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Challenges in Implementing the Ethical Norms in Research on Autistic Children in the Indian Context

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Abstract— **Human subjects are used in numerous research experiments, clinical or non clinical, which involves collection of data from them and later, analysis of data. The participants are exposed to primary risk of the research when the researcher attempts to collect, use and apply information accessed from the participants. This makes ethics in research a very vital subject while conducting research in human subjects.**
Research with children adds more dimensions to ethical norms where permission from parents / guardians are also required. Further, the magnitude of this vulnerability intensifies while research is conducted on children with special needs and protecting their rights and welfare become imperative.

This paper looks into the issues on conducting research on autistic children. The intermingling of ethical principles, participants rights, research goals, socio-cultural context and working with very vulnerable special population brings out crucial issues for the researcher on implementing the ethical goals, which are discussed in the present study.

This paper aims at identifying the challenges in implementing the ethical norms in research on autistic children in observation based studies in the Indian context. The participants are extremely vulnerable children with special needs. The objective of the paper is also to highlight the Indian socio-cultural environment which plays a critical role in research on human subjects.
Finally, the paper arrives at tentative recommendations on how to treat autistic children as research participants and suggests appropriate modifications of current guidelines, wherever required, so that ethical norms are widely understood and adhered to. The need for awareness about ethical norms in research on human subject is stressed on.
The present paper is based on case studies on 42 autistic children to develop diagnostics and therapeutic test batteries for the autistic children as reference. The challenges in implementing ethical norms while conducting research studies on these children are underlined.

To discuss these vital issues, the study looks into the guidelines issued by the World Medical Association (WMA), the Council for International Organizations of Medical Sciences (in association with World Health Organization WHO), the Indian Council of Medical Research (ICMR) and National Committee for Ethics in Social Science Research in Health (NCESSRH).

The paper identified the challenges in the Indian context so that ethic norms are widely adhered to. Appropriate suggestions suitable for children with developmental disorder based on Indian context have been made. A research work on autism should contribute towards the welfare of the autistics and just treatment of participants in research calls for special attention

Keywords— **Ethical norms in research on human subjects, autism**

I. INTRODUCTION

Human subjects are used in numerous research experiments which involves collection of data from them and later, analysis of data. Experiments carried out on human subject in clinical based studies require investigation and collection of biological specimens while analysing epidemiological aspects. In non clinical studies, investigation may be in the form of surveys, questionnaires, interviews, and focus groups. In fact, without human subjects, developments in medical science or social science will be

drastically impaired. However, the participants are exposed to primary risk of the research when the researcher attempts to collect, use and apply information accessed from the participants. This makes ethics in research a very vital subject while conducting research in human subjects.

II. ETHICS IN RESEARCH ON HUMAN SUBJECTS

A concrete guideline on ethics in medical research can be traced back to 1947 when the Nuremberg Code was published. It was the first international tool which focussed on the ethics in medical research and brought out an elaborate guideline to safeguard the integrity of the research subject. Provisions were laid down for the adherence of ethical conduct during research involving human subjects and emphasized on obtaining voluntary consent from the participants. Numerous German and Japanese researchers were notorious for conducting inhuman experiments during the World War II. Later, when the horrors performed by Nazi physicians in the concentration camps were revealed, it left the world in shock as to how appalling uncontrolled experiments could become [10]. Soon a trial of the physicians were carried out and in the due course, the Nuremberg Code was formulated which eventually became the archetype for ethics to be followed during experiments with humans. It became imperative for any medical research on humans to be done 'only after free and informed consent of the subject and in light of a reasonable relation between risks and benefits' [1].

Instances of gross disregard for ethics in research on human subjects was witnessed in the past. During 1932 to 1972, in Alabama, an experiment was conducted on 399 black men for a study on the last stages of *syphilis* [11]. The participants were not informed about the experiment conducted on them, nor were they provided a treatment for cure, despite the availability of medicines. The last stages of syphilis included tumors, heart disease, paralysis, blindness, insanity and death and the experiment noted these deterioration of the subjects as they were deliberately left to succumb to the disease. Data was collected from their autopsies as well. The devastating experiment led to the death of 28 men due to syphilis while another 100 succumbed to related complications. Further, wives of 40 men were infected and many children were born with congenital syphilis [11]. This infamous study is known as the *Tuskegee syphilis experiment.*

As various inhuman experiments came to light, the *National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research* was formed between 1974-1978 to develop the ethical principles to guide research and to recommend rules and procedures to protect the rights and welfare of human subjects [10]. The Belmont Report was issued by the Commission in 1979, establishing a robust ground for the adherence of rules and regulations while conducting research on human subjects in the US focusing on three principles of *respect for person*, *beneficence* and *justice*. They later formed the basis for informed consent, assessment of risks and benefits by ethics committees and selection of subjects [11]. Ethical principles in research on human subjects safeguards the participants in research from similar threats.

Further, the World Medical Association (WMA), in its 18th General Assembly in 1964, developed a set of guidelines to safeguard the rights of participants in clinical research in the *Declaration of Helsinki*. Following numerous revisions, the guideline contains 32 principles, focusing on *informed consent, confidentiality of data, vulnerable population and requirement of a protocol, including the scientific reasons of the study and review by the ethics committee* [13]. The Declaration of Helsinki states that *'in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.*

Soon bioethics spread in the academic arena to form a distinct form of study. Andre Hellegers founded the Kennedy Institute of Ethics in 1971 at Georgetown University and a new field of research in medical ethics, 'bioethics' came up which was defined as 'the study of the ethical dimensions of medicine and the biological sciences' [10]. Further, Dan Callahan, who founded the Hastings Center in 1974, vouched for bioethics as a new discipline. Additionally, public commissions and committees took up bioethical issues.

Government regulations were set up which strongly emphasized on the need to set up an institutional review board (IRB) in all research institutions to ensure the ethics in research on human subjects. The IRBs would be in charge of review and approval of all scientific proposals intending to use human subjects. Consequently, IRBs were formed and researchers, physicians and scientists were required to follow ethical research principles and regulations to protect the welfare and rights of subjects. In the 1980s and 1990s, bioethical concerns spread its wings to many regions at a global platform.

India was not free of controversial research works. In 1970s and 1980s researchers at the Institute for Cytology and Preventive Oncology in New Delhi, carried out a study on 1158 women patients of different stages of cervical dysplasia or precancerous lesions of the cervix. These patients were not treated so that the advancement of the lesions could be observed and their progress to cancer, if any, could be noted. The study concluded with 71 women developing malignancies and lesions in 9 patients advanced to invasive cancer [13].

In 1982, the Council for International Organizations of Medical Sciences (CIOMS) in association with World Health Organization (WHO) developed the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. They especially stressed upon ethical issues in less developed countries like investigator's duties regarding consent, appropriate inducements, special/vulnerable populations, therapeutic misconceptions and post trial access. In 1980, the Indian Council of Medical Research (ICMR),

released a *Policy Statement on Ethical Considerations involved in Research on Human Subjects*, which became the first official guideline for establishment of ethics committees (ECs) in all medical colleges and research centres in India [6], [13]. In 2000, the ICMR released the *Ethical Guidelines for Biomedical Research on Human Subjects* which laid down guidelines for researcher in India to follow while conducting research on human subjects. A revised guidelines were made available in 2006.

At present international regulatory documents that have become manuals to conduct of research on human subjects include the Helsinki Declaration of 2000, CIOMS 2002, UNESCO document 2005 and ICMR Guidelines (specifically for India). The four principles which constitute the basis for ethics in research [6], [12] :

(i) The Principle of Non-maleficence which states that the research must not cause harm to the participants in particular and to the people in general.
(ii) The Principle of Beneficence states that research should make a positive contribution towards the welfare of people.
(iii) The Principle of Autonomy notes that research must respect and protect the rights and dignity of participants.
(iv) The Principle of Justice notes that the benefits and risks of research should be fairly distributed among people.

International Ethical Guidelines for Biomedical Research Involving Human Subjects states 21 principles [2] - Ethical justification and scientific validity, Ethical review committees, Individual informed consent, Obtaining informed consent Essential information for prospective research subjects, Obtaining informed consent: Obligations of sponsors and investigators, Inducement to participate in research, Benefits and risks of study participation, Special limitations on risk when research involves vulnerable individuals, populations or communities with limited resources, Fair distribution of burdens and benefits in the selection of groups of subjects in research, Research involving vulnerable persons, Research involving children, Research involving individuals with mental or behavioural impairments where they are not capable of giving adequately informed consent, Safeguarding confidentiality and Strengthening capacity for ethical and scientific review and biomedical research. Further, Dan Callahan emphasized on the interdisciplinary nature of the field of bioethics and noted that ethical dimensions should be supplemented with legal, political, psychological and social dimensions [10].

The ICMR's *Ethical Guidelines for Biomedical Research on Human Subjects* has 12 general principles to be followed by all biomedical researchers and stressed on safeguarding the dignity, rights, safety and well-being of the participants. It stressed on the need of a well-documented informed consent which was sensitive to an individual's autonomy, considerate for vulnerable populations, reduced therapeutic misconception and provided post trial access. These principles are influenced by another dimension, the socio-cultural environment in the Indian context. The socio-cultural environment plays a critical role in giving a direction to any research work on human subjects.

Jawaharlal Nehru University is India's premier research university, promoting international level research in different disciplines and a formal mechanism for the creation of an environment of ethical research become essential. The Institutional Ethics Review Board in Jawaharlal Nehru University (IERB-JNU) for research involving human participants was set up in 2009 as per international norms and guidelines [8]. An M.Phil level four-credit course on Ethical Issues and Concerns in Research on Human Subjects is being offered by the Centre for Linguistics and is open to all the students in JNU. The IERB-JNU strives to maintain standards of excellence in research involving human subjects and preparing students to meet challenges of ever changing relationship between science and society. IERB-JNU has been conducting orientation programs to spread awareness and educate future generations of researchers for ethical research.

III. RESEARCH ON CHILDREN WITH SPECIAL NEEDS

Research with children adds more dimensions to ethical norms where children are incapable of giving consent to participate in research and permission from parents / guardians become mandatory. As per the Declaration of Helsinki, 2013, children are primarily susceptible and are at a likelihood being under greater harm [7]. As such, the Indian Council of Medical Research (ICMR) has released a new document, *National Ethical Guidelines for Biomedical Research Involving Children* in 2017. The Guideline clearly states that any research on children must consider the level of their physical, cognitive, emotional, and psychosocial development.

Further, the magnitude of this vulnerability intensifies while research is conducted on children with special needs and protecting their rights and welfare become imperative. ICMR [7] states that the children are not cognitively or emotionally capable of giving consent to research participation on their own behalf**.** Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

Risk or harm is another crucial dimension in research involving children which may be in the form of physical (e.g blood sampling), psychological (e.g. separation from parents) or social. Any form of pain and discomfort should be prevented during research on children [7]. According to the ICMR Guideline 2017, major consideration while conducting research on children should be Scientific validity of the work, analysis of risks involved, safety, autonomy, confidentiality and voluntariness.

This paper looks into the issues on conducting research on autistic children. Autism is a developmental disorder marked by deficits in social interaction, verbal and nonverbal

communication, and repetitive behaviors or interests. There are major deficit in communication and the lack of language and communication ability hampers the autistic child's ability to express and many a times leads to behavioural problems. Autism cannot be cured, but early intervention may help maximize the child's language and communication level.

The intermingling of ethical principles, participants rights, research goals, socio-cultural context and working with very vulnerable special population brings out crucial issues for the researcher on implementing the ethical goals, which are discussed in the present study.

IV. AIMS AND OBJECTIVES

The present study is a non-clinical observation based study on highly vulnerable subjects belonging to special population, that is, autistic children. Investigation involved surveys, questionnaires, interviews and direct observation. The paper will focus on two facets – the challenges in applying ethical norms and recommendations to overcome them.

This paper aims at identifying the challenges in implementing the ethical norms in research on autistic children in observation based studies in the Indian context. The participants are extremely vulnerable children with special needs. The objective of the paper is also to highlight the Indian socio-cultural environment which plays a critical role in research on human subjects.

Finally, the paper arrives at tentative recommendations on how to treat autistic children as research participants and suggests appropriate modifications of current guidelines, wherever required, so that ethical norms are widely understood and adhered to. The need for awareness about ethical norms in research on human subject is stressed on.

V. METHODOLOGY

The present paper is based on case studies on 42 autistic children to develop diagnostics and therapeutic test batteries for the autistic children as reference. The challenges in implementing ethical norms while conducting research studies on these children are underlined.

The study discusses interaction with the parents / guardians of 20 autistic children from special education centers in Guwahati, Assam. Interactions with 10 special educators from these centres have also been reported.

To discuss these vital issues, the study looks into the guidelines issued by the World Medical Association (WMA), the Council for International Organizations of Medical Sciences (in association with World Health Organization WHO), the Indian Council of Medical Research (ICMR) and National Committee for Ethics in Social Science Research in Health (NCESSRH).

VI. DISCUSSION

The intermingling of ethical principles, participants rights, research goals, socio-cultural context and working with special population brings out challenges for the researcher on implementing the ethical goals. Issues focused in the paper are ethical justification and scientific validity, special limitations on risk in research involving autistic children, Individual informed consent, obtaining informed consent focusing on the autistic research subjects, inducement to participate in research, benefits and risks of study participation and safeguarding confidentiality.

The following discussion highlights the complexities and tries to draw suggestions to mitigate them.

4.1 Ethical justification and scientific validity

The Council for International Organizations of Medical Sciences (CIOMS) in its guideline states that *'the ethical justification involving human subjects is the prospect of discovering new ways of benefiting people's health.'* A research can be ethically justifiable only when it is carried out to:

- *Respect* and *protect* the participants
- *Morally* acceptable within the community in which the research is carried out

Due to the extreme vulnerability, autistic children should be included in research only for the benefit and wellbeing of the autistics. Respecting and protecting the autistic individual becomes very important, more so because they are unable to understand or express their need for respect and protection. The researcher has to judge, plan and implement these needs on a case to case basis. The ethical line has to be drawn by the researcher and ensure their comfort and well-being.

Benefits received by the participant could be direct or indirect. The direct benefit should be better tests and treatments for the autistic individuals. This could be specific to the participant, other individuals in the participant's special education centre / school or the immediate community.

The indirect purpose could be to generate information increasing the understanding of autism which could become a guide for future research in autistic management.

4.2 Special limitations on risk in research involving autistic children

Special limitations while conducting research on children with autism have to be implemented. The autistic child's inability to give or refuse consent raises various concerns for the participants. Research on children with autism involves the consent of parents/ authorized guardians. Parents / guardians are not the direct participants in the research and thus not the focus of the research. Numerous questions are answered by them on behalf of the child which are used in the research.

The researcher depends on their judgment and assessment for many facts about the child. This has added complexities.
Any discomfort, mood swings, stress, rejection of an activity should be regarded as refusal and it should be respected. These cues should be considered as refusal and comprehended by the researcher, parents, guardians or special educators. This has to be ethically respected with special consideration for the following:

- Inconvenience to the participant
- Session duration and regularity
- Comfortable / familiar environment
- Understanding the individual needs of the child

Any research should ensure social, physical, emotional and psychological safety of the child as its prime goal.

4.3 Individual informed consent

Research guidelines asserts that an investigator must obtain the voluntary informed consent in all biomedical research involving human subject and while considering research on children with special needs, who is not capable of giving informed consent, the permission of a legally authorized representative is mandatory.

Generally, the Informed consent is in two parts - the Participant Information Sheet (PIS) and the Informed Consent Form (ICF). The PIS & ICF provides the following information to the participant:

- A brief description of the study objectives in simple language (verbal & written)
- Purpose of the study
- Identity of the researchers & Institutional affiliations
- Study Procedures
- Risk & Benefit of study, including the discomfort it may entail.
- Compensation
- Confidentiality
- Rights of participants
- Advantages and disadvantages of the research
- Sources of funding
- Any possible conflicts of interest
- Future use of information

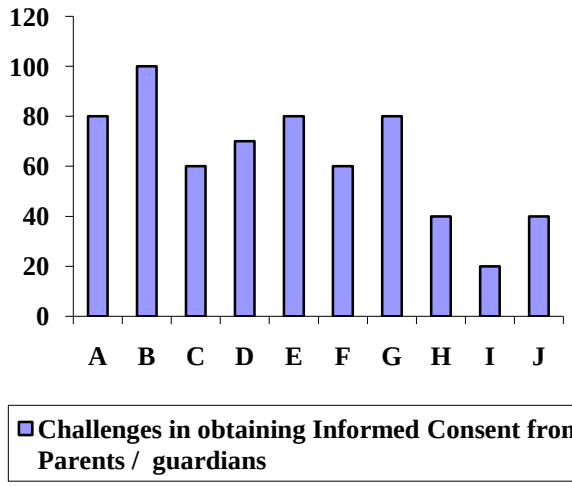
Once the information has been explained to the participant, a written Informed Consent should be obtained.

1) *Obtaining informed consent focusing on the autistic research subjects*

Two very crucial right of the research participants are that the consent should be given *voluntarily* and that consent can be *withdrawn at any time*.

The children with autism (like any other developmental disorder), are legally, physically and mentally incapable of giving consent and consent must be obtained from parents or legal guardians.

Obtaining the consent from the participant's parents or guardians brings out many challenges for the researcher. Parents / guardians of the children are trapped in the vicious circle of complexities of bringing up a special child. To give their consent, parents / guardians, at the foremost, seek direct benefit. They may not want their child to participate in research activities and may even be apprehensive of the researcher's intent. Research objective which marks future benefits may not interest parents / guardians. The study notes the major challenges in obtaining individual informed consent from parents / guardians as mentioned in *Fig.1*.



A – Apprehensive about their child's participation in research / fear of research risk | B – Desirous od firect benefit | C – Unwilling to sign consent form | D – Difficulty in understanding an elaborate consent form | E - Doubt about research / researcher's motive | F – Lack of awareness about community benefit of a research | G – Fear of social stigma in case confidentiality is compromised | H – Denial / difficulty in acceptance of a special child | I – Past negative experience | J – Lack of awareness of available intervention programs

Fig. 1: Challenges in obtaining Informed Consent from parents / guardians

80% of primary care givers showed apprehension about their child's participation in research, majorly due to fear of research risk. They feared research oriented intervention could interfere with their child's regular routine and hamper their development. They feared that research participation could

give rise to behavioural problems and once the research concludes, the Institute's / special education centre's educators may not be able to tackle these problems. 60 % of parents/ guardians lacked much awareness about community benefit of a research. These fears led to 80 % doubting the research / researcher's motive. They were more desirous of direct benefit (100%) for their autistic child.

Moreover the consent form also created complexities for the parents/ guardians. While 60% were unwilling to sign the consent form, 70% had difficulty in understanding an elaborate consent form. These issues are discussed in details in a later segment.

Further, 80 % worried of social stigma in case confidentiality of the participant was compromised. The social intricacies led to 40% of parents/ guardians being in a state of denial / difficulty in acceptance of a special child. They believed, that they would keep the child in a special education centre for a few months and soon integrate him/ her in a normal school as 'the problem was a temporary one.'

20% reported past negative research experience where they faced difficulties including researchers leaving without intimation, not sharing research data after completion of research work, using photographs of their child without permission.

40% lacked awareness of available intervention programs. Those parents / guardians have tried to put their child in regular schools but, many regular schools do not have the facility to accommodate special children. As a result, the parents / guardians have kept the children at home without actually knowing about the availability of special education centers in Guwahati.

Investigating deeper into the major challenges in obtaining individual informed consent from parents / guardians, the paper divides these concerns into three segments.

A. *Expectations of the parents / guardians from a research work*

Parents / guardians gave their consent for their child's participation as subjects in research with some expectation from the researcher and the work. 100% of the parents / guardians sought direct benefit, better training modules and better autism management vis-à-vis the child. As a result, research proposals which were directed for autism understanding without direct benefit for the participating child were denied permission for participation. Only 40% of the parents / guardians were willing to give their consent for a research work aiming for the welfare of the society at large or future research benefit.

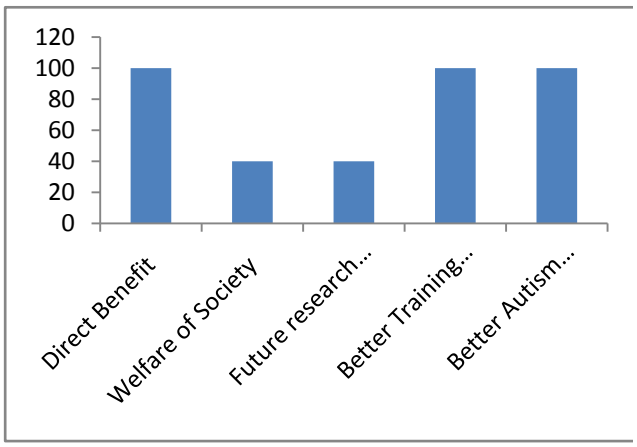


Fig. 2: Expectations of the parents / guardians from a research work

Autism is a life-long condition with neither cause nor cure. Many research comprise of understanding the cause of autism or its major features, developing diagnostic batteries, developing training modules for parents and children, which may or may not have direct benefit on the child participating in the research.

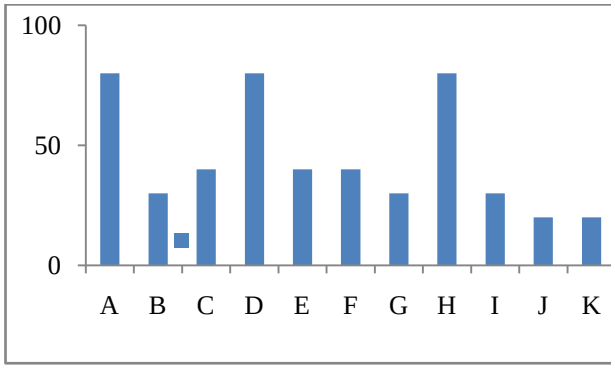
A. *Challenges in Voluntariness / Participation in the research*

Obtaining consent from parents / guardians for the autistic child's participation in research is often confronted with socio-cultural hurdles, misconceptions and stigma.
The parents have to face the social stigma of having an autistic child, in fact, a child with a mental disorder. 80% of parents have stated the kind of shame and embarrassment they have to face. As a result, they keep their child away from social contact, even avoid taking them to their relatives. In fact, many parents make all possible efforts to hide the fact that their child is autistic, so much so that they hide and get their child to a special education centre. More than a label of autism, children with developmental problem are said to have 'mental problem' or 'mental retardation'. This force of social stigma in compounded with the fact that 30% of parents deny that their child has autism. One child's parents got into a defensive tone when a researcher suggested that the child may have a developmental problem and professional help or consultation with a paediatrician would be helpful. The parents said that the child was taking some time to adjust to his new school and there was no problem with the child at all.

The child, after 2 years (at the age of 8 years) was diagnosed with autism in AIIMS.

Another challenge that a researcher faces in obtaining a consent is that the parents / guardians look for cure at any cost. 40% of parents believed that drug therapy can cure autism and tried many have tried different medicines for autism cure while 40 % of parents have tried religious methods as a means of cure. Some parents have tried both drug therapy and religious methods.

Denial of the fact of having an autistic child, attempts to cure autism and failure thereby leads to dejection and 80 % blamed their destiny for the current state. Shockingly, 20% of husbands even blamed their wife for having an autistic child. Further, 80% of mothers said that the approval from spouse was necessary before they could give the consent.



A - Social stigma | **B** – Denial | **C** - Drug therapy can cure autism | **D** - Blaming destiny | **E** - Curing by religious methods | **F** - Lack of awareness of intervention programs | **G** - Fear of research risks | **H** - Consent from spouse | **I** – Waste of time | **J** – Past negative experience | **K** - Blaming wife

***Fig. 3: Challenges in* voluntariness / participation in the research**

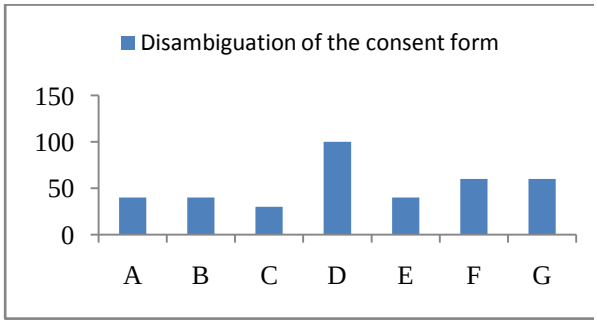
Autism research has achieved substantial growth in Guwahati, with many special education centers providing facilities for autism management and care. However, 40% of parents / guardians were clueless about availability of intervention programs and believed that allowing their child to participate in research would be futile. 30% believed that such research was a waste of time. They opinion that they are paying fees for their child's education and it is a waste of time to get involved in work which has no direct benefit for their child. In fact, some parents told the researcher to 'make the child talk' through their research. Further, 30% feared risks of research.

20% of parents / guardians stated that they had faced negative experience in past research participation.

A. The consent form

As the consent for the child's participation has to be taken from the parents / guardians, the researcher has to disambiguate of the consent form to them. However, the major hurdles arise in the socio-emotional barriers specific to the Indian context among the parents / guardians.

The consent form needs disambiguation because of it lengthy and complex structure. The parents / guardians sometimes fail to understand its structure, the research objective and the nature of study, which may create mistrust towards the researcher or the special education centre.



A – Difficulties in understanding the nature of study | **B** – Difficulties in understanding the Research objective | **C** – Lack of knowledge about autism | **D** – Risk- benefit ratio | **E** – Advantage of being observation based study | **F** - Apprehensive of signing the consent | **G** – Knowledge about their rights

***Fig. 4:* Disambiguation of the consent form**

40 % have mentioned difficulties in understanding the nature of study while 40 % found difficulties in understanding the Research objective. 30% of parents / guardians lack knowledge about autism and even if they are aware of a diagnosis, they have very marginal knowledge about autism.

100 % of parents / guardians have expressed the necessity for an adequate risk- benefit ratio which the research work must ensure. Though the consent form mentions about the research being observation based study, yet only 40% of the parents / guardians mentioned that it is an advantage. They are apprehensive of any negative impact of the research process on the child as a result of participation, thus believing in presumed harm. 60 % were apprehensive of signing the consent form. They instead said they would verbally assist in giving information about their child but not be comfortable to sign the form. Moreover, 60% of the participants understood their rights while 40% remained doubtful if, after signing the consent form, such rights would be easy to avail as their child was admitted at the special education centre where the research would be conducted.

The participant's right to quit the study at any point, assurance of confidentiality, complete information of the study (before

and during the participation) and sharing the results of the study are crucial aspects for respecting the research participants which the researcher must ensure.

4.3 Inducement to participate in research

Inducement to participate in research may be reimbursement for lost earnings, travel costs and other expenses incurred in taking part in a study. Moreover, subjects may also be given compensation for inconvenience and time spent. CIOMS further states that the payments should not be huge so as to induce subjects to give their consent to participate in the research against their better judgment.
For autistic children participating in research, the inducement that is usually provided in an observation based study is:

- Therapeutic benefit, may by indirect
- Cost for travelling
- Minimal refreshments

However, parents / guardians seek direct benefit and research for future use may not be a strong inducement to participate in research.

Moreover, while some children participate as research subjects at their home, many others do so at the special education centre where they attend regular classes. However, the researcher nor the special education centre can coerce the participant / parents / guardians to participate in the research by means of threat or negative outcome.

4.4 Benefits and risks of study participation

The Helsinki Declaration of WMA, 2000 states that *at the end of the trial, every participant should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study*. However, it also notes that benefit may be indirect, that is, to the community rather than direct benefit to the participant. Indirect benefit could be 'improving living conditions, establishing counseling centres, clinics or schools and giving education on maintaining good health practices.'
The researcher needs to ensure that potential benefits and risks are reasonably balanced and risks are minimized. Risks to participants could be:

- Inconvenience to the participant
- May not have direct benefit
- Disruption of normal / daily academic routine

Limitations on risk have to be applied when research involves autistic children and risk should not exceed routine medical or psychological examination of the child.

4.5 Safeguarding confidentiality

The researcher must secure the confidentiality of subjects in the research data.

The confidentiality norms from the Indian perspective needs to be analyzed while safeguarding confidentiality of the autistic child. The multifaceted network of social stigma, apprehensions and denials need to be dealt with very sensitively by the researcher.
The challenges that are faced while safeguarding confidentiality are:

- Revealing identity like school/ village/ neighbourhood at the time of publication
- Data archiving (where participant details are noted)

5 *Recommendations*

The following segment gives recommendations for implementing ethical norms in research on children with autism as participants.

5.1 Ethical justification and scientific validity

The study recommends that a general sensitization of society towards research is needed. Research on autism is very crucial for understanding the condition and bringing out better management of autism. The parents / guardians / society should welcome research and benefits, direct or indirect, should be an accepted outcome. Moreover, awareness about ethical norms in research on human subjects in the society is very crucial. Many researchers and special educators lack awareness about ethics in research in human subjects A balance between the sensitization and knowledge will substantially enhance research.

Awareness should extended in the following areas:

- Awareness about ethical norms in research on human subjects (Parents, Educators & Education Centers)
- Have professional competence to work with autistic children
- Respect the needs of the participants
- Researchers should be familiar with the cultural, social and economic circumstances of participants, groups or communities

5.2 Benefits and risks of study participation & working with autistic children

Respecting and protecting the autistic individual is of prime importance in research on human subjects. A comprehensive effort by the special education centers and researchers would enable minimizing risks and maximizing benefits for autistic children. Some recommendations are:

- Establishing parent counseling centers in schools / special education centers

- The research sessions should not, in any manner risk the physical, social and/or psychological well being of the participants
- Session duration and regularity should be individualized on a case-to-case basis
- Understanding the individual needs of the child
- Sessions should be held at comfortable environment which the child is well acquainted to (preferable at home or school / special education centre which the child attends)
- Research sessions to be of such length that it does not stress the child
- If the child is stressed, the session should be stopped immediately and an alternative session should be allotted
- Every participant should be assured of access to diagnostic and therapeutic methods identified by the study

5.3 Informed Consent

For ethical research work , the informed consent should be well structured with information about the purpose of research (its goals and objectives), identity of the researchers, reasons for selection for participation in the study, harms and benefits (direct/indirect, immediate/long term) of research and their participation, the extent of privacy, anonymity and confidentiality, future use of information, right not to participate and withdraw and non-disclosure of information. Special mention should be mentioned for handling vulnerable populations keeping in mind the Indian context.

The Consenting Process should involve three components :

i. **Disclosure**, explicit communication with the participants;
ii. **Capacity**, which means physical/ mental/ cognitive/educational/ legal ability to comprehend the study and its consequences;
iii. **Voluntariness**, to be able to decide freely without coercion, force, inducement, manipulation or any other way in which voluntariness may be compromised.

Further, the PIS – ICF forms would be accepted better with focus on the following:

- Awareness aimed at school / education centre level
- Awareness for special educators
- PIS- ICF form should aim at brevity
- Removing suspicion about PIS- ICF form (Parents, Educators & Education Centers)

Addressing parental concerns is very important, such as:

- Awareness of research benefits and participation
- Counseling for acceptance of the autistic child
- Counseling for putting child's benefit over social stigma
- Awareness to remove fear of the unknown risks
- Adequate briefing about the details of the project
- Adequate information should be provided about duration of participation
- Adequate information should be provided about the procedures to be followed
- Adequate information should be provided about any risks or discomforts to the participants

5.4 Safeguarding confidentiality

The researcher and the entire team has the obligation to maintain privacy, anonymity and confidentiality about the research participant. The researcher should maintain appropriate methods to safeguard privacy while data collection and storing records. The researcher should understand the cultural, social and economic circumstances of the participant. Any research participant's integrity must always be safeguarded and respected. Prominent recommendations for safeguarding confidentiality are:

- The participants' right to privacy, anonymity and confidentiality should be respected at all time
- Revealing identity like school/ village/ neighbourhood at the time of publication should not be done unless necessary
- Data archiving (where identity of participants are noted) should be maintained with full responsibility and protecting the privacy

VII. CONCLUSION

Ethics in research is a very vital subject while conducting research *o*n human subjects, especially children with developmental disorders.

The Indian context brings various culture specific challenges in the implementation of ethics in research in human subjects. The situation becomes more critical when the subjects in concern are children with developmental disorder. Moreover, many researchers and special educators lack awareness about ethical norms in research on human subjects. Areas have been noted to sensitize them on this issue.

The paper identified the challenges in the Indian context so that ethic norms are widely adhered to. Appropriate suggestions suitable for children with developmental disorder based on Indian context have been made. A research work on autism should contribute towards the welfare of the autistics and just treatment of participants in research calls for special attention.

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