

Inducement & Compensation in Research

By

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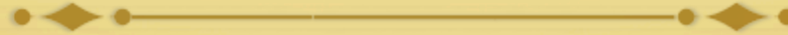
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Introduction



- ✦ Often, clinical research subjects are offered payment, in an effort to enhance recruitment by providing an incentive to take part or enabling subjects to participate without financial sacrifice

Introduction



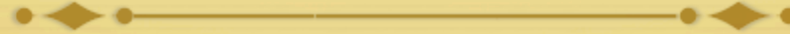
- ✦ Although this is common , yet the practice is uneven and many times contentious in many societies.

Introduction



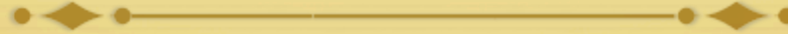
- ✦ Concern exists regarding the potential for payment to unduly influence participation and thus obscure risks, impair judgment, or encourage misrepresentation.

Introduction



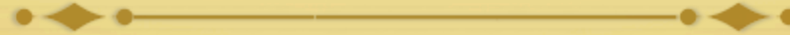
- ✦ Heightening these concerns is the participation not only of adults but also of children in pediatric research trials.
- ✦ Thorough assessment of risks, careful eligibility screening, and attention to a participant's freedom to refuse all serve to reduce the possibility of compensation adversely affecting the individual and/or the study.

Introduction



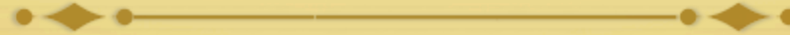
- ✦ Research Ethics Committees review currently evaluate payment proposals with minimal guidance from federal regulations.
- ✦ Here, reasons for providing payment, payment models, & ethical concerns are examined.

What is inducement



- ✦ A positive motivational influence
- ✦ In the context of research, is a reward given to anyone who volunteer to participate in a research

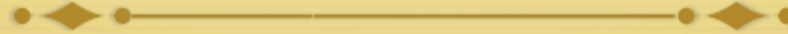
What is inducement



Inducements could be in form of

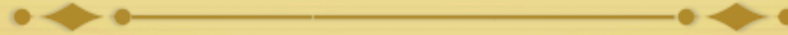
- ✦ **free care**
- ✦ **medical examination**
- ✦ **provision of drugs**
- ✦ **Gifts**
- ✦ **Cash** (appears to be the most common type of inducement, Dicket et al, 2002).

Need / Basis for Inducement in Research



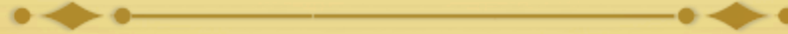
- ✦ Reimbursement for expenses (and possibly lost wages lost wages) to reduce the barrier of financial sacrifice for participants

Need / Basis for Inducement in Research



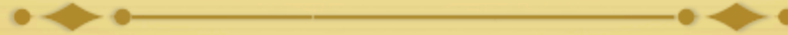
- ✦ Fair compensation or remuneration for the time and inconvenience of research participation (e.g. staying in a hospital, answering personal and sensitive questions)

Need / Basis for Inducement in Research



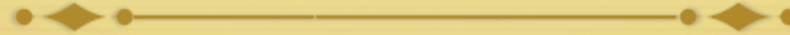
- ✦ Participation in a research involves risks (physical, psychological, emotional) and benefits

Need / Basis for Inducement in Research



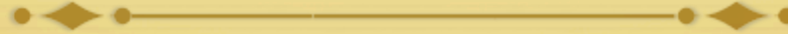
- ✦ Some participants do not directly benefit from a research but bear the risks.

Need / Basis for Inducement in Research



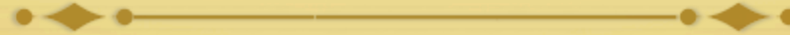
- ✦ At times, a specific population or people with peculiar attributes are required

Need / Basis for Inducement in Research



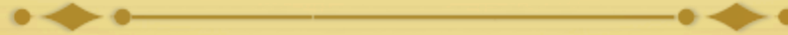
- ✦ Some research require enrolment a large number / sufficient number of people promptly

Challenges Involved in Inducement



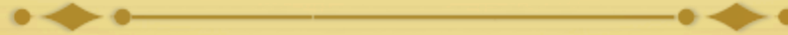
- ✦ Raising excessive or unrealistic enthusiasm about the possible benefits of the research to potential participants could be a potential source of undue inducement

Challenges Involved in Inducement



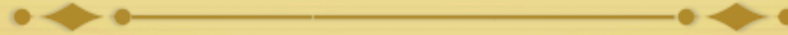
- ✦ E.g. promising prospective participants that a drug being tried will cure a health condition (Dunn and Chadwick, 2002)

Challenges Involved in Inducement



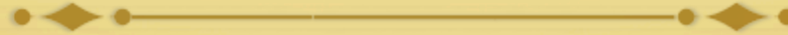
- ✦ At the same time payment should not be too low as to serve as an exploitation of research participants

Challenges Involved in Inducement



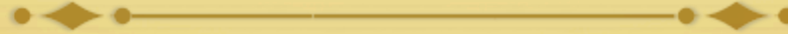
- ✦ It is sometimes difficult to distinguish between acceptable inducement and undue influence to participate in research in some settings
- ✦ For example, an unemployed person or student may view payment differently from an employed person

Challenges Involved in Inducement



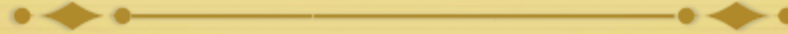
- ✦ Someone without access to care may or may not be unduly influenced to participate in research simply to receive such care
- ✦ E.g. in the trial of the drug Trovan by Pfizer, best care and best available bed space was offered to anyone willing to participate

Key point



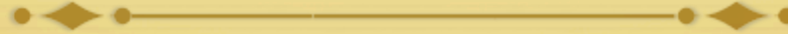
- ✦ A prospective research participant may be induced to enroll in research to obtain a better diagnosis or access to a drug not otherwise available (CIOMS, 2002)

Key point



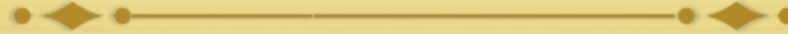
- ✦ Payments in money or in kind to research participants should not be so large as to persuade them to take undue risks or volunteer against their better judgment.

Key point



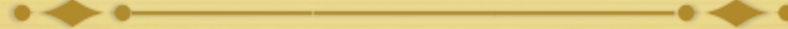
- ✦ Payments or rewards that undermine a person's capacity to exercise free choice invalidate consent (CIOMS, 2002)

Compensation for Research-Related Injuries



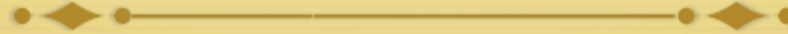
- ✦ Where appropriate, as determined by HREC, researchers and sponsors shall provide complete medical care and commensurate compensation for all research related injuries that participant may suffer

Compensation for Research-Related Injuries



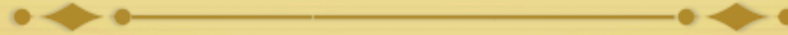
- ✦ Where appropriate, as determined by HREC, researchers and research sponsors may be required to provide evidence of insurance coverage of the research to provide adequate compensation for research related injuries, their care and compensation

Compensation for Research-Related Injuries



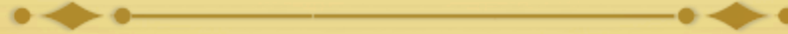
- ✦ Under no circumstances may research participants be asked to waive their legal rights, including the right to legal redress of research related injuries & compensations

Free Treatment/Referral



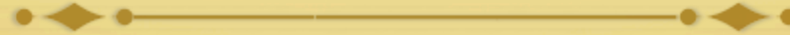
- ✦ Prospective participants found to have unrelated disease to the research or cannot be enrolled in a research because they do not meet inclusion criteria, should be offered appropriate provide free treatment or refer such persons to an appropriate agency for care

Free Treatment/Referral



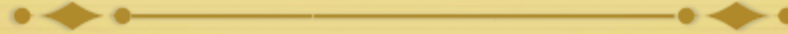
- ✦ A guardian asked to give permission on behalf of an incompetent person should not be offered any recompense other than reimbursement for travel cost

Free Treatment/Referral



- ✦ A participant who withdraws from a study due to adverse events such as side-effects of the study drug, or withdraws on health grounds should be paid as if full participation has taken place

How to Make Inducement Ethical



- ✦ A participant who withdraws for other reasons should be paid on a pro-rated basis:
- ✦ An investigator who must remove a participant from a study for willful noncompliance is entitled to withhold part or all of the payment p 46 (CIOMS, 2002)

Problems With Inducement in a Setting Like Nigeria



- ✦ The distinction between ethically acceptable monetary inducement and undue inducement of research participants is blurred in Nigeria because of widespread poverty
- ✦ For example, the percentage of Nigerians living in absolute poverty rose from 28% at independence in 1960 to 48% in 1998 (UNDP, 2001). Poor persons may enroll in a research that is not in their best interest if there is a prospect of receiving of inducement

Problems With Inducement in a Setting like Nigeria



- ✦ There is no written policy in many institutions in Nigeria regarding payment of research participants; so each researcher uses his own judgment in fixing the amount of money to be paid to research participants
- ✦ Monetary inducement is contentious because of precedent setting
- ✦ Payment of a uniform amount of money to research participants in all research is not realistic because budgets and risks vary

Problems about inducement contd

- ✦ One way of addressing this problem may be to offer research participants in-kind payment instead of money.
- ✦ Although the materials offered also have financial value, it may have diminished role of inducement if this is not disclosed during recruitment process
- ✦ Many research projects in Nigeria are increasingly adopting this strategy of offering research participants condoms and educational materials such as posters and handbills on HIV prevention as an alternative to monetary payment

Role of HREC



- ✦ All payments, reimbursements and medical services provided to research participants must be approved by the HREC
- ✦ Monetary and in-kind payment must be evaluated in the context of the traditions of the particular culture and population in which they are offered, to determine whether they constitute undue influence

Conclusion



- ✦ Inducement is required to recruit and or retain participants in a research
- ✦ Although inducement is necessary, it should not be so large as to compromise the integrity of voluntary informed consent

Conclusion

- ✦ Investigators and sponsors of research require initial and continuing education of payment of appropriate inducement to research participants
- ✦ Local Ethical Review Committees have important roles to play in ensuring that inducement is appropriate to the local setting
- ✦ There is need for written policy to guard researchers and sponsors of researchers in setting ethically acceptable inducement for participants

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