KNOWLEDGE AND PRACTICE OF INCENTIVES FOR RESEARCH PARTICIPATION IN JOS

A DISSERTATION IN THE DEPARTMENT OF SURGERY

SUBMITTED TO

THE FACULTY OF CLINICAL SCIENCES, COLLEGE OF MEDICINE, UNIVERSITY OF IBADAN, IBADAN, NIGERIA

IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF DEGREE OF MASTER OF SCIENCE IN BIOETHICS

BY

ODEH, SAMUEL ODU

MATRIC No: 148570

APRIL, 2012.

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ABSTRACT

The administration of incentives for research purposes has come under intense controversy. Many are concerned about the morality of giving of incentives, thinking that it has the capacity to unduly influence research participants to under – value the risks inherent in any research enterprise against the benefits derivable for their participation. Also, the harnessing of different categories of people for the same study makes it more difficult to appropriate incentives in a manner that would be ethical. Many researchers tend to recruit participants for studies without adequate understanding of the concept of incentives. In the Jos environment, two University Teaching Hospitals, a residency training centre, and a University exist where researches are carried out. There has been no documentation from Jos as regards the knowledge and practice of incentives for research participation. The study therefore was carried out to assess the knowledge and practice of incentives for research participation in Jos. The study interviewed seven key informants, held two focus group discussions and administered one hundred minimally structured questionnaires. Of the hundred questionnaire given out (fifty each to research participants and researchers), 31participant respondents (62%) and 24 (48%) researcher respondents returned their questionnaire. The concept of research was clear to both categories of questionnaire respondents, the research – participant respondents (RPR) and the researcher – respondents (RR). They all admitted that a research is a scientific investigation into any issue of interest. About 16% of RPR claimed that they learnt about research from their doctors, and this group represented the highest single source of information about studies. The RPR (12.9%) indicated that the major motivating

factor for their participating in researches was their willingness to aid research. The RR consisted of medical practitioners (62.5%), non – medical practitioners (29.2%) and students (4.2%). About 71.4% of RR claimed that they follow the due informed consent process to recruit participants. About 42.9% merely recruited from their clinics while 21.4% also included advertisements to recruit participants. The RR who claimed to be aware of ethical guidelines about research participation accounted for 70.8%, while 29.2% admitted that they were not aware of any guidelines. Among those who claimed to have been aware of ethical guidelines, only 23.5% could correctly mention any current ethical guidelines on protection of human participants in research. RPR understand incentives to be a form of inducement or motivation, to ensure better cooperation from them. They agreed that incentives strongly influence the level of participation in research (45.5%), even though 9.1% were uncertain about the influence of incentives on research participation. The items for incentives administration, according to the RPRs included cash, writing materials, drugs, and stipends for academic conferences. For 75% of RPRs, incentives are not considered as bribes, though 20.8% are uncertain about the morality of incentivization. The majority of RPRs (54.2%) would prefer to have incentives administered at the onset of any study. if given a choice 69.6% of RPRs opined that they would opt for cash as the item for incentives administration. The suggestions proffered by RPR to improve participation in researches included improving the quality of incentives, and ensuring better enlightenment about researches. About a third, 8 (33.3%) RR claimed they use incentives regularly, while 9 (37.5%) had never used. Another 7 (29.2%) admitted that they rarely used incentives. The items employed in incentives administration, according to RR included drugs, plastic containers, free medical examinations and laboratory investigations, payment for transportation, and provision of refreshments.

According to RRs, 29.2% of them would prefer to give incentives at the onset of studies, 37.5% midway into the study, and 33.3% at the end of the study. The types of incentives suggested by RR are monetary (41.7%) and non-monetary (33.3%). A quarter of RR were not sure what to suggest as a standard for incentives in Jos. RRs perceived that the reactions of research participants were 'acceptable' (i.e., displaying an obvious willingness to receive the incentives) 69.2%, 'excited' (i.e. showing visible emotional display of happiness on receiving the item) 15.4%, and 'neutral' (i.e. an apathetic attitude to the offer) 15.4%. The RR further opined that the administration of incentives could also have some on – toward consequences on the research process. Some of these, they reasoned included a tendency for participants to get greedy (26.7%), participants holding the study to ransom (20%), or even for the participants getting the wrong perception of the essence of researches. About three quarter of RR are of the opinion that incentives significantly influence enrolment and the behaviour of participants. 21.7% however opine that the incentives have negligible impact on the outcome of research. The sources of fund for researches according to RR included personal salary income (65%), institutional research grants (30%), and drug companies (5%). RRs would like to consider the following factors when administering incentives; availability of funds, willingness of participants, nature and duration of researches, location of the study, age of participants, and the medical condition of the participants. Over two – third of RR did not consider incentives as bribes, while a quarter thought an incentive is a bribe. A little less than a tenth part was uncertain. Key informants (KI) interviewed included human participant researchers, members of research ethics committees, medical education and healthcare administrators, community and labour leaders, and lawyers. The KI believed that generally, people in Jos are apathetic to researches. In their opinion,

people are always in search of ventures that yield financial gains, and understandably, show poor response to enterprises like researches that do not give financial gains. They also stated that researchers in Jos lack funds and materials to prosecute researches, and that majority of researchers are more 'certificate - driven' than being passionate about discoveries. In Jos, the KI believe that environment and culture play significant roles in people – perception of incentives, and the roles in this case are on more on the negative than the positive. Majority of the informants would like to consider cash payment for a uniform standard of incentives administration. It was however also stated that setting a uniform standard for incentives administration would be herculean. According to them, the basic concern would arise from how to determine an ethically acceptable limit to be applied to all participants. The opinion of a minority of KI however was that incentives are never morally right, being a form of inducement. For instance, it was stated by one who; *"...could not yet imagine a situation where inducement/incentives would be morally right"*, that incentives use in research was a necessary moral wrong. The KI opined that Jos being a resource – poor setting would require the exploration of other non – cash means of incentivizing research participants. They gave examples of giving awards, plaques of recognition, thank you cards and visits, among others. It is concluded that the knowledge and practice of incentives for research participation in Jos is still infantile, and most researchers are certificate driven, rather than being in pursuit of discoveries. The rationale for incentives administration in Jos was largely identified as paying participants for out-of-pocket expenses and recognition for contribution, although a minority identified the provision of inducement or incentive as a motivational item.

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The distance between my home and the programme site was no small one, and I was away from my home for most of this period. I place on record my most profound appreciation to

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Above all, I am eternally grateful to the Almighty God, my Saviour and Eternal Fortress, and who has always been my Help and Shelter from storms.

CERTIFICATION

I hereby certify that this study was carried out by ODEH, SAMUEL ODU. under our supervision at the Department of Surgery, Faculty of Clinical Sciences, College of Medicine, University of Ibadan, Ibadan.

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Professor O. O. Omotade Dr Temidayo Ogundiran

Supervisors

DEDICATION

This work is dedicated to my wife and children.

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Chapter one

Introduction

1.1 Concerns of incentives

There is considerable confusion over the ethical appropriateness of using incentives in human research. Offering payment to clinical research participants, in an effort to enhance recruitment by providing an incentive to take part or enabling subjects to participate without financial sacrifice is a common yet uneven and contentious practice (Grady, 2005). Concern exists regarding the potential for payment to unduly influence participation and thus obscure risks, impair judgment, or encourage misrepresentation. Thorough assessment of risks, careful eligibility screening, and attention to a participant's freedom to refuse, all serve to reduce the possibility of adversely affecting the individual and/or the study. Available works reflect conflicting positions, some that it is appropriate and others that it amounts to coercive offer or undue influence

(Goldenberg *et al,* 2007). Many researchers have examined the effects of providing a variety of incentives to subjects. The Belmont Report recommended the establishment of Institutional Review Boards (IRB) or Human Subjects Committees (HSC) to regulate researches involving human subjects. This report outlined two considerations for beneficence in research: (a) maximize possible benefits, and (b) minimize possible harms.

Although payments are usually monetary, both patients and normal healthy volunteers may be offered other rewards in lieu of or in addition to money. Regardless of the form of remuneration or motivation, the issues for IRBs remain the same, to consider whether participants in research are recruited fairly, informed adequately, and 'paid' appropriately. Taking into consideration the subjects' medical, employment, and educational status, and their financial, emotional and community resources, the IRB must determine whether the rewards offered for participation in research constitute undue inducement. Undue inducements may be troublesome because offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment; and they may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling or continuing as participants in a research project.

In 1900, renowned American military surgeon Walter Reed paid study participants USD100 in US gold to allow themselves to be bitten by infected mosquitoes in the famous yellow fever experiments and an additional USD100 if they consequently contracted the viral disease. Paying human subjects for their participation in research became routine in the 1920s and 1930s. Other non-monetary forms of compensation were also common, such as meals, transportation, and burial costs. From the early

1950s, when the world's largest clinical research complex, the NIH Clinical Centre, opened, documents show that normal healthy volunteers were regularly paid for their participation in biomedical research or money was given to the church or group that organized and recruited these volunteers (Grady, 2005).

Inappropriate efforts to increase participation in research fall into two general categories: coercion and undue influence. Coercive interactions are those that imply directly or indirectly that a potential participant might lose rights or privileges for not participating in the study. Undue inducement occurs when the incentives used to increase participation become the primary reason why subjects participate, or when the number or nature of contacts with participants to encourage participation is excessive. Although there is no single incentive strategy that will work for all groups, there are a few key insights that can guide the development of successful incentive programs.

Although there are few studies that directly compare various types of incentives using rigorous methodology, the available studies suggest that enrolment is particularly amenable to improvement through incentives (Adua and Sharp, 2010). Researches measuring participation in studies with and without incentives consistently find that participation improves when incentives are offered.

Worries about incentives are typically cast as concerns about coercion, undue inducement, or exploitation and are largely overstated and misunderstood. To start, coercion is never acceptable in research. Fortunately, true coercion is incredibly rare in research (Emmanuel, 2004), and no offer of money or health care can coerce anyone unless there is some threat of harm to the potential participant for refusing to participate. For a situation to be defined as coercive, a potential participant must be made worse off

for refusing to participate than if he or she had never been presented with the option in the first place.

1.2. Undue influence

Undue influence and manipulation may arise when potential participants are recruited by individuals in a position of authority. The influence of power relationships on the voluntariness of consent should be judged from the perspective of potential participants, since the individuals being recruited may feel constrained to follow the wishes of those who have some form of control over them (e.g. employer and employees, teachers and students, commanding officers and members of the military or correctional officers and prisoners). This control may be physical, psychological, financial, or professional, and may involve offering some form of inducement or threatening some form of deprivation. In such situations, the control may place undue pressure on the prospective participants. At the extreme, there can be no voluntariness if consent is secured by the order of authorities (e.g. between physician and patient or between professor and student). These relationships can impose undue influence on the individual in the position of dependence to participate in research projects. Any relationship of dependency, even a nurturing one, may give rise to undue influence, even if it is not applied overtly. There may be a greater risk of undue influence in situations of ongoing or significant dependency.

Pre-existing entitlements to care, education and other services should not be prejudiced by the decision of whether or not to participate in or to withdraw from a research project. Accordingly, for example, a physician should ensure that continued clinical care is not linked to research participation.

1.3 Coercion

Coercion is a more extreme form of undue influence, involving a threat of harm or punishment for failure to participate. Coercion would negate the voluntariness of a decision to participate or to remain in a research study.

1.4 Incentives

Incentives are anything offered to participants, monetary or otherwise, for participation in research (incentives differ from reimbursements and compensation for time, efforts, transportation, lost wages, etc). Because incentives are used to encourage participation in a research project, they are an important consideration in assessing voluntariness. Where incentives are offered to participants, they should not be as large or attractive as to constitute an inducement to take risks that one would otherwise not take. The offer of incentives in some contexts may be perceived by potential participants as a way to gain favour or improve their situation. This may amount to undue inducement and thus negate the voluntary aspect of the consent of participants.

1.5 Poor Risk – Benefit Appreciation

When incentivizing, it is important that the value of the incentive aligns with the perceived difficulty of the action. Because decision making is perceived as difficult, an incentive must be large enough to create the tipping point between contemplation and action. The fear is that with undue inducement, patients would lose appreciation of the contents of risks and benefits. The argument has also been put forward that this may appear conjectural as ethics review committees would have prior to the actual knowledge of the subject, assessed the risk – benefit profile of the research and to approve would have judged the risk – benefit calculus favourable.

1.6 Outcomes:

Research on incentivizing outcomes is still evolving. There are reports that incentives influence the course of researches, either in the recruitment process or in the outcome. The use of monetary incentives appear to be favoured as a potent influence in this regard. However, there still exists some level of controversy on the exact influence of incentives on research outcome (Singer *et al*, 1999). The level of outcome that is targeted by an incentive should be considered carefully.

1.7 Types of Incentives

There is a lack of definitive empirical evidence to indicate which types of incentives are the most effective. Very few studies have compared the success of multiple incentive strategies in diverse populations, but a few key insights arise from the available research. First and foremost, effective incentive strategies should be geared towards the population they are targeting. Members of lower socioeconomic groups can be motivated by incentives that are less valuable than those required to effectively incentivise individuals in higher-income brackets.

Wendler *et al* (2002) put forward the following analysis concerning the ethical concerns raised by the potential for payment to distort parents' and children's decision making. They consider it critical to differentiate research related payments into four (4) different types:

- **Reimbursement payments** compensate parents and children for their direct research-related expenses and should be based on the actual costs (eg, transportation, meals, and lodging) that families incur.
- **Compensation payments** compensate parents and children for the time and inconvenience of research participation. Levels of compensation payments should be

a function of the demands (clinic visits, hospital stays, and research procedures) that research places on families.

- **Appreciation payments** are bonuses given after children's participation to thank them for their efforts.
- **Incentive payments** encourage children's research enrolment. Payments may be designed to act as incentives, for instance, when an investigator intentionally reimburses families above their actual costs to encourage enrolment.

Payments may also inadvertently act as incentives if they unintentionally exceed families' costs and, thereby, act as incentives without being intended as such. The potential for payment to distort parents' or children's decision making varies across the four types of payment. Reimbursement payments repay parents for the direct costs of research participation, ensuring that it is "revenue neutral." For this reason, reimbursement payments should not distort parents' or children's decision making and seem ethically acceptable. Indeed, it seems IRBs should consider requiring investigators to reimburse parents, particularly when they incur significant direct costs and the research offers little or no potential medical benefit. Compensation payments are intended to "zero out" the incremental time, burdens, and inconveniences that research participation adds to families' lives, above direct financial outlays. Unfortunately, unlike reimbursement payments, the precise level of compensation needed to "zero out" families' research burdens cannot be determined simply by adding up their actual expenses. Instead, IRBs will have to estimate the point at which compensation payments "zero out" the level of burden that families have in a given protocol. The complexity of this determination introduces the possibility that compensation payments may sometimes inadvertently exceed families' actual burden, providing an incentive for them to enrol in research. The potential for compensation payments to act as inadvertent incentives is

increased by the fact that a protocol's level of burden will vary from family to family, with protocols that seem burdensome to some families and innocuous to others. In practice, investigators will not be able to determine the level of compensation needed to precisely "zero out" different families' burdens. Instead, research institutions should develop standardized levels of compensation for the time children spend in research and the research procedures they undergo. It has been argued that compensation payments for the time adults spend in research should be commensurate with wages for unskilled, but essential, jobs. Analogously, compensation payments for the time adolescents spend in research could be based on the minimum wage for teenagers, with children compensated for the time they are engaged in research activities. To minimize the potential for compensation payments to distort parents' decision-making, they should be directed to the person who bears the burdens of research participation, typically the child. At the same time, some protocols require parents to contribute their own time, for instance, staying with a young child during research procedures. Banning all compensation payments to parents could block families with fewer economic resources from participating in such research. As with children's subjective sense of burden, the monetary value of a given amount of time will vary widely from family to family. To guard against the possibility that adequate compensation for some parents may act as an inadvertent incentive for others, compensation payments to parents should be calibrated to the economic resources of the least well-off families. By analogy to payment for adults who participate as subjects, payments to compensate parents who contribute to their children's research participation could be based on minimum wage levels for adults. When calculated accurately, compensation payments ensure that children and their parents are compensated for the incremental time, burdens, and inconveniences that research participation adds to their lives. Hence, with these payments in place, additional

appreciation payments seem unnecessary. In addition, if families learn before enrolment that appreciation payments are being offered, they may inadvertently act as incentives. This suggests the best approach may be to ban additional appreciation payments, provided compensation levels are adequate. By compensating families for the direct costs and burdens of research participation, reimbursement and compensation payments eliminate the financial obstacles that might keep most families from participating in research. It is hoped, with these obstacles eliminated, that families will decide to enrol in research because they want to help others and/or believe that the research is in the child's best interests. However, in some cases, even altruism and the potential for direct benefit to the child, combined with reimbursement and compensation payments, may not be enough to encourage sufficient enrolment (Wendler *et al*, 2002)

1.8 Timing of Incentives

Promised incentives may be less effective than those provided at the time of action, or shortly thereafter. Immediacy fosters effectiveness by providing a strong link with the desired action required of the subject. The reward then acts as positive reinforcement for continued participation. It has also been shown that periodic rewards could be more effective than one-time rewards because they support ongoing participation.

1.9 Aims and objectives

The study was conducted to assess the knowledge and practice of incentives, and the perception of incentives among select research populations in Jos. It was also to determine the influence of incentives on research outcomes in our environment.

1.10 Hypotheses

Ho: The Jos researchers do not know of or practice incentives administration for research participation.

H_1: Researchers in Jos know of incentives and practice incentives administration for research participation.

Chapter two

LITERATURE REVIEW

2.1. Introduction

Over the past few years there has been considerable confusion and frustration as to the ethical appropriateness of the use of incentives in research involving human subjects (Grant and Sugarman, 2004). This derives in part from the sensitivity to what constitutes incentives, the use of incentives, and the incentivised. The matter is complicated further by the existence of one set of ethical considerations that arises whenever incentives are employed, whether in medical research, and another set that are involved in research with human subjects irrespective of whether they participate voluntarily or in response to incentives. The workers (Grant and Sugarman, 2004) reported that in a vast majority of situations, the use of incentives in medical research will not pose ethical problems. Offering payment to clinical research subjects, in an effort to enhance recruitment by providing an

incentive to take part or enabling subjects to participate without financial sacrifice is a common yet uneven and contentious practice in the US. Concern exists regarding the potential for payment to unduly influence participation and thus obscure risks, impair judgment, or encourage misrepresentation. Heightening these concerns is the participation not only of adults but also of children in paediatric 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 (Grady, 2005).

An ethical analysis of incentives requires a definition of the term, but this is unexpectedly difficult to do as 'incentives' is so widely used and indiscriminately so, that the concept has lost boundaries. For instance, it sometimes refers to 'reward', 'motivation', 'external prompts', etc. A reward, unlike an incentive is always understood to be merited or deserved. Similarly, to liken incentives to motivation is to deny the phenomenon of habitual behaviour, or action consequent on a sense of responsibility. It is however an external prompt as it requires an individual's response (Grant and Sugarman, 2004). Ideally, incentives are to be reimbursement for participation in research, and should attract concern if taken together with the research context and the financial and emotional resources of the subjects. Another potential problem is that if incentives are too attractive, subjects might misrepresent themselves in order to participate in the study (45 CFR 46).

Increasingly, people worry that undue inducement for research participation in developing countries compromise the voluntariness necessary for informed consent. Participants are described as poor, poorly educated, and powerless especially when compared with the researchers (Emmanuel *et al*, 2005). Incentives strictly speaking share certain set of core characteristics, and the concept has a distinct meaning, referring to a kind of offer employed in a negotiation (Grant and Sugarman, 2004). Grant and Sugarman, (2004) further posited

that if the desired action would result naturally or automatically, then no incentives would be necessary, as the principle behind incentives is the suspicion that the desired action would not spontaneously occur. Grant and Sugarman (2004) went further to state that incentives are ways of getting other people to do what they are desired to do, and that they involve relations of power. Indeed, they are best understood as an alternative to other forms of power e.g. persuasion and coercion.

According to Grant and Sugarman (2004), the characteristics of incentives would be;

- To have an offer made, which is an additional benefit
- The offer is usually made as a discrete prompt expected to elicit a particular response
- The offer is made in the context of an authority relationship
- The offer is intentionally designed to alter the status quo of the person by motivating the person to tilt in mental judgment.

The Indian Council of Medical Research (ICMR) Code (2000) in its principle of non-exploitation recommends that as a rule, research subjects be remunerated for their involvement in the research, and that each research shall include an inbuilt mechanism for compensation for the human subject either through insurance cover or any other appropriate means. The ICMR Code (2000) does not convey any precise prescription of incentive administration. What was of concern was its ethical principle on compensation for participation for which it made a non obligatory statement but cautions thus;

> *"no compensation to guardian on behalf of an incompetent person except for refund of out of pocket expenses".*

More particularly, it states in principle 4;

> *"particularly in a country like India with the level of poverty that is present, it is easy to use inducements, especially financial inducements to get individuals and communities to consent. Such inducements are not permissible. However it*

is necessary to provide for adequate compensation for loss of wages and travel/other expenses incurred for participation in the study".

It however further made the clarification that:

"Subjects may be paid for the inconveniences and time spent and should be reimbursed for expenses incurred in connection with their participation in research. They may also receive free medical services. However payment should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in research against their better judgement (inducement). All payments, reimbursements and medical services to be provided to research subjects should be approved by the Institutional Ethics Committee...".

Pino (2011) in his position stated that in conducting focus groups or one-on-ones, surveys by mail or via the web, the conversation with clients inevitably leads to incentives. He further asked; 'are they appropriate? If so, what should the incentive be? And, perhaps sadly, but realistically, how little can we pay to generate participation? A good starting point in the determination of incentive appropriateness is to examine the respondent imposition factor. That is, what are we asking a research participant to do? To him, most research efforts modest in length and inconvenience do not require an incentive'. So, to recognize when it is necessary and when it is not, he posited some questions (and answers) to review when contemplating the appropriateness of an incentive.

- Are we asking someone to spend an inordinate amount of time to participate in our research?

  Generally speaking, across all projects, no matter the methodology, anything over 15

to 20 minutes in length has such a drop off in participation that you should consider an incentive.

- How much effort is involved?

  Simply put, the more effort required on the part of the participant, the greater the need for a commensurate incentive. What hoops are we asking a participant to go through? Are they requested to leave the comforts of home to go to a testing facility? Are they asked to participate when it is convenient for them or for us?

- Who are we talking to?

  Somewhere between the adages of "time is money" and Animal Farm's "We are all equal, it is just that some of us are more equal than others" is the reality that it will take more money to motivate some people than others.

- But if they are really interested in the topic, is an incentive really necessary

  Clearly some research topics are of greater interest to some than others, pay an incentive if it is typically warranted regardless of the topic. Again, you should be concerned about the representativeness of your research audience by avoiding those who might be exceptionally fanatical about the research topic.

- What type of Incentive

  Incentives typically fall into one of the following categories: cash, tangible gifts, information, or lotteries in which only a few "lucky winners" are chosen. Cash is by far the most common. Its universal acceptance makes it the most logical and flexible alternative. Tangible gifts can include anything from software to a t-shirt. Lotteries

can be effective incentives, as well. Large cash awards, colour TVs and other high-ticket items are often a good lure, particularly as a way to reduce fulfilment.

- Timing of the Incentive

  For the most part, incentives are offered after the participant has completed his or her task. However, a small "token of appreciation" offered upfront, can have a very positive impact on the response rate. In this scenario the "obligation factor" cannot be underestimated.

Pino's (2011) concluding remarks were, 'what is your incentive to learn about incentives? When used properly, incentives can save you time, and, yes, even money. What's more, knowing when they are appropriate or not can make the difference in the reliability of your data and whether a study succeeds or fails'.

In Nigeria, the National Health Research Ethics Committee (NHREC) was inaugurated in 2005 in line with the President's directive for strengthening of a mechanism that will ensure the protection of Nigerians participating in researches. The NHREC was a replacement of a dormant Health Research Ethics Committee that had been in existence since the 1980s (National Code of Health Research Ethics, 2007).The Code addresses very significantly the issue of protection of researchers from exploitation in Section E, (r), 2 and from undue pressure from sponsors, institutions, participants and any other source. This principle created an inbuilt assumption that a protected researcher could led to a protected research participant. This is evident from the requirement of what according to the document constitutes an ethical research;

- Social and scientific value
- Scientific validity

- Fair selection of participants while minimizing risk
- Evident valid attempt to *minimize risk and maximize benefit*
- An independent review
- Informed consent as a *sine qua non*
- Respect for potential and enrolled participants
- *"..... nothing must be done to undermine the trust relationship that is at the heart of researcher(s) – participants relationship"*
- Protection of the interest of participants, researchers, sponsors and communities.
- Adherence to the principles of good clinical and laboratory practice.

The code also prescribes an inclusion of incentives (inducements) to participants as part of the informed consent document (f. 5.xiii). However, the discretionary allocation of the burden of assessment of incentives in research to the researcher and the Research Ethics Committee may jettison the quality of judgment regarding the definition and extent of risk, and by inference dimensions of inducement. This study aims among other things to assess the knowledge researchers and participants have about incentives in Jos, Nigeria.

The payment of human subjects for their participation in scientific research in the US is a common and longstanding practice that has been documented for well over 100 years. As far back as the 1820s, William Beaumont, whom many consider to be the father of gastric physiology, gave patient Alexis St. Martin, food, lodging, clothing, and $150 for the opportunity to study his stomach contents for 1 year. In 1900, renowned American military surgeon Walter Reed paid study participants $100 in US gold to allow themselves to be bitten by infected mosquitoes in the famous yellow fever experiments and an additional $100 if they consequently contracted the viral disease. Paying human subjects for their participation in research became routine in the 1920s and 1930s." Other

non-monetary forms of compensation were also common, such as meals, transportation, and burial costs. From the early 1950s, when the world's largest clinical research complex, the National Institute of Health (NIH) Clinical Centre, opened, documents show that normal healthy volunteers were regularly paid for their participation in biomedical research or money was given to the church or group that organized and recruited these volunteers (Gray, 2005). In Nigeria this kind of data is still lacking, and this study represents a modest search to establish one.

2. 2 Incentives and decision making process

Bentley and Thacker (2004) assessed the influence of monetary payment on decision making process in research participation. They adopted the model of Dickert and Grady (2001) and evaluated willingness to participate, propensity to neglect to tell about restricted activities, and risk taking. They concluded that monetary payments make subjects more willing to participate in research. However, they could not substantiate that those payments blind subjects significantly. They did however raise a concern, the potential for payments to diminish the integrity of study findings. Although the practice of paying subjects to participate in research is not new, it continues to serve as a point of debate among many in the research community (Bentley and Thacker 2004). The debates centre around blinding subjects to risks, causing subjects to conceal information which may disqualify them from the study, and whether varying levels of monetary payments will have the same effects on the willingness to participate at varying levels of risks.

Monetary incentives are increasingly used to help motivate survey participation. Research Ethics Committees have begun to ask whether, and under what conditions, the use of monetary incentives to induce participation might be coercive. The article reports research from an online vignette-based study bearing on this question, concluding that at

present the evidence suggests that larger incentives do not induce research participants to accept higher risks than they would be unwilling to accept with smaller ones. Monetary incentives are often used to facilitate survey recruitment and motivate participation among individuals who might otherwise not respond (Church, 1993, Singer, 2002). Although financial remuneration may have been a motivating factor on the part of the research team to approach potential research participants, it does not appear to have impacted the rate of consent for that study (Unger *et al*, 2010). Other factors reported as affecting the rates of consent are; the approach to recruitment, strength of expertise of the researcher, and patients' judgment of the recruitment.

Napoles – Springer *et al* (2000) evaluated the level of participation in research with older African – Americans and Latinos. Their result indicated that affordable housing, enough money, adequate transportation and safer neighbourhoods were urgent priorities, and superseded health concerns. Distrust of researchers, lack of information, care giver obligations, fear of exploitation, and lack of benefits were identified as barriers to research participation. Study members were willing to participate in research provided they were fully informed, and perceived tangible benefits and congruence between the objectives of researches and participants influence.

Festinger *et al* (2009) however opined differently. Findings from their study have demonstrated important implications for the ethical conduct of human subject research. They posited that the incentivized consent procedure may be useful for improving consent recall in research studies, particularly those involving potentially serious side effects. The results also provide an important "proof of concept" regarding the utility of motivational procedures for improving recall of consent information.

Do financial incentives blind potential research participants to the risks of research when making decisions regarding participation? Motivated by cash payments or an attractive financial package, an individual could have less interest in evaluating or understanding study details, reading the consent form, or attempting to understand the goals, purposes, and risks associated with a study. This may be of little concern; however, if a clinical research protocol has almost no risks or has been approved by an IRB that has judged the level of risk to be acceptable. If, in addition, there are other mechanisms in place during the informed consent process to assure that participants adequately understand relevant risks, then this seems like a misplaced worry and may even represent "unwarranted paternalism". Further, limited evidence suggests that the offer of payment does not obscure the risk perception of potential research participants, and there are no data to suggest that it does. Others worry that money can impair judgment or compromise voluntary decision making. But voluntary decisions are motivated by various factors, sometimes including money, and are not necessarily motivated by altruism alone. When people are choosing a job, making purchases, or making other voluntary decisions, they often consider the monetary aspects of their choice in the form of salary, benefits, or sales price. Decisions are generally complex and multifaceted, however, and are rarely based solely on monetary considerations. Similarly, people participate in clinical research for multiple reasons, and money may be one among those reasons or even the main reason. Limited data suggest that the offer of money is one factor in the decision making of some, but not all, potential participants. Even if money is one reason or the main reason to participate in research, does the offer of money impair judgment (Grady, 2005)?

2. 3 Assessment of Risks and Benefits in research

Risk is a multidimensional concept involving probability and magnitude of harm to research participants. Benefit is the magnitude of positive outcome without reference to its probability. Risks could be physical (bodily harm), psychological (self, emotional), social (discrimination, stigmatization), or economic. Analysis of risk depends on whether one is considering a therapeutic or non therapeutic research. Therapeutic procedures should pass the test of clinical equipoise, being consistent with the minimum standard of care. Equipoise arises from earlier studies or split opinions in the clinical community. It requires an approximate equality in treatment's therapeutic index, a combination of potential benefits, risks and uncertainty. For non therapeutic interventions, risks determination is not by assessing benefit to individuals participating, so benefit - risk calculus is inappropriate, and a risk – knowledge calculus is applied instead.

The concept of minimal risk has been adopted, and refers to the risk of harm anticipated not greater (considering probability and magnitude) than those ordinarily encountered in daily life or during performance of routine physical and psychological examinations or tests. Emphasis is placed on non therapeutic risks. However, risks vary from place to place. Benefits (incentives) depend on whether one is considering a therapeutic or a non therapeutic research. In a therapeutic research, benefit may include relief from disease, reducing suffering or provision of diagnostic information. In non therapeutic research people join for altruistic reasons to benefit society. The criticisms against payments in research have included the weakening of economically disadvantaged persons, and the tendency of making participants 'salaried workers' and changing the relationship between researcher and participant. Evidence shows that payment is a major motivation especially in researches. In therapeutic researches health improvement appears to be the primary motivation.

In developing countries, lost wages, transport and other inconveniences make a study justification for payment. Incentives will indeed be necessary to recruit adequate number of participants, and will help to overcome opportunity costs, inertia, and distrust, and to enhance recruitment of hard – to – get participants. It represents a fair compensation for time and inconvenience for participation. Rao and Sant-Cassia (2002) argue that omitting to inform patients recruited to a trial about the payments that are received, above and beyond reimbursement costs, corrupts the following research ideals:

- Clinician equipoise—i.e. doctors' clinical decision-making should be balanced and accountable.
- Voluntary consent—without full disclosure of information relevant to the study, a patient's ability to grant voluntary consent is compromised.

Although details of payment are disclosed to research ethics committees (as stipulated by The Royal College of Physicians, 1999), they argue that this is not sufficient and without full disclosure to potential participants, informed consent cannot be given. The attitude still prevails that patients can always ask about payments if this is important to them. But it is disingenuous to expect patients to know that something they have not been told anything about is important enough for them to ask about (Grady, 2005).

2. 4 Incentive models

Different ethical issues emerge over payment for research subjects when wages are substituted for incentives (Grant and Sugarman, 2004). They argued that earlier prescriptions of payments (Dickert and Grady (2001)) are faulty because the models appear oblivious of the relationship between duties/responsibilities and wage labour.

In an attempt to address the controversies about incentives, some payment models have been proposed. These include;

- The market model (MM)
- Wage payment model (WPM)
- Reimbursement model (RM)
- Appreciation model (AM)
- Fair share model (FSM)

In the MM payment serves as incentive, and the amount determined by supply and demand. It does yield rapid recruitment and possible profit to participants. However, it could create undue inducement resulting in incomplete assessment of risks/benefit, competition between studies and differential payment depending on the study locations.

The WPM payment serves as compensation for time and effort, and is designed to be commensurate with wages for unskilled but essential jobs. The model recognizes individual contributions, uniform pay across studies, and less risks of undue inducement. This unfortunately may have little impact on recruitment, and has the tendency to under-compensate some. Moreover, the model does not apportion responsibilities or duties to the wages. Grant and Sugarman (2004) drew the attention further with the hypothetical case, i.e. if the research subject is contracted to provide a service or to do a work for a certain number of hours, is he still entitled to renege on the contract and quit the study?

The RM services express expenses incurred with/without reimbursement of lost wages. It makes research participation revenue – neutral, has less risk of undue inducement but may have little impact on recruitment, and is with 'uneven' reimbursement. In AM, payment is a reward, a token appreciation given at the end of the study. It is not market dependent, avoids undue inducement but with less impact on recruitment and no basis for consistency.

FSM views participants as partners, with payment based on percentage of the per – patient – compensation due the investigator/institution. Payment is only for concluded components of the research only. It is however based on per payment compensation rather than on the level of risk borne.

There are emerging opinions now to distinguish between payments to healthy participants and to patient participants. These are of the view that healthy persons would be better motivated by money while the patients would prefer healthcare services. This position is probably conjectural, as there is no empirical evidence adduced for this distinction.

Offering incentives may help participants more clearly distinguish research from treatment and thus reduce the risk of therapeutic misconception. A patient's acceptability of risk reflects his goals and values, and payment may influence these calculations. Excluding financial reward from the research enterprise may violate individual's autonomy to determine what monetary value if any, he places on participation in research. Opponents of the payments suggest that it may entice economically disadvantaged persons and lead them to bear disproportionate amount of risk of research (contravening the principles of justice). However, it may be agreed too that measures which help to increase the participation of economically under-average people in research is ethical, and makes the research beneficial, even though it does not necessary mean undue representation. This is a position that can happen especially in economically disadvantaged communities.

Monetary incentives are increasingly used to help motivate survey participation, demonstrating their intended and unintended effects on response rates, sample composition, response bias, and response quality. Institutional review boards have begun to ask whether, and under what conditions, the use of monetary incentives to induce

participation might be coercive and to question the use of such incentives in surveys of "vulnerable" populations, including surveys of injury and violence. Reports on the ethical principles underlying the requirement for voluntary informed consent as well as current regulations and a broad theoretical and empirical literature bearing on this question have been done, concluding that incentives are never coercive. The question of whether they exert "undue influence" in a specific situation is more difficult, but it may be the wrong question to ask (Singer and Bosarte, 2006).

2. 5 Difference between inducement and undue inducement

Undue inducement is relative to the due inducement. Emmanuel *et al* (2005) posit that even if an inducement makes a person change his course of action, it does not make it undue. They asserted that inducements are pervasive aspects of everyday life as goods are being offered to change people's behaviour without raising ethical concerns about violating autonomy or voluntariness. Inducements come as more money, more vacation time, easier work schedule, good salaries or even educational benefits. Indeed, according to Grant and Sugarman (2004), to speak of 'fair incentive' makes no sense because incentives are not a form of compensation, but rather a design to motivate or incite to an action. It thus cannot be either fair or involve a fair amount as there is no corresponding loss or expenditure for which it is meant to compensate. Ethical issues raised by the use of incentives often go unrecognized because incentives are understood as an economic paradigm in the form of trade rather than being a form of power, thereby obscuring the real facts at stake. Titmuss (1997) explained that the use of inducements can determine the character of the parties involved, even when the incentives cannot be characterized as bribes; incentives being able to induce people to do the right thing, though for the wrong reason. The use of

incentives can be manipulative even when incentives cannot be described as outright blackmail. This is the type they would like to describe as 'undue influence'.

Undue inducement is rarely, explicitly and precisely defined (CFR 46·116, CIOMS, 2002, Levine, 1988, OHRP, 1993). The worry is that the good offered leads to poor judgement, and assume substantial risks of harm that compromise their welfare (Lemmens and Elliott 1999). CIOMS guideline 7 states;

> *'Payment in money or in kind to research subjects should not be so large as to persuade them to take undue risks or volunteer against their better judgement. Payments or rewards that undermine a person's capacity to exercise free choice invalidate consent'*

The characteristics that make for an undue inducement have been listed to include an offered good, excessive offer, poor judgement and risks of serious harm. All these must be present to have an undue inducement. If any of the characteristics is lacking, then there is no undue inducement (Emmanuel *et al*, 2005). The workers further described harm without poor judgement as just misfortune, and harm from poor judgment without an offered good as imprudence.

Harris (2005) draws an important distinction between inducements that are unacceptable because 'participation is against the interests of the subject' or inducements that 'are coercive in the sense that they are irresistible', and incentives that are unacceptable because 'the type of incentive offered is illegitimate or against the public interest or immoral in itself'. He does not argue against inducement *per se*, but makes the point that some inducements are unacceptable simply because of what they are. For example, offering preferential health care treatment (not related to the research) as an inducement may not be irresistible or coercive, but it would be unacceptable because it is

unacceptable to offer anyone preferential treatment that is not based on clinical need in a publicly funded health care system.

If we exclude inducement that is immoral in Harris' sense, we still have to determine when an inducement is undue because it apparently undermines the process of consent to the extent that it encourages someone to participate when to do so is actually contrary to his or her best interests. Also, some harm are relatively minor, only embarrassing, annoying, unfortunate or even painful, but are neither sufficiently severe nor permanent to constitute undermining of a person's fundamental interests (Macklin 1981, McNeill 1997, Newton 1982). Undue inducement requires substantial risk of serious physical, psychological, economic, or other harms which threaten a person's basic concern. In this situation however, the interest of a volunteer participant may be uncertain. Undue inducement relates to risks that are clearly unreasonable. Everyday kind of harm is reasonable.

Another dimension to undue inducement is that the evaluation of undue inducement is not of harms posed by individual elements (Wertheimer, 1996). When the work is balanced by the salary or the risk of injury by the excitement, the risk – benefit ratio must not be excessively unfavourable. Payments may constitute undue inducement by reducing the interest in understanding risks related to the research, and decreasing the voluntary nature of the decision to participate.

Undue inducement is not well defined as there is no evidence that money actually alters the perception of risks, and voluntary decisions can be made even when inducements are offered. It is even likely that other incentives may be as powerful as or more power than money.

2. 5. 1 Undue inducement and coercion

Faden and Beauchamp (1986) defined coercion as an extreme form of influence by another person that completely controls a person's decision. Such an influence should be able to deprive the person of autonomous choice, thus requiring a threat of some severe negative consequences (Grady, 2001). Inducements are offers not threats, though may become undue, exploitative or morally impermissible. Macklin (1981) noted that the concept of inducement is weaker than the notion of coercion. She described undue inducement as one making subjects to lie, deceive, or conceal information that may disqualify them from the study if known. Some people however view inducement as unethical. It is posited that the reason for concern about inducement is that those most susceptible to inducement may be the least able to assess the aims and technical information relating to the research (McNeil, 1997). McNeil (1997) accuses researchers of advancing inequality via inducement as they use those of low socio-economic class to benefit those of high socio-economic class. It is asserted that the lower the payment, the higher the chances of volunteers to be of the lower socio-economic class. Others are more emphatic, that there should be no pay at all for research participation. Some apply some degree of flexibility arguing that inducement is appropriate but that there only should not be a ceiling to the amount involved. Brody (1998) reasons that if a protocol is IRB approved, then the risk – benefit ratio must have been acceptable and so inducement cannot harm the subjects, debunking the notion of coercion and exploitation. This appears also to be the position of the Nigerian Health Research Ethics Code (2007). According to Palmer (1985), inducement can be undue only in cases of research involving the highest acceptable risks of physical or psychological injury; or in cases of unreasonable risk, i.e. death, which the IRB would not have approved in the first place. The reports on the influence of monetary incentive in increasing or decreasing motivation are indeed conflicting, making room for potential misconduct in researches.

Undue inducement is often confused with coercion, exploitation, injustice, deception, and misunderstanding (Christakis, 1988). It is stated;

> '*providing truthful information to avoid deception does not address exploitation, and ensuring good understanding does not obviate undue inducement'*.

Both undue inducement and coercion make a person do what may be unethical, illegal, or imprudent. But they are different. Undue inducement carries a positive good while coercion entails a threat that the person considers a worse circumstance if they do not do the desired action (Emmanuel *et al,* 2005). Consequently, the remedy for coercion is to eliminate the threat whereas for undue inducement is to reduce the value of the offered good. Walzer (1983) went further to state that undue influence is said to have been exercised when one person exerts power that he rightly wields in one area in which he ought not to have any particular influence, and it could be also described as injustice, not necessarily coercion.

Coercion

In this respect, a useful distinction can be drawn between coercion and persuasion. It is generally thought that persuasion, by most means, is not the same as coercion. If this is correct, and clearly there may be a point where the two overlap, then the principle needs to be applied with caution; inducements that merely persuade are acceptable, whereas those that coerce are not. Much hangs on the extent to which the means used are irresistible. Coercion is taken to have occurred where irresistible pressure is exerted. Persuasion, on the other hand, provides an individual with additional reasons to act in a certain way, but these reasons are not overriding reasons. Persuasion is thereby thought to be consistent with the operation of free choice. Accordingly, offering inducements can be regarded as persuasive rather than coercive. These inducements are generally given in addition to reimbursement (Draper, 2009). To say that persuasion reflects an operation of a free choice

is however not a truism. Some persuasions may be coercion in themselves, depending on the office, power, and position of the person making the persuasion. For example, the clinician who would examine a medical student would almost not have his persuasions turned down. In this sense therefore, persuasion becomes about synonymous with coercion.

By definition, coercion is understood to involve a threat of physical, psychological, or social harm in order to compel an individual to do something, such as participate in research. However, money for research participation is an offer or an opportunity and not a threat and therefore cannot be perceived as coercion. Existing guidelines warn against undue inducement and its potential to compromise informed consent, although there is disagreement about what exactly constitutes undue inducement and consequently disagreement about the extent to which it is a valid problem in research. The US Code of Federal Regulations requires that informed consent be obtained under circumstances that minimize the possibility of coercion or undue influence. An inducement in clinical research is deemed undue and therefore troublesome if it is so attractive that it can blind prospective subjects to potential risks or impair their ability to exercise proper judgment (Grady, 2005).

There are, however, a number of potential negative reasons, other than monetary ones, why doctors may be inclined to unduly influence a patient to participate in research, e.g. furthering their medical/academic career or professional 'back scratching' for colleagues. Whilst there may be a reason for caution in relation to any motivation that may lead to coercion of patients against their interests, actual evidence of coercion to participate in research is absent from the literature. Similarly, there is as yet no robust evidence that financial inducements actually increase recruitment rates to research studies.

2. 5. 2 Undue inducement and exploitation

Exploitation is a moralised concept i.e. a transaction is exploitative only if it is unfair (Coleman and Bonesseau, 2006). The moral weight of exploitation is in its degree of wrongness. Exploitation is often a micro-level wrong to discrete individuals in distinct relationships and transactions, having its root in macro-level injustice. The various moral upshots that exploitation might involve for parties to the transactions/for society constitute the moral force of exploitation, and this is related to the moral weight. It is admitted that in a reasonably just society, people will find themselves in situations in which they can strike an agreement that will produce mutual gains, and some of those cases will give rise to allegations of exploitation (Barry, 1989). To exploit a person involves the harmful, merely instrumental utilization of him or his capacities, for one's own advantage or for the sake of one's own end (Buchaman, 1985). Exploitation usually arises because of the difference in power, knowledge, and authority between researcher/participant, researcher/sponsor, and local/international researchers.

Exploitation necessarily involves benefits or gains of some kind to someone. Exploitation resembles a zero-sum game i.e. what the exploiter gains, the exploitee loses, or minimally for the exploiter to gain, the exploitee must lose (Torney, 1974). It demands that there is reasonably eligible alternative for the exploitee and the consideration or advantage received is incommensurate with the price paid. One is not exploited if one is offered what one desperately needs at a fair and reasonable price (Benn, 1988). It sums up that exploitation consists in wrongful behaviour that violates the moral norm of protecting the vulnerable.

Kant interprets exploitation as one merely using another as a means to his own advantage rather than an end itself. Marxists and Libertarians agree that there is a force – inclusiveness definition, in exploitation, but that this is not obligate for the definition of

exploitation. Force – inclusiveness is coercion, and compromises the voluntariness of consent just as fraud compromises the rationality or advisability/validity of consent. Exploitation is about interactions, about 'how much' and not 'what' each party receives, making the key issue to be fairness, not 'equalness'. The presence of vulnerability may make exploitation more likely but does not inherently entail exploitation. In the Kantian opinion, exploitation carries the elements of coercion and fraud where the patients' autonomy is undermined. Rawls views fairness at the macro-level distribution of rights, liberties and resources for the basic structure of society (not applicable at the micro-level). Exploitation requires unfair distribution of advantages from an interaction. Whereas exploitation entails a person getting too little, undue inducement requires receiving too much, an excessive offer. The solution to exploitation is to give more, to increase the amount to the exploited whereas for the undue inducement it is to give less (Emmanuel *et al*, 2000, 2005). Indeed, for exploitation to exist, the relationship must be asymmetrical, the subordinate party must need the resource that the super ordinate supplies, the subordinate must depend upon some particular super ordinate for the supply of needed resources, and the super ordinate enjoys discretionary control over the resources that the subordinate needs from him (Grant and Sugarman, 2004).

Exploitation is a psychological, rather than a social or an economic concept. For an offer to be exploitative, it must serve to create or take advantage of some recognised psychological vulnerability which in turn disturbs one's ability to reason effectively. It has been argued that in exploitation, there would be evidence that the exploitee is coerced, is defrauded, or cannot reason effectively. Two models of exploitation are described, the mutually advantageous exploitation in which both parties gain from the exploitation, and the harmful exploitation model. There are also the distribution between non consensual exploitation (the exploitee did not give valid consent), and the consensual exploitation

(where the exploitee has given voluntary and appropriate informed consent to the transaction).

2. 5. 3 Undue inducement and unfortunate circumstances

Many people worry that poverty or otherwise compromised circumstances may force people to take an inducement. These circumstances undermine autonomy and voluntariness, therefore informed consent (Emmanuel *et al*, 2005). Irresistible offers become undue inducement only when the person's unfortunate circumstance and compromised judgement are combined with accepting a seriously unfavourable risk – benefit ratio that threatens fundamental interests (Emmanuel, 2004; Pace and Emmanuel, 2005). Distressing situations that create limited options do not necessarily compromise autonomy and voluntariness, and so tempting offers in desperate circumstances that have clear good results are not undue inducements.

2.6 Undue inducement in clinical research

Emmanuel *et al* (2005) believe that undue inducement cannot happen in clinical research that fulfils basic ethical requirement. Normally, incentives are balanced against risk of harm and are typically integral to all things considered decision making. Data safety management boards provide oversight for IRB approvals and minimise actual or expected harms. In this situation, worries are most often than not, misguided. This was corroborated by Grant and Sugarman (2004), that in medical research, incentives induce people to do something inherently good (assuming that the research is necessary, sound in design, and conducted in integrity), not to violate their duties.

It is unknown how often misrepresentation occurs in clinical research and also unclear whether money is uniquely capable of inducing this kind of deception. Perhaps we should worry more about the possibility of desperate patients engaging in deception if they perceive the therapeutic intervention or agent under study to be their best or only remaining therapeutic option. Careful attention to eligibility criteria in the screening history, physical examination, and laboratory tests can minimize, although not eliminate, the possibility of misrepresentation in order to enrol in research trials. In addition, mechanisms such as prorating payments over time might help minimize the possibility of misrepresentation during a study. Additional concerns about the ethics of offering payment to research subjects have received less attention. Some worry that payment might be more attractive to individuals with low socioeconomic status, and thus the payment of subjects could result in a disproportionate research burden on this population. In addition to worries about distributive justice, a skewed subject pool could confound the generalizability of data. Interestingly, offering no money or such a small amount of money that participation in research is inaccessible to those who are economically disadvantaged also has the potential to skew the subject pool and contravene principles of distributive justice, especially for research perceived as beneficial to participants (Grady, 2005).

Emmanuel *et al*, (2005) posit that any worry would mean that IRBs are not functioning properly and are ineffective at assessing the risk and benefit of research, hence approving protocols with unfavourable risk – benefit ratios. In their opinion, it could also mean that the mistake is in defining appropriate levels of risks and benefits posed by a research trial, or that a poor understanding of the definition of the term inducement. It however may be superfluous to assume that all IRBs at all times would exhibit sufficient diligence

in protocol assessment and approvals. Thus it is recommended that the review system be improved, resources be focused on better training of IRB members, and better evaluation protocols encouraged.

There are no data yet to indicate that payment leads to poor comprehension or that high inducements make comprehension worse. Indeed poor comprehension in developing countries is said not to be restricted to inducement for research. Adjusting incentives appears as an indirect and unproven method of improving research participants understanding (Adebamowo, 2009). With reference to infection with the human immunodeficiency virus and AIDS, providing antiretroviral drugs in trials on a restricted basis does not constitute undue inducement. The drugs may serve as inducement, but this does not pose risk of poor judgment, rather it enhances autonomy (Emmanuel *et al*, 2005).

2. 7 Compensation in Clinical research

Compensation in research is "something done to make up for losses or costs incurred in the course of participating in a study". Compensation covers payments for participation (time) as well as reimbursements for costs associated with participation in a clinical trial. Payments to research participants for participation in studies are not considered as benefits. Compensation is not always straight forward to calculate. Compensation that is easy to address includes reimbursements for meals, babysitting, and bus fare to and from the research site. Reimbursements involve refunding the trial participants for any resources they would have used or that they are expected to use in order to participate in a trial, e.g. transport and lunch. There are three categories of compensation payments that are often problematic and are difficult to calculate. These are payments for time, pain and inconvenience. In international research, calculating compensation levels becomes a very complex exercise that investigators, sponsors and ethics committees would rather not

tackle. Compensating trial participants for time, pain and inconvenience is difficult to calculate since it is based on the value of an individual's time and the cost they attach to the pain and inconvenience. The value of an individual's time depends on several factors such as local economic conditions and individual personalities. What may be one person's due inducement may be another person's undue inducement. Whilst it is acknowledged that compensation for time, pain and inconvenience are difficult to compute, it is generally agreed that trial participants need to be compensated for their time, pain, risks and other inconveniences. Compensating participants for their participation serves as a means of appreciating the risks and inconveniences of participating in research since participation in research, represents some form of sacrifice (Ndebele *et al,* 2008).

Clinical research depends on the successful recruitment and retention of participants. Fundamental to avoiding exploitation and demonstrating respect for research participants is care and attention to the selection, recruitment, and enrolment of groups and individuals in research. Decisions about who should be invited to participate in research take into consideration not only scientific objectives, but also dynamics of risk and benefit, and vulnerability. People participate in research for a variety of reasons. Understanding these reasons can help in recruitment as well as careful enrolment. The social value of research and the imperative to ensure scientific validity justify strategies to enhance recruitment of eligible participants to research protocols. Many primary care-based research studies have failed to meet their recruitment targets. Several means of increasing recruitment rates are possible, including offering incentives to potential participants, or to those helping with recruitment to the trial, or both. Clinicians' and patients' decisions to participate in research will be influenced not only by payments, reimbursement and incentives but also by their feelings of obligation and the perceived

benefits of participation. It could be argued that the need for payment or incentive should be a secondary consideration as participation in research is a moral obligation; likewise that the potential benefit is itself sufficient recompense.

The traditional position, that we should not pay patients to participate in clinical trials, is widely accepted, though sometimes challenged in the ethics literature (Grady, 2000). Large financial payments are regarded as an undue inducement because those from a more financially or socially deprived background may participate solely on the basis of financial need. Taking advantage of need and desperation is often regarded as exploitation, consisting in the exploiter's using something about the person for the exploiter's ends by playing on some weakness or vulnerability in that person. Proper respect for others is violated when their vulnerabilities are treated as opportunities to advance our own interests or projects. It is degrading to have one's weaknesses taken advantage of, and dishonourable to use the weaknesses of others for one's ends.

Payment suggests that the recipient makes a profit from their labour in the ordinary sense of being paid (e.g. getting wages for a job of work). This may also, but not always, include being compensated for antisocial hours or for risks taken as part of the job. There is ordinarily no ethical objection to receiving payment for one's labour. Questions about payment for research participation, however, need to take into account that participation in clinical trials may involve more than one's labour; it may involve donating samples of bodily tissue or fluid. This convention does not, however, extend to reimbursing participants for any expenses incurred in participating in the research. Indeed, similarly, rigorous justification is usually required if it is proposed that reimbursements should not be given. Research ethics conventions around payment and reimbursement are in

accordance with other areas where a distinction is drawn between reimbursement and payment.

Reimbursement is meant to cover the actual costs to the participant of participating. However, reimbursing participants also raises ethical issues and the unease that is felt about payment spills over into questions of equitable reimbursement and also feeds back into the concerns about exploitation. Fixing reimbursements for loss of earning for research participation at a similar level may violate the principle that the 'burden' of research participation should be shared equitably by all groups in society. This rate will be sufficient to fully reimburse many on lower incomes. Those, however, who are on higher incomes effectively, shoulder some of the financial burdens of conducting the research, which may in its turn deter them from participation.

The 'burden' of the risks to participation needs, of course, to be balanced against the potential health benefits that participants may receive if they take part in medical research. It is also possible that those on higher incomes may be happy to donate what is effectively loss of earning to a research effort. There is, however, little evidence to support this conjecture. On the other hand, offering a rate of reimbursement that would be commensurate to actual loss of earnings appears to violate the principle of equal pay for equal work. If, however, a clear line exists between reimbursement for loss of earnings and being paid, there is no violation of the principle of equal work for equal pay because no participant is actually being paid for their participation (Draper *et al*, 2009).

Injury in research may result from procedure adopted, medication/ devices being tested, and failure to follow approved research protocol. International guidelines on compensation for research associated injuries vary widely. Some suggest that sponsors/institutions are obligated to compensate for injuries regardless of who is to blame or whether participants

are paid. Others feel that subjects are aware of these risks and yet agreed to join the study. Practically however, it may be difficult to determine the relationship between the injury and the research participation, especially if it develops a while after the research is over. The cost of providing compensation includes the need to adjudicate claims and resolve disagreements. Participants need to be told whether compensations are available for injuries, and if so what they are, and where they can be obtained from. This information on compensation is certainly incentive in disguise.

In the United States, sponsors/institutions are not required to provide compensation. However, in many European countries clinical trials insurance is mandatory through which participants are covered regardless of fault. In Nigeria, researchers are enjoined to obtain insurance in case of research injury. The Department of Health Services – Public Health Divisions acknowledge that research depends on the successful recruitment and retention of participants, and as such researchers often will give money/other forms of compensation to participants. Compensation/incentives is not a general obligation, but may be offered in specific studies. Federal regulations do not specify restrictions on payment, however they do indicate that an investigator shall seek consent only under circumstances that provide the potential participants sufficient opportunity to consider his choice to participate, and that minimizes the possibility of coercion or undue influence (45 CFR 46. 116).

Furthermore, it is suggested that judgments on the reasonableness of a particular sum of money or other forms of payment be based on;

- Complexity of the research as it relates to the inconvenience to the participant
- Type and number of procedures to be performed
- Time involved
- Reimbursement for expenses
- Anticipated discomfort of the study

- Subject population.

  "The amount and type of incentives shall not be so large as to constitute a form of undue influence, and will be examined in relation to the risks and burdens of the research".

  The regulation prescribes that inducement must be identified during the consent process and documented in the informed consent form, including the amount, type and schedule of payment (if applicable); and that it should not be contingent upon completing the study (21 CFR 50.24).

2. 7. 1 Incentives in the incompetent and the vulnerable

Beauchamp and Childress (2009) described the vulnerable persons as incapable of protecting their own interests because of sickness, debilities, mental illness, immaturity and cognitive impairments. They are often unprotected by relevant laws on rights, exposed to potentially harmful circumstances, lacking in decision making capacity and socio- economically impoverished. Also classified as vulnerable are those easily susceptible to intimidation, manipulation, coercion or exploitation.

Some reports assume or assert that it is legitimate to pay healthy subjects but not patient-subjects for their participation in research (Lemmens and Elliott, 2001.). Healthy subjects are often motivated by money to participate in research, receive little or no benefit from participation, and may appropriately be considered independent contractors in research. Paying money to healthy volunteers is widely accepted, although concerns about undue inducement and distributive justice may still pertain. Although patient-subjects are often paid to participate in research, there is concern

about paying patient-subjects because of their vulnerability. Certainly illness can make people vulnerable in multiple ways. Presumably, patient-subjects are considered more vulnerable in research studies than healthy subjects because of the nature of the relationship with their physician and because of possible confusion about the difference between participation in clinical research and the receipt of clinical care, the so-called therapeutic misconception. Although this is an empirical question, it is at least plausible that offering payment to patient-subjects in research could help them distinguish participation in a research study from the receipt of clinical care and thus actually decrease their vulnerability. Offering money in return for participation might also enable a patient to say no to the physician instead of feeling obligated to do what the physician suggests. The goal of payment is to reduce the financial sacrifice that research subjects have to make, to compensate people for their time, or to show appreciation for their contribution. Patient-subjects equally deserve and should be paid comparably to healthy subjects. When patient-subjects participate in research that offers them desirable therapeutic benefits, money may seem irrelevant and unnecessary, even though not morally objectionable. However, when patient-subjects and healthy subjects are both asked to undergo certain identical study procedures for research purposes, in the interest of fairness, the two sets of individuals should be compensated similarly, as both are contributing to the development of generalizable knowledge to benefit others (Grady, 2005).

Offering payment in paediatric research involves special challenges not found in research with consenting adults. Research with children is vital. However, children do not provide their own consent to research but are enrolled by their parents or legal guardians, generally in accord with the child's best interests. Payment to parents for

their child's research participation could potentially sway parental decisions in favour of participation since there is no personal risk to them. To avoid making children commodities, some argue that parents should not receive money as incentive for their child's research participation (Institute of Medicine, 2004). However, making it possible for a child to participate in research can be inconvenient and costly for parents. Consequently, some find carefully calculated payment to compensate parents for time and inconvenience acceptable and unlikely to contribute to significant distortions in parental judgment, while others believe that compensation to parents should be limited to reimbursement for expenses. The American Academy of Paediatrics recommends the giving of gifts instead of money to children in a post-trial appreciation model (AAP, 1995), although many institutions do not appear to follow these recommendations. Giving money or non-cash gifts to children directly instead of to their parents is also difficult because children appreciate money and gifts differently depending on their age. Further empirical and conceptual research is needed to resolve when and how payment should be offered in paediatric research (Grady, 2005).

Chapter three

METHODOLOGY

3.1 Study Area

The study was undertaken in Jos using the Jos University Teaching Hospital (JUTH), ECWA Evangel Hospital (now Bingham University Teaching Hospital), Our Lady of Apostles (OLA) Hospital, (a residency training centre), and the University of Jos.

Jos the capital of Plateau state, is located in the middle belt region of Nigeria with a land size of 26,890 sq Km, and a population of 3,178,712 of which 622,872 reside in Jos metropolis. The state of Plateau has a population density of 103 persons per sq Km. Temperature is usually of a mean of 18 ^{o}C to 22 ^{o}C. The main occupation of the people is farming, and the vegetation is of the savannah type. The state has a history of mining activities with visible evidence of destruction of the surface soil.

3.2 Ethical clearance

The protocol for the study was submitted to the ethics committee of the Jos University Teaching Hospital, and a clearance obtained (appendix E).

3.3 Study Population, Design, and Data Collection

The study chose fifty (50) current, former and potential research participants serially; fifty (50) researchers who have had ethics committee approved protocols and those without ethical clearances serially.

Key informant interviews were conducted with seven (7) key respondents made up of heads of research/health institutions, community and labour leaders, and key researchers. These have experiences in research, administration, and community management. Among them were Chairmen of research ethics committees (former and current), researchers and human rights lawyers.

Two (2) focus group discussions were held consisting of lay persons, clergies, former and current research participants, youth and women leaders, researchers, students, community leaders and labour unionists.

The key informant interviews and focus group discussions were carefully transcribed. The KII were held at the instances and convenience of the respondents using pre determined question guide (shown in Appendix C).

Semi structured questionnaires (shown in appendices A and B) for research participants and researchers were distributed to respondents following a courteous approach and explanation of the study to them. Following the oral consents given, the informed consent form (Appendix D) was given along with the questionnaires for the respondents to sign and return with the filled questionnaires.

3.4 Inclusion and exclusion criteria

i. The study recruited those who have participated in earlier researches; those who were potential research participants; and those engaged in carrying out studies, reviews, or who are in positions to contribute to policies on research incentives in Jos.

ii. The KII recruited only those perceived to have good knowledge of policies on research

iii. Only those who gave their informed consents were recruited

3.5 Limitation of study

i. The study was restrictive in nature and others who would have loved to participate, having required knowledge were excluded.

ii. The sample size could have been larger and the power of analysis made stronger.

iii. No incentives were proposed nor administered as this was the instrument being tested. Use of incentives could have been of some valuable information. A possible next level of this work would be to introduce graded incentives in type, magnitude and timing, and to study their impacts on recruitment and outcomes.

iv. The specific role of education was not tested in this study, and this is considered a limitation.

3.6 Analyses of data

A mixed method of analysis was employed, using simple descriptive analysis and a qualitative evaluation of the responses.

Chapter Four

RESULTS

4.1 Research participants

One hundred questionnaires were given out, fifty each to research participants and to researchers. Thirty – one (62%) research participants responded by filling and returning their questionnaires, and twenty – four (48%) of researchers category responded.

The ages of the respondents from the research – participant category are from 17 years to 54 years. Twenty – one out of the 31 (67.74%) participants who returned the questionnaire (67.74%) are males while 32.26% are females. For the researchers – category, 17 (70.8%) were males and 7 (29.2%) females.

4.1.1 Degree of Responses

Of the fifty (50) questionnaires given out to the research participants, 31 were returned, representing 62 % of the respondents.

Table 1. The demographic characteristics of the research participants' category

Gender	N	Number that have participated in research earlier (%)	Number that have not participated in research earlier (%)
Male	21	9 (42.9)	12 (47.1)
Female	10	6 (60)	4 (40)

Table 2. Sources of Knowledge about Research in the research participants category

Source of information about research	Frequency (%)
From my lecturer	2 (6.5)
My office	2 (6.5)
By chance	2 (6.5)
Academic records	1 (3.2)
Friends	3 (9.7)
My doctors	5 (16.1)

Five (5) participants (16.1%), learnt of research from their doctors, 3 (9.7%) from their friends, 2(6.5%) each from their teachers, office and by chance respectively one person (3%) knows of research as part of work schedule.

Table 3. The motivation for participating in research as given by research participants

Motivation factor	N	Percentage
To aid research	4	12
For knowledge	6	18
For certification	1	3
Interest	2	6
Courtesy of researcher	1	3
Unidentified	18	58
Total	31	100

Six 6 (18%) were motivated to participate in research for purposes knowledge; 4 (12%) for aiding researches; 2 (6%) for their interest in the subject of study, and 1 (3%) each due to courtesy of the researcher, and as "obligation" for graduation. Eighteen research participant respondents did not identify any particular motivation.

4.1.2 Reasons for non – participation in earlier researches

Some of the participants that responded to the questionnaire explain why they had not participated in any research earlier than the present study, indicated that they were never before invited to participate (81.8%); others, who were invited but declined participation in earlier studies stated that it was because they did not understand what the research was all about (18.2%).

Table 4. Reasons for non – participation in earlier researches as given by research participants

Reason for non – participation	N	Frequency (%)
Was never invited	9	81.8
Invited but did not understand the research	2	18.2
Total	11	100

4.1.3 Receipt of incentives for participating in researches

Fifteen research participant respondents answered the question on whether they had previously received incentives for participating in researches. Six (40%) indicated that they had been motivated while nine (60%) were not motivated in any way.

Table 5. Frequency of receipt of incentives for participation in research

	Yes	No
Received incentives	6 (40 %)	9 (60 %)

Types of incentive received for participation in research

- Money
- Writing materials
- Drugs
- Academic scholarship
- Examination score

Six 6 (40%) of those who had participated in earlier researches indicated they were offered and collected some form of motivation for their participation. 60% were not motivated in anyway. 4 (66.7%) of those who received some form of motivation believed it was an incentive, but 2(33.3%) thought otherwise. Items the participant claimed they were given include; money, writing material, drugs, and academic scholarship (to attend seminars/workshops).

However, in the questionnaire, they were not required to indicate the type of researches they were invited to participate in.

4.1.4 Participants' understanding of Incentives

Research participants were asked to define incentives in their own words. They following were the responses given:

Participants understanding of what an initiative is, include;

- any item given as a gift to motivate you for doing something a form of inducement.
- a motivating factor that prompts somebody to take a responsibility
- Something to keep my interest
- Appreciation
- Something to encourage me
- it is a form of help
- A reward for a job done
- A gift or honorarium
- Something given for better cooperation compensation
- Something given to someone for a work done without prior promise of any gift.
- paying someone for work done
- I don’t understand

Participants understand incentives as a form of motivation, encouragement, compensation; a help, a reward, an appreciation or an honorarium. Some admitted that these motivations could make one perform better, keep an interest going and generate better cooperation. Two responses were that there should not have been any indication that an incentive would be administered and that

participants should be kept ignorant of whether incentives would be given or not.

4.1.5 Appreciation of incentives

The respondents who were given writing materials and drugs respectively said they would have preferred money, a certificate of participation, or a feedback/thank you.

4.1.6 Influence of incentives on research participation

Respondents believe that the types of incentives given influenced their participation in the following ways;

Table 6. Influence of incentives on participation as perceived by participants

Response	n	Frequency (%)
Not at all	3	27.3
Strongly	5	45.5
Weakly	2	18.2
Not sure	1	9
Total	11	100

Majority of respondents believe that incentives influence participation and preference hypothetically was given to money. Sixteen 16 (69.6%) respondents are of the opinion that preference for incentive should be money, and furthermore that the amount of money involved would influence participation proportionately. 2(8.7%) respondents were not sure of incentive would influence them in any way, but 5(21.7%) emphatically said they would not want to be influenced.

4.1.7 Timing of incentives

Research participant respondents were asked at what point in the course of the study they would like to collect incentives if that were to apply to the study they were participating in. Their responses are shown below.

Table 7. Time the participants would prefer to receive incentives:

Time to administer incentives	Frequency (%)
Onset of study	13 (54.2)
Mid-way into the study	0 (0)
At end of study	7 (29.2)
All through the life of the study (instalments)	2 (8.3)
No specific timing	2 (8.3)
Total	24 (100)

Thirteen 13(54.2%) respondents prefer to have incentive before commencement of research, 7(29.2%) at the end, 2(8.3%) all through the period of study, and another 2(8.3%) not specific. None (0%) opted for payment midway.

4.1.8 Is an incentive a bribe?

To further clarify the concept of incentives, the research participant category was asked if they view incentives as bribery. Their perceptions are shown below:

Table 8. The perception of incentives as bribe by participants

Response	n	Frequency (%)
Yes	1	4.2
No	18	75
Not sure	5	20.8
Total	24	100

Majority (75%) of respondents think an incentive is not a bribe 20.8% are not sure, but 4.2% believe it is a bribe.

4.1.9 Awareness of guidelines about protection of human research participants:

Research participant respondents were asked if they were aware of any legislations or guidelines about protection of human research participants. The responses are shown below:

Table 9. Awareness of guidelines on protection of human research participants by participant

Response	Frequency (%)
No	24 (92.3)
Yes	2 (7.7)

Ninety - two 92.3% of respondents are not aware of any form of legislation on incentives, but 7.7% said they are. One respondent who claimed to know referred so the "law of the federal republic of Nigeria". The other cited no guideline.

4.1.10 What is a Research?

Research participant respondents were asked to define 'research'. Their definitions are given below.

Responses include:

- Findings
- Finding out more about something
- Careful study of a subject
- Systematic investigation

Eighty – three (83.9%) (i.e. 26 respondents) of the research participants are aware that a research is a careful or systematic investigation, aimed at finding out (discovery). However 5 (16.1%) in the participant category could not define a 'research'.

4.1.11 Duration of involvement in researches:

The study sought to find out how long the research participants have been involved with researches. The durations as given are shown in the table below.

Table 10. Duration in which research participants have been involved in research

Duration (years)	Frequency (%)
<5	6 (50)
6 – 10	5 (41.7)
11 – 20	0
>20	1 (8.3)

The duration of participation in researches was, for most research participants, average of 10 years, with majority under 5 years.

4.1.12 Participants' suggestions on improving participation:

- Improving incentive
- Public enlightenment
- Proper explanation of research to participants (informed consent process)

4.2 Informed consent process

The study was explained in details verbally and in the informed consent form. Of the 100 questionnaires given out attached with informed consent forms, only 20 of the 55 returned was accompanied with signed forms representing 36.4%. Those who returned the informed consent form unsigned however indicated their consent verbally and they were taken for their words, having duly responded to the questionnaires. Their hesitation to document their consent by appending their signatures was however, not investigated.

4.3 Response of researchers - category

The age range of the category of researchers who participated in the study is 26-52 years, consisting of seven female (29.2%) and 17 males (70.8%).

Table11. Distribution of respondents according to occupation (researchers - category)

Occupation	N	Frequency (%)
Medical doctors	15	62.5
Lecturers	7	29.1
Town planners	1	4.2
Students	1	4.2
Total	24	100

4.3.1 Duration of involvement in researches of the researchers – category

The study sought to find out how long the researchers who responded have been involved in the research enterprise. The responses are shown in the table below.

Table 12. Duration of involvement of researcher - respondents in research activities

Duration (years)	Frequency (%)
<5	7 (9.2)
6 – 10	7 (9.2)
11 – 20	6 (25)
>20	4 (16.7)

Most researcher – respondents have been involved in research activities for between eleven to twenty years (25%), followed by the category of over twenty years (16.7%). 9.2% have been involved in research activities for less than ten years.

4.3.2 Process of recruitment of research participants by the researcher – respondents

The researcher gave responses to how they recruited research participants into the studies. The methods they employed are given in the table below.

Table 13. Method of recruitment of participants used by researchers

Method of recruitment	N	Frequency (%)
Voluntary indication	10	52.6
Clinic attendance	6	31.6
Advertisements/ questionnaires	3	15.8
Total	19	100

Nineteen (79.2%) of the researcher – respondents were specific about their method of recruitment. Ten (52.6%) of these, employ the informed consent

procedure, (i.e. explaining the studies to subjects, and seeking due consent, to recruit participants). Six (31.6%) merely recruited their patients from the clinic. They gave no evidence of sought consent; and 3(15.8%) used questionnaire/advertisements to recruit their research participants.

4.3.3 Researchers Awareness of guidelines for protection of human research Participants.

The researchers were asked of their knowledge of any guidelines on the protection of human research participants. Their responses are shown in the table below.

Table 14. Researcher respondents' knowledge of guidelines on protection of human participants in researches

Response	N	%
Yes	17	70.8
No	7	29.2

Seventeen (17) researchers (70.8%) claim awareness of guidelines for protection of human research subjects and (29.2%) are not aware of any. Of those who claim they are aware, the guidelines they are aware of include (as listed below):

a) Helsinki
b) 'Ethical clearance'
c) 'Consent'

d) ‘Human right protection ethics’

e) ‘Safety and confidentiality’

f) ‘Ethical committee’

g) Belmont’s report

h) Nuremberg Code

i) Drug trials and new innovations

j) Identify confidentiality

Only 4 researchers made reference to the Helsinki declaration, Belmont Report, and the Nuremberg code, representing 23.5% of the knowledgeable about guidelines on protection of human research participants.

4.3.4 Definition of Incentives by Researchers

When asked to define an ‘incentive’, the following answers were given (listed below) as definition of incentives by the researchers;

- Provision of support for research
- Reward given for full participation
- Gift given to encourage/motivate a person.
- To motivate their ignorance
- Gifts to entice people with participating in one’s research.
- Stimulates to aid participation
- Little things to encourage participation
- A motivation to participants
- Giving gratification to the participant before enrolment
- Inducing those being used with materials or monetary things

- Payment for services/goodwill
- Remuneration/honorarium
- A form of stipend/allowance

Generally, the majority of researchers are of the opinion that incentives are instruments of motivation, encouragement and enticement. However, a minority are of the opinion that incentives are stipends, honorarium, allowance, gratifications, and payment for services/goodwill. Some respondents opine that incentives are inducements, rewards or stimuli for participation.

4.3.5 Need to use incentives in the past:

Some researcher – respondents used incentives regularly (33.3%), and those who never used incentives or used by rarely represented 37.5% and 29.2% respectively, in the researchers populations. These are shown in Table 15 below.

Table 15. Past use of incentives by researcher – respondents

Previous use of incentives	N	Frequency (%)

Used regularly	8	33.3
Used rarely	7	29.2
Never used	9	37.5
Total	24	100

4.3.6 Expected outcome from use of incentives:

Fifteen (15) researchers (62.5%) stated their expectations from the administration of incentives. Nine of these (60%) expected better cooperation from participants; 2(13.3%) each expected improved research outcome and enrolment; one (6.7%) believes it serves morally on compensation for participation. Another was not specific about the expectation from incentivization (6.7%).

Table 16. Expected outcome of incentives as perceived by researchers

Perceived expected outcome of incentives	Frequency (%)
Better cooperation from participants	9 (60)

Improved outcome	2 (13.3)
Improved enrolment	2 (13.3)
It is only a moral obligation, (to satisfy researcher's conscience)	1 (6.7)
No expectation	1 (6.7)

4.3.6.1 Items used as incentives

The researcher who admitted having used incentives described their terms of incentivization as shown in table 17:

Table 17. Items used for incentives by researchers in Jos

Items used as incentives	Frequency (%)
Drugs	2 (9.1)
Plastic containers	3 (13.6)
Paid for transportation	1 (4.6)
Free medical check up	3 (13.6)

Food	5 (22.7)
Paid for laboratory tests	1 (4.6)
Cash	5 (22.7)
Drinks	2 (9.1)

Some of the researchers responded that they offered more than one type of incentives in some cases. The use of food and cash appear most used, followed by free medical check up and drugs. Payment for transportation does not appear favoured, and one responded gave out plastic containers.

4.3.6.2 Factors Researcher- respondents considered in giving incentives to participants

The most important factors the respondents would like to put into consideration in giving out incentives are shown in table 18.

Table 18. Factors researcher – respondents would like to consider in administering incentives

Factors considered to give out incentives	Frequency (%)
Availability of funds	8 (21.0)
Willingness of participants	4 (10.5)
Nature of research	2 (5.3)
Time frame for the research	2 (5.3)
Socio – economic status of subjects	13 (34.2)
Perceived input of participant to the research	2 (5.3)
Age of participants	2 (5.3)

Location of research	4 (10.5)
Medical condition of subjects	1 (2.6)

Majority of respondents would consider the socio-economic status of the participants as prime factor (34.2%), followed by the availability of funds (21%), willingness to participate (10.5%), and the location of the study (from residence of the participants (10.5%). Others factors in the minority include (nature of the research (5.3%), research duration (5.3%), perceived input of the participant to the research (5.3%), age of the participant (5.3%), and the medical condition of the subjects (2.6%).

4.3.6.3 Time Researcher – respondents would like to administer incentives:

The researcher – respondents were similarly asked at what time during the study that they would like to administer incentives. The responses as given are shown in table 19.

Table 19. Time researcher – respondents would prefer to administer incentives

Time preferred to give incentives	N	Frequency (%)
Commencement of study	7	29.2
Midway into the study	9	37.5
End of study	8	33.3
Total	24	100

Twenty – one (87.5%) of researchers hold that incentives should be given and three (12.5%) go against its use. Respondents, who believe incentives should be administered

recommend that incentives should be administered midway into the study (37.5%), end of study (33.3%) and at the commencement of study (29.2%) in that order of preference.

4.3.6.4 Perceived impact of incentives by researchers – respondents

The perceived impact of incentives on enrolment, behaviour of participants, and research outcome as enunciated by researcher – respondents are shown in table 20 below.

Table 20. Percentage response of likely impact of incentives as perceived by researcher – respondents.

	Impact on enrolment	Impact on participants' behaviour	Impact on research outcome
No impact	0	0	0
Significant impact	18 (75%)	19 (79.2%)	12 (52.2%)
Negligible impact	4 (6.7%)	2 (8.3%)	5 (21.7%)
Not sure	2 (8.3%)	3 (12.5%)	6 (26.1%)

Majority of researcher – respondents perceive that incentives will enhance enrolment (75%), the behaviour of participants (79.2%) and the outcome of the study (52.2%). 16.7% believe there would be negligible effect on enrolment and 8.3% not sure how incentive can influence enrolment. Some researcher – respondents are not sure of the role of incentive on participant behaviour (12.5%), and on research outcome (26.1%).

Others are of the perception that the influence would be negligible on subject behaviour (8.3%) and research outcome (21.7%).

4.3.6.5 (a) **Assessment by Researchers of Participants' reactions to incentives used,**

In the opinion of the researchers, the reactions/responses of their study participants to the incentives are as shown in table 21.

Table 21. How the researcher –respondents perceive the response of their study participants to the Incentives used.

Perceived response of participants to incentives	Frequency (%)
Acceptable	9 (69.2)
Excited	2 (15.4)
Neutral	2(15.4)

Researcher – respondents describe the reaction of the participants to be acceptable in majority of cases (69.2%) and in 15.4% of cases where either excited or neutral. ["Acceptable", according to the researchers meant that the participants did not object to the item used, neither would they have opted out of the research if the incentives were not given. "Excited" implied that the item for incentives visibly altered the psychological mood of the participants, giving an impression of enthusiasm. "Neutral" was used to apathetic to the use of the incentives.]

4.3.6.5 (b) **Regrets of researchers to use of incentives**

Researchers expressed their regrets in the use of incentives as shown in table 22.

Table 22. Regrets of researcher – respondents in the use of incentives

Regrets	Frequency (%)
No regrets	5 (33.3)
Makes participants greedy	4 (26.7)
Holds study to ransom	3 (20)
Limited resources	2 (13.3)
Wrong perception of research by participants	1 (6.7)

Majority (33.3%) of researcher – respondents have no regrets administering incentives. However, 26.7% of the respondents are worried that it makes participants greedy, 20% feels it holds the study to ransom and 13.3% worried about limited resources available to use. 6.7% of researcher – respondents fears that it sends the wrong signal to participants about the research.

4.3.6.6 Incentives thought to be best for our environment:

In an attempt to design a uniform incentive model for the Jos environment, the following represent the opinion of the researcher – respondents.

Table 23. The opinion of researchers on the best incentives for research in Jos

Proposed incentives	N	Frequency (%)
Monetary	10	41.7
Non – monetary	8	33.3
Not sure	6	25
Total	24	100

Researcher respondents are of the opinion that financial incentives would be the best for our environment (41.7%). 33.3% of them however differ, thinking more in favour of non-monetary incentives; and 25% respondents not sure of what would be the best for Jos environment.

4.3.6.7 Sources of incentives administered in researches by researcher – respondents

Sixty-five (65%) of researcher – respondents funded the incentives used in their studies from their personal income, 30% had some form of sponsorship in the form of research grant from their institutions, and only 5% had assistance from pharmaceutical companies (table 24).

Table 24. Sources of incentives used for studies

Sources of incentives used	Frequency %
Personal income	13 (65)
Institutional research grant	6 (30)
Drug companies	2 (5)

4.3.7 Clarity of the terminology 'incentives' to researcher - respondents

Is incentive synonymous to a bribe? This was a question posed to the researcher – respondents. It was clear in the minds of majority of respondents (66.7%) that an incentive is not a bribe. However, 25% believe it is a form of bribe, while 8.3% were not sure (table 25).

Table 25. The perception of the morality of incentives by researcher – respondents in Jos

Response	Frequency (%)
It is a bribe	6 (25)
It is not a bribe	16 (66.7)
Not sure	2 (8.3)

4.4 Summary of key informant interviews:

Seven (7) key informant interviews were conducted, and consisted of the following categories of persons (shown below):

Key informant	Description
AA	Human subject researcher; Current member, REC; superintendent of tertiary health organization.
BB	Human subject researcher; past REC chairman.
CC	Superintendent of tertiary health institution; current REC chairman
DD	Human subject researcher, Academic, Labour activist.
EE	Lawyer, Community leader, unionist
FF	Human subject researcher, chairman, medical advisory committee, former member, REC.
GG	Human subject Researcher; Former Dean of Medical College; Former Commissioner for Health.

4.4.1 Definition of research by key informants

The key informants defined a research as a scientific inquiry or investigation leading to new discoveries. Research, some said, should be based on a hypothesis, and on a driving principle of guided decision for publishable findings. In the opinion of some, what we have in our environment can not in their truest senses are called researches. Much of what we have, they posited, are certificate driven pursuits which play down on the required rigorous search for new discoveries. One informant, is however,

comforted that research is a developing enterprises and later on, the people will get the principle right.

On the issue of the response of people to research in our environment, every key informant agrees that it is poor, and unfortunately so. Some of the reasons advanced include low literacy level, poverty, and that research is relatively still alien to our social culture. The majority of informants believe that the potential research participants in this environment are not very cooperative. They adduce reasons such as lack of motivation/incentives and the nature of the research to be responsible. In this environment, the informants claim that people are not too patient with "follow-up" visits for research, and also with invasive procedures such as venepuncture and the like an informant put it this way:

> *"Generally, people are not interested in participating in research, the reason, even they cannot state".*

Another informant puts it as:

> *"Researches are poor due to lack of materials for meaningful investigations. Our people are looking for gains in virtually everything, and research does not appear to be a profitable venture in an economic sense."*

An informant, who had been a chairman of a research ethics committee opined differently:

> *"People are involved in research knowingly or unknowingly, due to illiteracy. Thus they usually respond to research participation with excitement"*

Another respondent was quite emphatic about the poor attitude towards research in our environment.

"Any venture that does not yield immediate cash reward is not usually well tolerated. Even to respond to a questionnaire, you would need to pursue people, and in addition may have to dilute the questionnaire to make it as friendly as possible, such as the tick only option format".

There are others however who have hope for a better response to research participation in our environment. It was put in this way;

"What we have is a certificate oriented drive, not really a rigorous scientific investigation. But we will get there"

4.4.2 Ethical clearance

Not all the key informants have had their research protocols reviewed by any ethics committee. They however appreciate the review function of such a committee.

4.4.3 Definition of incentives by researchers

The responses of the informants appear to convey understanding of what an incentive is. For instance, one said;

"An incentive is a material appreciation given to make people perform an activity, to encourage them to be more committed.

The respondent would rather not use the word 'induce' and as explained, feels that using inducement would appear to connote some form of illegality. Another would prefer to equate incentives to inducement freely;

> *"Incentive is an inducement to influence people to participate in a study"*.

It was however added;

> *"It is not any particularly different from bribery, compensation or coercion"*

A respondent would want to be more specific as to what should constitute incentives. While it is believed that incentives are inducements in quarters, designed for encouragement, they should be seen as;

> *"A kind of support given to participants in the form of transportation cost, refreshment, accommodation, or the like"*.

A caution was added to the understanding of incentives. In this situation, a participant may not negotiate or determine what should constitute an incentive; as such an individual may choose what is hazardous to his health. It was put in this way;

> *"An incentive is any degree of motivation within ethical limits. An ethical limit here is to imply that what is administered is not detrimental to the health of the participant. e.g., giving an alcoholic drink to a liver cirrhotic would not be the right incentive even if the participant so chooses"*

4.4.4 Use of incentives

Key informants are varied with the use of incentives in their previous studies. A respondent considered the category of participants in order to administer incentives. For instance, nurses were given financial incentives while patients had free laboratory services. The informant does not believe that money was the most effective, as some persons would have preferred drugs or socialization from lunch invitations.

The environment and culture are believed to influence incentives administration. Respondents believe that there is a need to individualize incentives, as personality differences are likely to play major roles e.g., participants' level of education, needs, interests, etc. Some participants it was claimed are even likely to ask for co – authorship of publications emanating from the research. On a holistic view, monetary incentives are viewed by most respondents to be the most effective item of incentivization because of the level of poverty.

A respondent indicated administering water guards to study participants. The items were said to be originally supplied to the organization and meant for a different category of non-research study patients. The diversion was justified on the grounds that items were about expiring, and that the participants were excited about items. On whether this an after-thought or pre-planned, the response, the response was;

> *"Research participants should not have any foreknowledge of what would be used as incentives. Only REC members should know about items to be used as incentives as that may be part of their review process"*.

Some respondents view the free laboratory services, monetization of transportation, free freshmen etc as equally effective. On one occasion the informant reported thus;

"We administered soft drinks, particularly 'malt' to people after taking their blood. We gave this because of the belief of the people that 'malt' drinks; having the same colour of blood would be a good replacement for the blood taken from them"

A word of caution was given by another key informant, on the use of the terminology 'incentives';

"We should be careful using the phrase 'incentives'. I would prefer to refer to it in this context as a token of appreciation. Normally, these items are given at the end of the research, and most of the participants never get to be recruited again into further studies".

4.4.5 Recommended standard for incentives Administration in Jos

It was generally difficult to determine what the ideal standard of incentives should be, according to the informants. Some of the respondents while admitting the difficulty would still recommend the use of money (cash) as incentives. They admit that this position is borne out of the poverty level in our environment. The worry about cash incentives is how to determine the amount of cash that would be sufficient as an incentive. Some recommend giving an amount just enough to pay for the cost of transportation and meals. It was stated by majority of respondents that REC cannot adopt any uniform standard of incentives. The advantage of the use of cash incentives, it was stated, would be the encouragement derived from participants' feeling of being engaged in ventures that yield added value. Where people come from different locations, it was recommended that the cost of expenses be borne retroactively including even re – fuelling of vehicles for owners of automobiles (or cash in lieu of

petrol). The monetary incentives, it was further argued, would make it possible to adopt a uniform measure of incentives, since all the studies would not be about the same thing all of the time.

Some respondents opined that the amount of money to be given as incentives should however depend on the environment/community in question. For instance, the locals may not require large amount of cash, while the enlightened would require larger amount to secure their cooperation. It is the suggestion of a few of the informants however, that as much as it is possible, a uniform amount of money should be given irrespective of the categories of persons. It is the view of some that disproportionate amounts would yield bad effects since;

> *"Ours is a resource poor environment, and the poverty mentality prevails. Indeed, setting a standard would be an uphill task because of differences in personalities".*

The other position about setting a standard for incentives administration is that monetary payments should be down – played in favour of free participation;

> *"Our standard of researches here is poor because of poor funding. Consequently, we have poor incentives, simply because you cannot give what you don't have. In the absence of the availability of cash, we should try the 'plea – option', i.e, begging the subjects and informing them of their very vital role in contributing to findings that would benefit the society".*

It is opined that people should be made aware of their contribution to improving the society by participating in researches. It is the belief of this category of respondents

that the participants perceived preference for cash is due to their not understanding the contributory roles; and advocacy in this direction would tilt the preference from cash to 'positive – contribution' value system. Furthermore, it will make people more flexible to demands of incentives, even in high – risk studies.

One informant sums the situation up in this way;

> *"Human beings are insatiable, so one cannot bend towards negotiations for incentives. But money is a strong factor. We however have not explored other methods, e.g., awards, plaques of recognition etc. Let me say that we yet cannot set a standard, no, we cannot. We have a problem with our value system. Take for instance our attachment to types of houses, cars etc, and we need to correct this. I would therefore recommend a mix to REC, monetary and non – monetary incentives. But always keep in mind that for now, money stands out".*

4.4.6 Incentives and other parameters

The understandings of the key informants about incentives and coercion, exploitation etc are diverse, as they are interesting. One stated;

> *"Incentives or inducement can never be morally right because it makes you do what you ordinarily never planned to do. I cannot think of a situation where inducement/incentives would be totally right".*

The respondent claimed that coercion, bribe, and exploitation all carry negative connotations like incentives. Indeed majority of the respondents have difficulty in establishing any significant differences between incentives and coercion, bribery,

compensation, exploitation and undue inducement. To them, a common denominator to all these is the existence of an ulterior motive, to make people do what they ordinarily would not have done.

A key informant in the minority however argued that incentives differ from other parameters. It was explained that the difference lies in the fact that coercion comes before an action while the incentive is administered after the study. Furthermore, it was posited that bribery cajoles or wins over a subject with a psychological threat as opposed to the physical threat in coercion. Some of the respondents felt that it would be difficult to make distinctions as there is always an element of one parameter in the other. The illustrations as given include;

> *"Compensation is given after a loss of something, but incentives are not about replacing any loss".*
>
> *"Inducement is like an appetizer while incentives are natural accompaniments of the process".*
>
> *"Undue inducement does not exist. There can only be undue influence"*
>
> *"Exploitation is a reflection of under – compensation or over – utilization".*

Chapter Five

DISCUSSION

Understanding research

The study interviewed seven key informants, held two focus group discussions and administered one hundred minimally structured questionnaires. There was a 67.7% response to the questionnaires administered. The concept of research was clear to both categories of questionnaire respondents, the research – participant respondents (RPR) and the researcher – respondents (RR). They all admitted that a research is a scientific investigation into any issue of interest. About 16% of RPR claimed that they learnt about research from their doctors, and this group represented the highest single source

of information about studies. The RPR (12.9%) indicated that the major motivating factor for their participating in researches was their willingness to aid research. The RR consisted of medical practitioners (62.5%), non – medical practitioners (29.2%) and students (4.2%). About 71.4% of RR claimed that they follow the due informed consent process to recruit participants. About 42.9% merely recruited from their clinics while 21.4% also included advertisements to recruit participants. The RR who claimed to be aware of ethical guidelines about research participation accounted for 70.8%, while 29.2% admitted that they were not aware of any guidelines. Among those who claimed to have been aware of ethical guidelines, only 23.5% could correctly mention any current ethical guidelines on protection of human participants in research.

On incentives

RPR understand incentives to be a form of inducement or motivation, to ensure better cooperation from them. They agreed that incentives strongly influence the level of participation in research (45.5%), even though 9.1% were uncertain about the influence of incentives on research participation. The items for incentives administration, according to the RPRs included cash, writing materials, drugs, and stipends for academic conferences. For 75% of RPRs, incentives are not considered as bribes, though 20.8% are uncertain about the morality of incentivization. The majority of RPRs (54.2%) would prefer to have incentives administered at the onset of any study. if given a a choice 69.6% of RPRs opined that they would opt for cash as the

item for incentives administration. Nine – tenths of RRs admitted they were not aware of any guidelines on protection of participants in researches. The suggestions proffered by RPR to improve participation in researches included improving the quality of incentives, and ensuring better enlightenment about researches.

About a third of RR claimed they use incentives regularly, while 37.5% had never used. Another 29.2% admitted that they rarely used incentives. The items employed in incentives administration, according to RR included drugs, plastic containers, free medical examinations and laboratory investigations, payment for transportation, and provision of refreshments. According to RRs, 29.2% of them would prefer to give incentives at the onset of studies, 37.5% midway into the study, and 33.3% at the end of the study. About 41.7% and 33.3% of RR suggested cash and non – cash incentives respectively for the Jos environment. A quarter of RR were not sure what to suggest as a standard for incentives in Jos. RRs perceived that the reactions of research participants were 'acceptable' (i.e., displaying an obvious willingness to receive the incentives) 69.2%, 'excited' (i.e. showing visible emotional display of happiness on receiving the item) 15.4%, and 'neutral' (i.e. an apathetic attitude to the offer) 15.4%. The RR further opined that the administration of incentives could also have some on – toward consequences on the research process. Some of these, they reasoned included a tendency for participants to get greedy (26.7%), participants holding the study to ransom (20%), or even for the participants getting the wrong perception of the essence of researches.

On the impact of incentives, as perceived by the RR, about three quarter believed that incentives have significant influence on enrolment for research, and on the behaviour of participants. About of the RR considered the effect of incentives on research

outcome to be significant. Less than 10% of RR considered the effect of incentives on enrolment of participants, and behaviour of participants negligible. On the research outcome, 21.7% of RR opined that incentives made negligible impact. Some RRs were not certain about the influence of incentives on enrolment, participant behaviour and research outcome (8.3%, 12.5% and 26.1% respectively).

The sources of fund for researches according to RR included personal salary income (65%), institutional research grants (30%), and drug companies (5%). RRs would like to consider the following factors when administering incentives; availability of funds, willingness of participants, nature and duration of researches, location of the study, age of participants, and the medical condition of the participants. Over two – third of RR did not consider incentives as bribes, while a quarter thought an incentive is a bribe. A little less than a tenth part was uncertain.

Key informant responses

Key informants (KI) interviewed included human participant researchers, members of research ethics committees, medical education and healthcare administrators, community and labour leaders, and lawyers. The KI believed that generally, people in Jos are apathetic to researches. In their opinion, people are always in search of ventures that yield financial gains, and understandably, show poor response to enterprises like researches that do not give financial gains. They also stated that researchers in Jos lack funds and materials to prosecute researches, and that majority of researchers are more 'certificate - driven' than being passionate about discoveries. KI admitted that incentives that incentives are given with the intent to motivate or

support participants (e.g. transportation, accommodation, refreshment, etc) where need be. In Jos, the KI believe that environment and culture play significant roles in people – perception of incentives, and the roles in this case are on more on the negative than the positive. Majority of the informants would like to consider cash payment for a uniform standard of incentives administration. It was however also stated that setting a uniform standard for incentives administration would be herculean. According to them, the basic concern would arise from how to determine an ethically acceptable limit to be applied to all participants.

The opinion of a minority of KI however was that incentives are never morally right, being a form of inducement. For instance, it was stated by one whom;

"...could not yet imagine a situation where inducement/incentives would be morally right",

that incentives use in research was a necessary moral wrong. The KI opined that Jos being a resource – poor setting would require the exploration of other non – cash means of incentivizing research participants. They gave examples of giving awards, plaques of recognition, thank you cards and visits, among others.

The role of incentives in motivating survey participation has been widely documented (Church, 1993; Singer *et al*, 1999). Reasons why people refuse to participate in surveys and how those reasons might affect the quality of the data collected have also been widely studied (Singer *et al*, 2003). Among these reasons are alienation from society and concerns about privacy and confidentiality. Much less attention has been paid to the motives for participation; the reasons may vary from one type of research to another and across demographic categories.

Response rate

The response rate in the present study to the questionnaire was 62% with more females than males who gave their consent to participate. This does not appear to support the anecdotal assertion that females are socially so inhibited and that they may not be able to exercise autonomy to participate in researches. At least, that does not appear to be represented in the Jos situation as the selection of the women was not particular to the emancipated category of women. Indeed, 16.13%learnt of researches from their doctors, supporting that the females could have been involved due to influence of their search for medical care.

Motivating factors for research participation

The participants' response showed that the greatest motivation for participating in studies was quest for acquisition of knowledge (19.4%). Most of the other participants were out of emotional attachment to their physicians, and the willingness to help or regard for the courteous approach by the researchers. This is rather encouraging since it gives a good signal that knowledge remains central to both the researcher and the participant. This position exemplifies what Groves *et al* (2000) called "leverage-saliency theory" to describe the decision to participate in a survey. They view this decision as resulting from multiple factors—some survey-specific (e.g., topic and sponsorship), others person-specific (such as concerns about privacy), still others

specific to the respondent's social and physical environment. Each factor may move a particular person toward or away from cooperation with a specific survey. Furthermore, these factors, they claimed, carry different weights for different persons, and they become salient when an interviewer introduces the survey and requests participation.

One respondent claimed that the motivation to participate in the study was for the purpose of graduating from school. The significance of this underscores what one key informant stated, that a number of people in Jos approach research with the goal of obtaining certificates, not necessarily for any discoveries. The concern here would be that the same "certificate – drive" might be playing out too for the researchers, e.g., resident doctors seeking fellowship status of their postgraduate colleges.

The human subject research enterprise does not appear to be a thriving venture in Jos. 81.8% of participants indicated that they had never before been invited to participate in researches. In arguing against the use of the phrase "incentives", one key informant suggested that in Jos the word should be substituted with "a token of appreciation" as one may not meet with the participants for another study again.

The concept of incentives in Jos

The concept of incentives is regarded by the participants in various ways. For instance, some referred to it as gift ',' help', 'reward ',' honorarium, compensation, or a 'payment'. Majority admit that the items were given to encourage participation, or ensure their cooperation. It is the opinion of many that the motivations were capable of ensuring a better outcome. It is to be acknowledged though that a minority of the researcher – respondents is of the opinion that incentives should not be given for

participation in researches. Some reports show that money is more effective than non-cash incentives, and that prepayment is more effective than a promised incentive (Draper *et al*, 2009). Incentives are also more effective in surveys where the response rate without an incentive is low. That is, incentives are especially useful in compensating for the absence of other motives to participate. They are also most effective in the absence of other persuasion efforts (Groves *et al*, 2000). Both monetary and non-monetary incentives are inducements offered to compensate for the absence of factors that otherwise might stimulate cooperation. Similar findings of the differential effects of incentives have been reported by Berlin *et al*, (1992), although this compensating effect of monetary incentives has not always been found. This is corroborated by this study in Jos.

Items used in Jos as incentives include writing materials, drugs, money, food and free laboratory tests. Preference for incentives was for money (69.6%). Some of the participant – respondents also added that money would influence them. Interestingly, 21.7% of researchers – respondents were emphatic that incentives would not influence them in any way.

When deciding whether to offer payment to research participants in a study, investigators should take into account the nature of the study, the nature of participant contributions and vulnerabilities, institutional or organizational guidelines, and local societal and cultural norms. In the research proposal submitted to their Research ethics committees, investigators should describe the rationale for payment, how the naira amount was calculated, and how and when payment will be made. Payment information should also be included in consent forms as prescribed by most codes for ethical research conduct. Research ethics committees 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. Therefore, discussion of payment should only arise after the risk-benefit ratio of a study is found ethically acceptable. RECs should review the justification for and the amount and schedule of payment and decide whether these variables are appropriate given the particular study and the population to be recruited. In making this determination, Research ethics committees should consider study risks, potential vulnerabilities of the targeted subject population, eligibility criteria and screening plans, proposed methods for assessing subjects' knowledge of risks and ability to make voluntary autonomous decisions, and local norms. These factors were adduced to by researchers - respondents in Jos. Plans for how and when money will be disbursed are also important. Prorating payment for studies involving multiple visits could minimize the possibility of inappropriately influencing someone to remain in a study just to receive a lump sum payment at the end. Payment according to actual time and procedures completed is consistent with offering money as compensation for a subject's time and inconvenience. About fifty – four percent (54.2%) of participants preferred to have incentives at the beginning of the study while 29.2% of researchers support same. Indeed, 37.5% of researchers would prefer to administer incentives mid – way into the study and 33.3% at the termination of the study. Only 8.3% of participants would like to wait till the end of the study to collect incentives. This appears suggestive of a hidden mistrust. The implication of this could be that if given a choice, researchers would not want to give incentives just as the participants would have held – back their involvement in studies. This unexpressed mistrust appears mutually perceived, and so create a divergence in time of administration of incentives between the participants and the researchers.

Majority of the participants and researchers do not accept that incentives are bribery (75% and 66.7% respectively). A large number of participants (20.8%) were not sure, just as 8.3% of researchers were, about the comparison between incentives and bribe. Ironically, more researchers (25%) than participants (4.2%) considered incentives as bribe.

About nine – tenths (92.3%) of participant – respondents and 70.8% researcher – respondents claimed to be aware of some guidelines for the protection of human subjects in research. The only participant – respondent who would name it responded by quoting "the law of the Federal Republic of Nigeria". Even among the researcher – respondents only 23.6% o those who claimed knowledge were actually knowledgeable, being able to cite correctly any of the ethical guidelines for the protection of human research participants. Others mentioned things like "ethical clearance", "consent", "safety and confidentiality", "ethical committee", "drug trials" "identity" and "new innovations" as the legislations they were aware of, about protection of human subjects in research.

Recruitment practices and incentivization

For the recruitment of participants, 52% researcher – respondents said they adopt the informed consent procedure while 32% simply converted their patients to research participants without the due consent procedure. This reflects poor knowledge and application of certain ethical principles of research. It is little wonder then that only 23.5% of researchers were truly aware of the ethical guidelines for human subject researches out of the 70.8% that claimed knowledge. This corroborates the position of

the research participants that a good number (33.3%) were recruited by their physicians.

The understanding of incentives appears vague in the minds of a numbers of researchers in Jos. For most, it is a compensation for participation, or a gift given to express courteousness or appreciation. They do however admit illogically, that incentives are instruments of motivation; the researchers prefer to give the instruments of incentives at the end of the study even when they did not have other upcoming studies to which the participants may be recruited in. The question is then asked; what was the participant motivated for? After all, the study is already over.

One fact appears to stand out from this present study, and it is that the researchers – respondents were grossly presumptuous about the participants. They assumed that the participants are poor, illiterates, and most likely unwilling to participate in studies, given by their responses. Almost all researchers – respondents and key informants claimed that money might be the preference for incentives in the Jos environment because of the level of poverty. They however admitted having being in the research enterprise for the average of 11 – 20 years, and with no evidence that non – administration of monetary incentives adversely affected studies. It is to be expected therefore, that research participants actually participated in studies out of their interest in acquiring knowledge as they claimed, and also as a product of their emotional attachment to their doctors, as opposed to the position of majority of the researcher respondents.

In a situation where some researchers believe that incentives are bribes, legally and morally wrong, it stands to reason that such ones are not likely to submit to any moral

urge to incentivize. The other option that better research advertisement be made with pleas for free participation might be more tenable. Firstly, the participants claimed that they be just too glad to hear a "thank you" from those who recruit them, or be communicated whatever the results of the study that used them, are. The preference for this position is buttressed on two grounds;

i. Most studies said to researches in Jos were actually certificate – oriented projects conducted by students (undergraduate and post graduate). These are usually not sponsored or supported by any form of grants. Thus it would be practically difficult to administer any meaningful monetary incentives. Even the few that are grant – supported claim insufficient funds for their projects.
ii. The purported prevailing poverty level in Jos applies to all the stakeholders, researchers and their participants. It would be easier therefore to the researcher to appeal to participants for free participation, as both parties are likely to adequately understand each other.

Ethics committees have an important role in developing guidelines in this area. Specific guidelines are needed considering existing local policies and procedures; payment models and their application in diverse settings; case study examples of types and levels of reimbursement; applied definitions of incentive and inducement; and the rationale for diverse payment practices in different settings. Respondents all agreed that it would be difficult for ethics committees to adopt any uniform standard of incentives in this locality. This appears true, but probably not only to the Jos environment. Some respondents had served on the Research Ethics Committees in different capacities, and had prescribed incentives, but do not have the moral push to implement or apply sanctions with regards to incentives administration. This further

supports the position that the knowledge and practice of incentives in Jos is currently suboptimal. Even the factors that the researchers would like to consider in applying incentives are conjectural. Good number of researchers – respondents were not sure how incentives would influence enrolment (8.3%), behaviour of participants (12.5%) or outcome of research (26.1%). This is even out of the response that 69.2% found their participants favourably disposed to the studies, and 15.4% out rightly excited.

A third (33.3%) of researchers – respondents expressed no regrets about using incentives, but 26.7% fear that incentivization would make participants greedy and 20% think that incentives would make the participants hold the study to ransom. These positions further buttress the conjecturality and presumptuousness of the researchers over the participants. No respondent admitted to any of these happening to his/her study in about the 20 years of research practice.

Evaluating whether or under what research circumstances money might impair a subject's judgment would be important, as well as the extent to which payment leads people to participate against deep objections. The other category of researchers was concerned about poor resources and wrong perception of researches by participants. One feels that these concerns would further lead credence to the suggestion that researchers attempt to convince potential participants of the study, funds availability, and their possible contribution to knowledge, then appeal for free participation. It however does not rule out the compensation/reimbursement for extra cost incurred by the participants. Ackerman (1989) gave a position on this earlier; IRBs wrestle with the role of incentives for research participation and have yet to come up with a universally accepted framework. For example, Ackerman (1989) laid out his view of the ethical issues posed by incentives from a human subject's perspective. While

incentives can be seen as consistent with the goal of encouraging social cooperation, which is valuable (so perhaps payment should be unrestricted), it may also undermine the requirement that research participation be voluntary. The prospect of economic reward may lead people to undertake risks that are not consistent with their true values and preferences. In addition, providing incentives may undermine the principle of fair treatment if it leads to disadvantaged persons participating in research at a higher rate than wealthier subjects. Ackerman prefers recruitment of altruistically motivated subjects and advises that payment be limited to reimbursement for expenses, but allows that this may make it impossible to conduct research so he also proposes that IRBs view research subjects as "wage labourers". In this framework, the level of incentives would be based on the time commitment required and the nature and number of procedures involved or the amount of risk subjects undertake. Alternatively, wage payments could be viewed as "pure inducements" – the amount geared to the level required to recruit an adequate number of subjects within the required period of time. His framework assumes that subjects are not exposed to excessive risk and that incentive levels are guided by the economic value of their time as "unskilled labour" on a part-time basis and increased in relation to the arduousness and the social value of the work.

The FGDs reflected two issues – ignorance of the research concept by lay persons, and similar positions as expressed by the key informants and questionnaire respondents. This suggests that the modest research activities in Jos do not appear to be appreciated by the community. Additional understanding of variation in local or regional norms and participants' values as they relate to money, as well as how to

consider the economic conditions in communities in which research will be conducted in formulating an approach to payment, would be useful.

Amidst increasing public interest and scrutiny of research one issue attracting growing attention is the question of whether payments to research participants are ethical. Practices seem to depend on the research setting and target group, the availability of funds, and what is accepted practice within particular disciplines and the ethics committees that oversee the research. Indeed, payments are seen as a necessary way of ensuring an adequate response rate from busy professionals and therefore as a way of ensuring the validity of the research. According to existing guidelines, the major ethical concern raised by research participant payment is its possible adverse impact on voluntary consent. Current National Health and Medical Research Council (NHMRC) guidelines for ethical conduct in research involving humans in Australia specify that "the consent of a person to participate in research must not be subject to any coercion or to any inducement or influence which could impair its voluntary character" (Fry *et al*, 2005).

It seems there are three possible stances one can take, and this has been enunciated by earlier reports (Ndebele *et al*, 2008) as;

i. payments are a fair reimbursement for participant contribution, effort, and expenses incurred
ii. payments represent undue influence on choice to participate thereby undermining voluntariness
iii. Payments serve as a fair influence on a participant's choice to engage in research and do not undermine voluntariness.

Conclusion

In practice, judging when research participant payments constitute undue inducement and when they are fair recognition is complicated. For one individual, a particular mode or amount of payment may be sufficient to cloud judgement regarding involvement in research, whereas for others payment may not affect their decision. Such judgements are not made any easier by the lack of clear and often conflicting guidelines. Policies and procedures do exist in different research institutions, however, they are rarely disseminated beyond the settings in which they were developed (Fry, 2005). The present findings suggest some interesting points about the basis of decision making on participant payment ethics, which could inform development of guidelines on this issue in our locality. The rationale for incentives administration in Jos was largely identified as paying participants for out-of-pocket expenses and recognition for contribution, although a minority identified the provision of inducement or incentive as a motivational item. However, the results also raise concerns about how researchers and ethics committees interpret the boundaries of incentive and inducement when making decisions about participant payment ethics, and what this might mean for expectations of consistent ethics committee decisions on this question.

Recommendations

The sample size for this study was relatively small. It is recommended that one would further carry on with this work using larger a sample population and to involve more categories of respondents.

The role of education was not particularly considered in this work. It is hoped that this would be taken into consideration in further work to assess the impact of education on the administration of incentives in Jos.

It is intended that in further stages of the work, each of the instruments of incentivization would be independently assessed with respect to their influence on the outcome of research.

Further empirical research is necessary to identify the manner in which ethics committees and researchers make decisions about participant payment practices using larger participants and over a longer duration of time.

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APPENDIX A

Questionnaire for research participants

1. Age.....
2. Sex a) male b) female [tick as appropriate]

3. Have you ever participated in any research study? a) Yes b) No

4. If' yes' in Q3 above,

How did you know about the research? (Tick as appropriate); (from my doctor) ,(from my friend), (by chance), (others, specify)……..

5. What motivated you to participate in the study?.....

6. Did you actually give your consent to participate in the study? a) Yes b) No

7. If 'no' in Q3 above, why have you not? a) I was never invited to, b) I was invited but declined, c) I did not like the terms of the research, d) I was afraid, e) I did not understand what the research was all about.

8. If your answer in Q3 was "yes" were you given any gift, remuneration or a promise to participate in the study'? a) I was given b) I was not given

9. If you were ever given any 'motivation' to participate, did you take it? a) yes b) No

10. Would you consider that the motivation could also be referred to as incentive? a) yes b) no c) don't know

11. What incentive(s) have you ever received for participating in a research? a) money, b) food items, c) writing materials, d) drugs, e) academic scholarship, f) nothing, g) none h)others (specify).....

12. What do you actually understand by the term 'incentive '?

13. Would you have preferred to have another type of incentive other than the one you got? a) yes b) no

14. Suggest what you would have loved to get as incentive for participating in a research study.....

15. Do you think the incentive you got in any way influenced the way you participated in the study? a) no, b) strongly yes, c) weakly yes, d) not sure

16. Would you have behaved in any way differently; a) if it were money, yes. b) if it was bigger, yes. c) Not sure, d) No

17. At what time would you love to collect an incentive to participate in a research? a) before commencement of research, b) midway into the research, c) at the end of the study, d) all the way through the life of the study, e)others, specify

18. Would you like to agree if told that an incentive means the same thing as a 'bribe". a) yes. b) no, c) not sure.

19. If your answer to Q18 is 'yes', why do you think so? ……

20. If your answer to Q18 is 'no', why do you think so'?.....

21. Are you aware of any legislation regarding 'incentive[1]? a) yes b) No

22. If your answer in Q21 is yes, what is the law you know of?.....

23. What is a 'Research? .....

24. How long have you been involved with 'Research'? a) below 5 years, b) 6-10 years,

c) 11 – 20 years, d) above 20 years

25. Kindly suggest ways in which you think participation in research can be enhanced. .....

THANK YOU.

APPENDIX B

Questionnaire for researchers

1. Age..
2. Sex. a) male, b) female
3. Profession.....

4. How long have you been involved in Research'.' a) below 5 years, b) 5-10 years,

c) 11 -20 years, d) above 20 years.

5. Does your research involve human participants? a) yes, b) no
6. What is your research focus? .....

7. How do you recruit human participants into your study?.....

8. Are you aware of any guidelines for protection of human subject research participants'? a) yes. b) no
9. If yes, which?.....
10. How would you like to define 'incentive' for research participation?.....

11. Have you had a need to use incentive at any time in your research studies?

a) regularly, b) rarely, c) never.

12. What were your expectations from the use of incentives for research?

13. What have you used previously to incentives in your studies? a) money, a) food, c) clothing, d) drugs, e) academic scholarships, f) others (specify).....

14. What three (3) most important factors would you like to put into consideration in offering an incentive to a participant? i).....ii).....

15. How would you like to define 'coercion'?.....

16. How would you like to define 'undue inducement'?.....

17. Would you agree that 'incentive' means the same thing as 'bribe'? a) yes, b) no, c) not sure.

18. At what time in the life of a research should incentives be given? a) before commencement, b) midway into the study, c) at the end of the study, d) it should not be given at all.

19. What would you consider as the influence of incentives on research enrolment'.' a) none, b) significant, c) negligible, d) not sure.

20. What would you consider as the influence of incentives on the behaviour of subjects in a research study? a) none, b) significant, c) negligible, d) not sure.

21. What would you consider as the influence of incentives on research outcome? a) none, b) significant, c) negligible, d) not sure.

22. How have people reacted to your policy on incentivising research subjects? .....

23. What ONE regret do you have about the use of incentives in research? .....

24. Are you aware of any legal implication of the use of incentives in research? a)yes b) no.

25. If your answer in Q 24 is 'yes[1], what is that law?.....

26. What research incentive do you think yields best for research studies? a) monetary, b) non-monetary, c) not sure

27. What is the source of the incentives you administer in your researches?.....

28. Kindly suggest ways in which you think participation in research can be enhanced .....

THANK YOU.

APPENDIX C

(Guide for key informant interview and focus group discussions)

1. How would you define 'research'?

2. What is the response of the people in this environment to research?

3. What factors would you consider responsible for their kind of response to research?

1. Have you had your research proposal approved by any Research Ethics Committee?
2. How would you define 'incentives[1]'?
3. What kind of incentives have you used/or approved in previous researches?
4. What informed the choice of incentives used, and how would you assess its (or their) effectiveness?
5. What other incentives do you think would have yielded different results?
9. What would you recommend (or did you use) as standard of incentives for use, or as criteria for protocol approval?

10. What things would you recommend to researchers and REC to adopt as appropriate for standard for use of incentives, and why?
11. How is incentive different from coercion, bribe, compensation, undue inducement, exploitation?

THANK YOU

APPENDIX D

Informed consent format

I, Dr Samuel Odu Odeh, a Masters of Bioethics student would like to undertake a study on Knowledge and Practice of Incentives in Research Participation in Jos, Nigeria. This Study would involve the use of questionnaires, interviews and group discussions. There are no foreseeable significant injuries to subjects in the course of this study. Information given shall be treated with utmost confidentiality, and every participant is at liberty to withdraw from the study at any point that he/she feels unable to continue. There shall be no untoward consequences for withdrawing from the study at any stage. The result of this study may not be of any particular immediate benefit to the participants, as it is basically for future generalizable knowledge. Attempts would however be made to avail results of the study to participants at the end of the research, on request initially, and later on vide other means of public dissemination of information. At any time during the course of the study or afterwards, you may feel free to contact the researcher using the addresses; Department of Human Physiology, Faculty of Medical Sciences, University of Jos [GSM Phone Number 0802 200 5638] or West African Bioethics Training Program/University of Ibadan, Department of Surgery. Alternatively, the Chairman of the Research Ethics Committee, Jos University Teaching Hospital, Jos, may be contacted.

Should you have understood the intent and procedure of this study, and are willing to consent to participate, kindly sign in the space provided below.

Initials/Signature of intending participant…….. Date……....

Signature of Researcher…….. Date……....

THANK YOU

APPENDIX E

Letter of ethical clearance to carry out study

JOS UNIVERSITY TEACHING HOSPITAL
JOS, NIGERIA

Phone: 073-450226 - 9
E-mail:juth@infoweb.abs.net

Cables & Telegram: JUTH
P.M.B. 2076
Jos.

Ref: JUTH/DCS/ADM/127/XIX/4424

Date: 21st February, 2011.

Dr. Samuel Odu Odeh,
Department of Human Physiology,
University of Jos,
Jos.

RE: ETHICAL CLEARANCE/APPROVAL

I am directed to refer to your application dated 29th November, 2010 on the research proposal titled: **"Knowledge and Practice of Incentives for Research Participation in Jos, Nigeria"** and your appearance before the Ethical Committee on 20th January, 2011.

Following recommendation from the Institutional Health Research Ethical Committee, I am to inform you that Management has given approval for you to proceed on your research topic as indicated.

You are however required to obtain a separate approval for use of patients and facilities from the department(s) you intend to use for your research.

The Principal Investigator is required to send a progress report to the Ethical Committee at the expiration of three (3) months after ethical clearance to enable the Committee carry out its oversight function.

Submission of final research work should be made to the Institutional Health Research Ethical Committee through the **Secretary in Room 14, Administration Department,** please.

On behalf of the Management of this Hospital, I wish you a successful research outing.

Hajia R. Danfillo
For: *Chairman, MAC*

INSTITUTIONAL HEALTH RESEARCH ETHICAL COMMITTEE
DESPATCHED
21 FEB 2011
JOS UNIVERSITY TEACHING HOSPITAL, P.M.B 2076 JOS