advocates argue that the use of financial incentives in health research offers potential advantages for different types of studies and in various socioeconomic contexts. For example, financial incentives are thought to be relevant in the recruitment and retention of healthy participants for phase I clinical trials, and in studies carried out in socioeconomically disadvantaged populations – either in poorer countries or in impoverished areas of richer countries [5]. Although this raises ethical concerns, financial incentives could overcome financial barriers to participation and be effective in obtaining samples with sufficient socioeconomic, ethnic and gender diversity. Interestingly, the potential advantages for health promotion are analogous: financial incentives can be effective and benefit society at large by fostering behavioural change and removing financial barriers so that individuals can adopt new behaviours [6].

There are four main ethical concerns regarding the use of financial incentives in health research. First, financial

Correspondence:
Prof. Nikola Biller-Andorno, MD, PhD
Institute of Biomedical Ethics and History of Medicine
University of Zurich
Winterthurerstrasse 30
CH-8056 Zurich
biller-andorno[at]
hmc.uzh.ch

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Mary Ani-Amponsah

Outline

Global evidence of financial incentives in research

How financial incentives impact breastfeeding research

Ethical issues

Looking into the future

Global evidence on financial incentives in health research

- There is extensive unmet social need that would require support and sustained charitable moves; this calls for a need to optimize research procedures as vulnerabilities are engendered (**CIPD, 2022; Toosi, 2017; Kaye, 2021**).
- Many participants engage in research for altruistic reasons (**Broekstra et al., 2020; Zutlevics, 2016; Young et al., 2020**)
- Monetary incentives is a common phenomena (**Cerasoli et al 2014; CIPD, 2022; Young et al., 2020**), persons in research can wane by reducing intrinsic motivation - to behave altruistically or undertake civic duties in matters needing research. Very few people engage as research participants for the benefit of others (**Zutlevics, 2016**)
- Financial incentives are considered as inducements – soon most potential participants might want to be paid (**Zutlevics, 2016**) but it is not necessarily a motivator in all circumstances (**Broekstra et al., 2020; Young et al., 2020**); differentiated strategies can be designed and tailored to enhance retention (**Costello et al., 2020; Toosi, et al., 2017**)
- Allowing inducements in research might lead to commercialization (**Zutlevics, 2016**) individuals who are motivated by civic duty might be influenced in their decision to participate in research (**CIPD, 2022; Halpern et al., 2021**) and direct their charitable efforts to other places of choice.

How financial incentives impact breastfeeding research

- The positive effect of breastfeeding on an infant's health and development is widely documented (**CDC, 2021; Manyeh et al., 2020; WHO, 2022**), but breastfeeding prevalence is low in many communities (**Relton et al., 2018; Manyeh et al., 2020; WHO, 2022**). Financial incentives to improve breastfeeding prevalence is a growing phenomenon.
- Financial incentives increase breastfeeding prevalence at 6 to 8 weeks (**Relton et al., 2018**); monetary incentives for breastfeeding considered unacceptable; rather investments into alternative, structural interventions to support breastfeeding recommended (**Gilles et al., 2015; Manyeh et al., 2020**).
- However, there is substantive evidence for preference across diversities based on individual characteristics; these mediate preferences for, and motives for incentive schemes (**Becker et al., 2018**); these open up new ethical dialogue spaces...

Looking into the future of incentives in health and breastfeeding research



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Farah Asif

Offering financial incentives to participants in health and breastfeeding research I

To give or not to give

What are the ethical issues?

What does empirical research tell?

Unanswered questions

Offering financial incentives to participants in health and breastfeeding research II

What is appropriate to offer as financial incentives?

How to assess?

Identifying responsibilities

To give or not to give I

- To give money as compensation for research participation that often involves the substantial time and effort, discomfort
- To give a “benefit” to research participants
- To give as a token of appreciation

To give or not to give II

- Do people participate in research for financial incentives?
OR
- Why do people participate in research?
 - Attracted to research and motivated to participate for curiosity
 - Philanthropy
 - For the sake of generation of scientific knowledge
 - Thrill
 - Attention provided by physicians
 - Hope of personal therapeutic benefit
 - Motivated to get money

What empirical research tells about financial incentives I

- Studies that have systematically investigated volunteer motivation have found financial rewards to be an important motivator among normal healthy volunteers in their decision to participate in clinical trials. Also evident is that differences based on demographic characteristics exist in the motivation and rates of volunteerism.
- Studies indicate that the offer of financial compensation is one of the main reasons why subjects participate in research.
- However, subjects often participate in research for non-financial reasons, such as to gain access to medical treatment or to contribute to the advancement of scientific knowledge or public health.
- Empirical research indicates that research subjects are not unduly influenced by modest financial incentives for participation.
- There are studies on healthy volunteers which have shown that while monetary incentives influences the decision to participate in research, it does not adversely impact judgments of risk.

What empirical research tells about financial incentives II

- Healthy volunteers who participate in Phase I clinical trials, in which participants receive no medical benefits, financial incentives play a major role, while only a small role in encouraging patients to enroll in Phase II or III clinical trials in which participants receive treatment.
- It should be remembered that empirical evidence demonstrating that payment is necessary and/or effective for the recruitment of clinical research subjects is limited.

Ethical issues

- Undue inducements
- Exploitation
- Biased enrollment or threat to study integrity
- Unequal payments
- Ethical issues related to vulnerable populations

Identifying responsibilities I

- It is researchers' responsibility to plan out and justify to the Research Ethics Boards (REBs) what amount of money should be offered as financial incentive.
- REBs should perform thorough assessment of risks.
- When offered, incentives should be appropriate in type and amount. Incentives should not be so large or attractive as to encourage disregard of the risks associated with participation.
- Researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and capacity of participants, the customs and practices of the community.
- When determining an appropriate level of payment, investigators and oversight committees should consider the amount of time participants spend on (1) research activities, (2) the risk, pain, discomfort, and inconvenience associated with research procedures, (3) travel costs.

Identifying responsibilities II

- Investigators and oversight committees should work together to establish appropriate financial incentives for research participants.
- Institutional Review Boards (IRBs) should not consider payment a benefit to offset research risks when deciding whether or not to approve a study. IRBs evaluate whether the risks in a research study are justified by potential benefits – otherwise unacceptable risks cannot be made acceptable by offering money to subjects.

David Yanagizawa-Drott

David B. Resnik

Why are financial incentives offered?

To promote enrollment

To compensate participants for their time, effort, etc.

Why is money an ethical issue?

May undermine free choice which is essential to informed consent

May encourage exploitation of low-income participants or children

Informed consent

To be ethically and legally valid, consent should take place under conditions that minimize the possibility of coercion or undue influence (Resnik 2018).

Review boards sometimes think the money can be coercive, but this is a conceptual mistake, because coercion involves force, intimidation, or the threat of harm (Wertheimer and Miller 2008).

Undue inducement

Review boards are sometimes concerned that offering participants too much money may interfere with their judgment and reasoning so that they are too eager to enroll or remain in the study.

As a result, they may lie to qualify for the study and earn money or to stay in the study, or they may overestimate personal benefits and underestimate risks when making the decision to enroll.

However, empirical research does not support the hypothesis that financial incentives interfere with the judgment and reasoning of research participants.

Studies on the influence of financial incentives on willingness to participate in research and judgments of risk

- **Bentley and Thacker (2004)** surveyed 317 pharmacy students concerning their willingness to participate in three different types of studies, stratified by risk (low, medium, high) and payments for participation (\$350, \$800, \$1800). They found that payment influenced willingness to participate but not perception of risk.
- **Cryder et al. (2010)** surveyed 1,857 participants who lived in Pittsburgh, PA or were readers of the New York Times. Participants were randomized to receive information about a hypothetical study. The groups were offered \$25, \$100, or \$1000 for participation. The study found that the amount of payment affected willingness to participate but did impact perception of risk.
- **Mantzari et al. (2014)** surveyed 275 university faculties and students and found that the amount of money offered influenced the decision to participate in a hypothetical study involving ingestion of an experimental medication but did not affect risk perception.
- **Halpern et al. (2021)** evaluated the effect risk perception and financial incentives on willingness to participate in two different clinical trials involving 1296 participants. They found that money affects willingness to participate but not risk perception.

Studies on research participants who lie to investigators to earn money

- Evidence indicates that a significant percentage of participants, especially so-called “professional research subjects” are willing to lie to investigators in order to earn money to qualify for studies (**Abadie 2010; Devine et al. 2013**).
- **Fernandez Lynch et al. (2018)** conducted a survey experiment involving 2,275 participants to determine whether the amount of money offered (ranging from \$0 for the control group to up to \$20) for study participation encourages individuals to lie to investigators about influenza vaccination status to qualify for a study. They found that 11% to 23% of participants were willing to lie to about their vaccination status if money was offered. However, the amount of money offered did not affect willingness to lie, so some people appear to be willing to lie to earn money in any case.

Limitations of these studies

- More research is needed on the relationship between demographic variables (such as income, race, ethnicity, and education) and the influence of money on willingness to participate, risk perception, and willingness to lie.
- It may be the case that low-income groups are more influenced by money than high-income groups.

Exploitation I

Exploitation involves taking unjust or unfair advantage of a person or a group of people (Wertheimer 1999).

Exploitation of individuals is a concern when people are underpaid for research participation in studies that offer them no medical benefits but expose them to significant risks (such as Phase I pharmacology trials) because these individuals would not receive a fair share of the benefits (Gelinas et al. 2018; Resnik 2019).

Payment should strike a balance between too much (possibility of undue inducement) and too little (exploitation) (Resnik 2018; Gelinas et al. 2018).

Exploitation II

Exploitation of groups is a concern because low-income people disproportionately participate in no-benefit, high risk studies (Elliot and Abadie 2008; Resnik 2019). Low-income parents may also exploit their own children by enrolling them in studies (Resnik 2018).

This is a difficult problem to address because it has to do with social and economic factors outside of the research context, such as poverty and socioeconomic disparities.

Offering more money to high-income participants to balance enrollment is not a solution, because this would be unfair. Expanding recruitment efforts to different groups may be a better solution.

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Q&A with the audience and the experts

Thank you very much

Contact

ethics@lactahub.org

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Next webinar Proportionality and Evidence-Based Pandemic Management, June 2022

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Contact

globalhealthethics@ibme.uzh.ch