Summer Placement In

ALEXIS HOPSITAL, NAGPUR

(April 5th to June 18th, 2022)

A Report By

Dr. Azmin Sheikh

Post-Graduate Diploma in Management (Hospital and Health)

2021-2023

International Institute of Health Management Research, New Delhi

Certificate of Approval

The Summer Internship Project of titled **"An audit cycle of consent form of the patients undergoing any Procedure/ Surgery at Alexis Hospital, Nagpur** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of Post Graduate Diploma in Health and Hospital Management for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed, or conclusion drawn therein but approve the report only for the purpose it is submitted.

Name of the Mentor: Ms. Divya Aggrawal

Designation: Associate Dean

IIHMR, Delhi

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COMPLETION OF SUMMER INTERNSHIP FROM ALEXIS MULTI-SPECIALITY HOSPITAL, NAGPUR

The Certificate Is Awarded To

Dr. Azmin Sheikh

In Recognition Of Having Successfully Completed Her

Internship In The Department Of

Administration

And Has Successfully Completed Her

Project On

An Audit Cycle of Consents of Patients Undergoing Any Procedure/ Surgery At Alexis Multi-Speciality Hospital, Nagpur

Date: 18th June 2022

Organization- Alexis Multi-speciality Hospital Private Limited

She Comes Across As A Committed, Sincere & Diligent Person Who Has A Strong Drive & Zeal For Learning

We Wish Her All The Best For Future Endeavours

Organization Supervisor

Alexis Multi-Specialty Hospital Pvt. Ltd.

Head-HR/Department Head

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Date: 18/06/2022

Internship Completion Letter

To whomsoever it may concern

This is to certify that **Dr. Azmin Nishad Hussain Sheikh** has completed her Internship at Alexis Multispeciality Hospital, Nagpur in **Department of Administration** from **05-April-2022 to 18-June-2022**.

She was involved in **"Administration & Quality Process of Hospital at Alexis"** the working, functioning, task & observations carried by her are found Excellent and we wish her success for future endevours.

Alexis is a **JCI** & **NABH** Accredited 200 Bedded Multispecialty Hospital located at Nagpur designed to provide quality and affordable healthcare services.

Regards

For **Alexis Multispecialty Hospital Pvt. Ltd**

Ms. Vishnupriya Sengupta
Senior Manager-Human Resources

FEEDBACK FORM

(IIHMR MENTOR)

Name of the Student: Dr. Azmin Sheikh

Summer Internship Institution: Alexis Multi-Speciality Hospital, Nagpur, Maharashtra

Area of Summer Internship: Administration And Quality Department

Attendance: 100%

Objectives met: YES

Deliverables: → Weekly progress updation
→ Synopsis finalisation
→ Report draft

Strengths: Hadworking, analytical & Intelligent

Suggestions for Improvement: Get better understading of the hospital operations.

Signature of the Officer-in-Charge (Internship)

(Mrs. Divya Aggrawal)

Date: July 06, 2022
Place: Delhi

FEEDBACK FORM

(Organization Supervisor)

Name of the Student: Dr AZMIN SHEIKH

Summer Internship Institution: ALEXIS MULTISPECIALITY, HOSPITAL NAGPUR, MAHARASTRA.

Area of Summer Internship: MEDICAL ADMINISTRATION, INCLUDING DAY TO DAY OPERATIONAL MANAGEMENT and QUALITY DEPT. (Focusing JCI Audit Preparation)

Attendance:
REGULAR

Objectives met: MEDICAL RECORDS AUDIT, as per JCI protocols (OPEN & CLOSED)

DEPARTMENTAL AUDITS INCLUDING FACILITY AS PER JCI SIDS.

Deliverables:
- Medical Records audit, analysis, gaps identification and Recommendations to improve the same was done.
- Training & implementation as per the gaps in dept.

Strengths:
- Communication is her great strength with effective teamwork
- Dedication towards the objective given & target achievement
- Polite & calm behaviour & positive attitude

Suggestions for Improvement:
- foster proactiveness
- Basic orientation towards the dept.

Signature of the Officer-in-Charge (Internship)

Dr Bharang Ramaiya
Asst. Hospital Administrator
Alexis Hospital, Nagpur

Date: 18/06/2022
Place: NAGPUR (Maharasha)

ACKNOWLEDGEMENTS

It is my esteemed pleasure to present this research project by thanking each and every one who helped me in this task.

I would like to thank my guide **Dr. Bhavana Ramaiya**, Asistant Hospital Administrator of Alexis Hospital and **Dr. Nilesh Agrawal**, Deputy director Administration, and **Dr. Tushar Gawad**, Hospital administrator, Alexis Hospital, Nagpur who helped me in immensely throughout the tenure of my summer internship. They rendered their valuable advice, precious time, knowledge and relevant information which enabled me to overcome every obstacle which came my way in the completion of this project.

I would also like to thank the extended team of Alexis Hospital, Nagpur, for their unlisted encouragement and moreover their timely support and guidance till the completion of my project. Their active participation to all my questions and queries during my internshiphas made this journey a true success.

I would also like to acknowledge my mentor and teacher **Ms. Divya Aggrawal** for enriching this project with her advice and suggestions.

I would also like to thank **My Family and friends** who supported me throughout in developing this project.

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ABBREVIATIONS

UAE	United Arab Emirates
JCI	Joint Commission International
NABH	National Accreditation Board for Hospitals
NABL	National Accreditation Board for Testing and Calibration Laboratories
ISO	International Organization for Standardization
IGBC	Indian Green Building Council
MRD	Medical Record Department
ICU	Intensive Care Unit
ICD	International Classification Of Diseases
TAT	Turnaround Time
OPD	Outpatient Department
OT	Operation Theatre
MT	Medical Transcriptionist
RMO	Resident Medical Officer
MRI	Magnetic Resonance Imaging

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OBSERVATIONAL LEARNING

a) Introduction: Alexis Hospital

Alexis Multi-specialty hospital is offering an initiative of the Zulekha healthcare group, UAE. The Group represents comprehensive healthcare that is available to anyone in need of medical attention and is delivered through three multi-specialty hospitals, three medical centres, and three pharmacies.

The Group has more than 3000 employees, including over 300 qualified doctors, staff nurses, and a host of paramedical staff.

With its constant interactive workshops and seminars on diverse medical and surgical themes, the Group has significantly contributed in recent years to setting benchmarks in continuing medical education programs for the entire Gulf region.

***Mission*: "To partner with every healthcare seeker in their effort to achieve good health, by providing efficient, expert and compassionate care."**

***Vision*: "To thrive as the most preferred healthcare brand in the country by providing highly advanced, easily accessible and truly dependable care."**

Values:

- Compassion and courtesy
- Honesty and Integrity
- Privilege and responsibility
- Planning and implementation
- Efficiency
- Passion
- Innovation
- Quality service and continuous improvement

Brief History

The Zulekha Healthcare company got its start in 1964 when its founder, Dr. Zulekha Daud, relocated from her native India to Sharjah, United Arab Emirates, to live out her dream of providing everyone with access to inexpensive healthcare. Dr. Zulekha quickly rose from being a fresh medical graduate to a working doctor caring for people from all walks of life. Zulekha Hospital was originally founded in Sharjah in 1992 after years of faithful service. The Zulekha Healthcare Group now consists of three UAE medical centres, three pharmacies, and two multidisciplinary hospitals in Dubai and Sharjah that offer specialist care in over 30 disciplines. In Nagpur, Central India, the Group has also opened Alexis, a multipurpose hospital.

This cutting-edge, 210-bed facility provides comprehensive multispecialty services in the following fields: Comprehensive Oncology Care & Radiotherapy, Cardiac Sciences, Neurosciences, Orthopedics, Critical Care, Minimal Invasive Surgery, Urology, Nephrology, Gastroenterology, Endocrinology, Gynecology, Pediatrics & Neonatology, Critical Care (CCU, ICU, NICU, SICU) & Internal Medicine, Joint In the future, Alexis Multispecialty Hospital will also have a Comprehensive Organ Transplant Unit to suit the clinical needs of Central India.

The hospitals are a representation of Dr. Zulekha's compassionate and caring attitude. It is referred to as the Zulekha spirit, and it is always present in the personnel and medical professionals. Zulekha Healthcare Group has grown to be one of the leading private healthcare networks in the Gulf under her distinguished leadership.

The Group represents comprehensive healthcare that is available to anyone in need of medical attention and is delivered through three multi-specialty hospitals, three medical centres, and three pharmacies. The Group has more than 3000 employees, including over 300 qualified doctors, staff nurses, and a host of paramedical staff. With its constant interactive workshops and seminars on diverse medical and surgical themes, the Group has significantly contributed in recent years to setting benchmarks in continuing medical education programs for the entire Gulf region.

Alexis hospital, Nagpur

The state of healthcare is constantly shifting around the globe. To create the greatest possible care for patients, clinicians and researchers work very hard. We at Alexis Multispecialty Hospital think it is our top priority to stay up with these developments and make the advantages of healthcare evolution available to every patient right away. In order to deliver end-to-end comprehensive medical treatment across multiple medical facilities, we have commissioned a trademark model interdisciplinary 200 bed tertiary care hospital in Nagpur, India's heartland. offers a plethora of medical knowledge with the best doctors, nurses, technicians, and management professionals in a setting that allows them to provide the best treatment possible through cutting-edge facilities that seek to leave no stone unturned in enhancing patient centric care.

Alexis Hospital, Nagpur strives to be the champion for quality and patient centricity and is a JCI, NABH, NABL, IGBC and ISO accredited Hospital.It has been designed as an energy efficient building that complies with the IGBC (INDIAN GREEN BUILDING COUNCIL). Alexis hospital has been awarded as the best hospital in Nagpur 2021, by Hansa research best hospital survey 2021.

GENERAL FINDINGS ON LEARNING:

a) <u>Admin Department</u>

1. **Daily Rounds**: I assisted in daily rounds with the Admin department. The rounds entailed visiting different departments in the hospital such as wards, Lab, MRD, OT, ICU etc. and assessing the quality initiatives being carried out in them. Also, giving feedback and carrying out re- assessment regarding the changes asked.

2. **Periodic counselling**: I was in charge of inspecting whether daily periodic counseling is been done in the ICUs and in wards (on every 7^{th} day of stay) and if not done then I had to escalate it to the doctors and get the periodic counselling done.

3. **File auditing**

Consents Audit: I was asked to perform both a retrospective and live consents audit. This project was aimed at assessing the completeness of the consents taken for different procedures. Various types of consents were studied such as anesthesia consent, high risk procedure consent, consent for minor patients, dialysis consents etc.
The parameters on which consents were assessed included:

- ✓ The right consent for the right procedure
- ✓ Signature of the patient and attendant
- ✓ Signature of the guardian (in case of minor patients)
- ✓ Signature of the interpreter (in case of international patients)
- ✓ Anesthesia consent in case of patients undergoing sedation
- ✓ High-risk consent in case of high-risk procedure,the task was completed in two phases:
- Audit from MRD files: This included randomly taking up patient files of a month and assessing the consents.
- Live audit: This included assessing the consents of presently admitted patients in wards and ICU's. The audit was conducted in the month of May.

MDS audit: I was assigned to audit the multidisciplinary sheet in which the daily notes are entered by the doctors. The appropriateness/ compliance of the notes was checked.

ICD code: Under JCI preparation, I was assigned different ICD codes and all the in-patient files were tracked with those ICD code diagnosis.

b) <u>OT Department</u>

1. **Surgical site verification Checklist Audit**: Every surgery mandates a surgical safety checklist to be filled in wherein different parameters pertaining to pre-op, during surgery and post-op are to be assessed. I was assigned to conduct an audit in order to identify the major areas where the filling of surgical safety checklist was lacking.

The audit consisted of two parts:

- Audit from MRD files: This process included retrieving files of patients who had undergone surgical procedures in the month and retrospectively looking back to assess the completeness of the surgical site verification form.

- Live audit: This included visiting the OT and assessing live the adherence of the staff to the surgical site verification form.
  The audit was conducted in the month of May.

2. Operation notes audit

The operation notes were audited whether timely entry was being done by the surgeons after surgery and whether the form is filled completely and appropriately.

c) MRD Department

I was posted in the department for 2 weeks to learn about the working of the department and to assess the working and manage the department too.

d) Lab tracking of outsource sample -TAT

I was assigned to track the outsource samples and estimate the TAT, like when was the sample sent to the lab and when was the report received from the lab, whether delayed or on time and if delayed the reason of delay like repeat sample, etc.

e) Radiology department

I was assigned to check the non-compliances of the department, I was provided with a checklist to check whether the department meets all the objectives on the checklist and also to observe the department for any non-compliances other than the list.

f) Reception

front desk process basic registration of the patient and billing and query handling and guided to respective OPDs of respective floor.

g) OPD

I was posted at the OPD reception to observe the process, to learn about the IPSG goals, hoe to identify a patient how and when to release the information and to whom, how the patient is guided, the nursing station how the patients' vitals are monitored and what different packages Alexis provide also the tie up with different companies.

h) Ward and IP pharmacy

Time-Motion study: I was assigned with a project to conduct a time-motion study in the wards of the hospital. The objective of the study was to identify the TAT of the STAT and routine medications prescribed. The project aimed at assessing the response time of the staff nurses and the pharmacists and also to identify other issues associated. It was done by the means of silent observation so as to assess the actual utilization of manpower in the wards and pharmacy and also identify possible causes of chaos on the floor.

i) Trainings organized –

I was assigned with the task to organize the trainings on hazmat spillage, blood spillage, fire safety for the staff like the MTs, RMO, and others

j) Trainings and meetings attended

I attended the following trainings and was also a part of the mock drills conducted for the codes.

-Hazmat

-Blood Spillage

-Fire Safety

-Code Blue

-Code Orange

-Code Red

- QAIC – Quality Assurance Indicator Meeting

- MRRC-Medical Record Review Committee Meeting

reviewing the progress and optimal functioning of the various committees in the hospital. A compliance report had to be submitted of the same, showing the committees which had complete compliance and the lagging points of the other committees.

CONCLUSIVE LEARNING AND LIMITATIONS

Learning

- The healthcare facility has helped me in learning the intricacies of working of a hospital.
- Hospitals require a strong management system for its the proper functioning.
- Regular quality improvement processes are required to keep the hospital at par and toimprove the quality of care for the patients.
- All the records should be maintained properly and all the processes should be tracked.

Limitations

- Maximum part of the documentation is manual which creates a possibility of error.
- Lack of staff and co-ordination between departments leads to delay in work such as discharge process.

PROJECT REPORT

ABSTRACT

There are many reasons why teams, departments or even whole organizations will want to improve the way informed consents are taken form the patients. If improper consents are taken from the patients, then there's a high-risk scenario for patient education and safety also dangers and consequences of poor informed consents, highlighting 'discontinuity of care, adverse events and legal claims of malpractice. There is also the human cost; the distress, anxiety and loss of confidence that we know poor informed consents can lead to for patients, their families and for staff too. This project focuses on the comprehensive assessment of informed consents prevalent in Alexis hospital, Nagpur. The aim is to calculate the percentage compliance of doctors and nurses with the existing practice of taking informed consents and giving recommendations to improve the same.

INTRODUCTION

Informed consent is a process by which a competent patient is given all the appurtenant information about his disease and the treatment procedures so that he is able to participate in choices regarding his health care. In India, legal age of consent is 18 years. Informed consents are the responsibility of the doctors and accountability for some or all aspects of care for a patient. It ensures patients right to education and information as it allows him/her to take proper decision regarding their health. It is generally agreed that a discussion of the procedure's nature, plausible alternatives to the suggested intervention, and the pertinent risks and benefits associated with the process are all part of an informed consent. It is essential that the patient comprehends the information offered and that their voluntary agreement is obtained. Both the information presented and the patient's understanding are crucial. Therefore, the information offered should be explained in layperson's terms.

The first crucial step in ensuring the safety of any surgery or procedure is obtaining accurate and prompt informed consents. Defects in or the lack of any one of the crucial components of the consent process might result in surgical or procedural mistakes. The goal of the consent procedure should be to offer patients with the safest and highest quality care possible. Existing national guidelines offer advice on the appropriate approach to getting consents.

Unfortunately, in hospital practice in many setups, patients and their families are mostly given very little or inadequate information. This study was designed to evaluate the current practice of taking informed consent in preoperative emergency and elective surgical procedures and also in the patients undergoing any diagnostic procedure or therapy in a private sector tertiary care hospital.

Efficient informed consents are beneficial for both the patients and doctors alike:

- **benefits patients**

  Proper patient education is provided and the patient is capable of taking the right decision. Less discontinuity of care – poor information regarding the procedure, its risks and benefits can lead to fragmentation and inconsistency of care. Decreased repetition- once properly counseled regarding the procedure/ surgery and everything well explained to the patient and relatives will invite less doubts and further queries for the consultants and other staff. Increased service satisfaction – Patient perception of professionalism is reaffirmed and improved.

- **benefits doctors**

  An effective informed consent session fosters the development of communication skills and offers a suitable venue for clinical education. With the shift toward a more litigious culture within healthcare, professional protection and accountability have gained in prominence. Informed consents that are transparent and responsible can shield a doctor from liability for mistakes that are made. Doctors can feel less alone and more in charge of a patient's care when they are well-informed and have the information they need. Giving patients the best care possible is very fulfilling and essential to a doctor's sense of job satisfaction.

  Poor informed consents where there is no written documentation or declaration, or what is written is unclear (e.g., too many abbreviations) lead to violation of patient's right to information act and is widely recognized as a major preventable cause of harm and the risks can be even higher like medico legal consequences. Who should take the informed consents and when? The consultants, RMO, clinicians can take the consents after proper patient education regarding the surgery or the procedure that has to be performed.

- ✓ ***HOW*** should it happen?

  all types of informed consents need a predetermined format and structure to ensure adequate information-exchange.

1. It should be supervised by the most senior clinician present and must have clear leadership.
2. Information presented should be succinct and relevant.

- ✓ ***WHAT*** needs to be handed over?

  Priorities need to be set to ensure that the essential information is communicated and understood. Also, all the alternatives, risks and benefits of the procedure/ surgery must be escalated to the patient and his/ her relatives.

  The need for a standard documented protocol is also mandated by JCI.

PROBLEM STATEMENT

Given the background, the current study is aimed at observing the compliance of doctors in the hospital to check the compliance of the consents taken from the patients and give recommendations to improve on the same, if needed.

GENERAL OBJECTIVE

- To determine the consent form compliance according to the JCI guidelines.

SPECIFIC OBJECTIVES

- To assess the compliance of the consents taken by the patients
- To ascertain the compliance of the doctors whether risks/ alternatives/ benefits explained properly.
- To ascertain whether proper declaration taken by the patient
- To assess whether proper declaration given by the doctor
- To give suitable recommendations to improve the informed consent practices.

METHODOLOGY

a) **Study Area**: This study was performed at the ICU and wards of a 200-bed tertiary care hospital in Alexis Multi-specialty hospital, Nagpur. The facility consists of majorly of wards and four types of ICUs, where patients can be transferred in-house:

- Surgical ICU
- Medical ICU
- Neonatal ICU
- High dependency unit [HDU]

b) **Study Period**: The study was conducted in a period of two months from 15th April 2022 to 31st May 2022

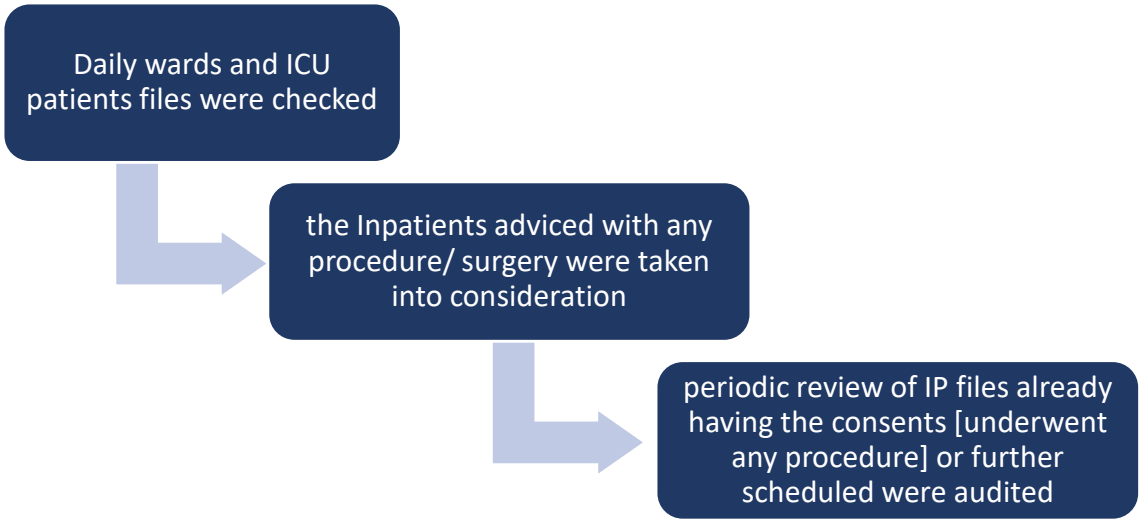
The study was conducted in two parts:

Parameter	Part A	Part B
c) Study Design	A cross sectional review of the files of patients in wards and ICU's. The sample of consents was taken up from the patients admitted in the wards and ICU who underwent any procedure or surgery or have planned.	Periodic review of the files of the admitted patients for any more advised or procedures which need informed consents in every ward and ICU.
d) Study Population	The study population was all the patients in different ICU's and wards in the period between 15th April 2022 to 31st May 2022	The study population were the doctors who took the informed consents.
e) Sampling Technique	Convenient sampling was done to select the desired sample from the study population.	N.A.
f) Sample Size	A sample size of 480 patient's informed consents was collected. The sample size was decided in accordance with the recommendations of the mentor. After including a margin of 10% (due to no advised procedure or surgery to those in patients)	N.A.

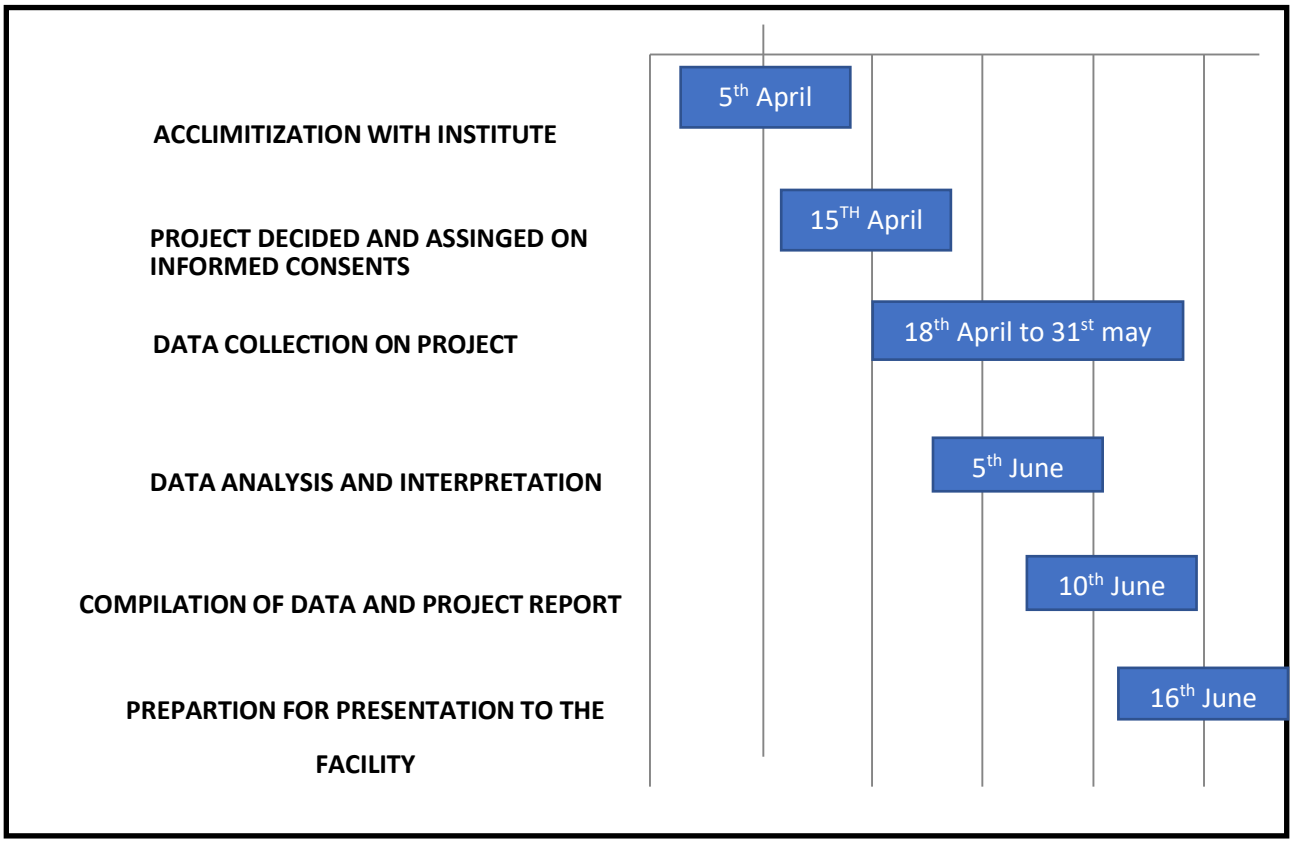
g) Study Variables

SPECIFIC OBJECTIVES	VARIABLES	STUDY POPULATION	TOOLS	TECHNIQUE
• To observe the compliance of informed consents.	Informed consent forms	In patient files in wards and ICU	Checklist	Observation
• To determine the compliance of declaration taken by the patients and doctors, also whether the risks / alternatives have been explained.	Completeness of the forms observed	In patient files in wards and ICU	Checklist	Observation

Mode of Data Collection: Data collection was carried out in the following steps:



g) Timeline:



RESULTS, FINDINGS AND DATA ANALYSIS

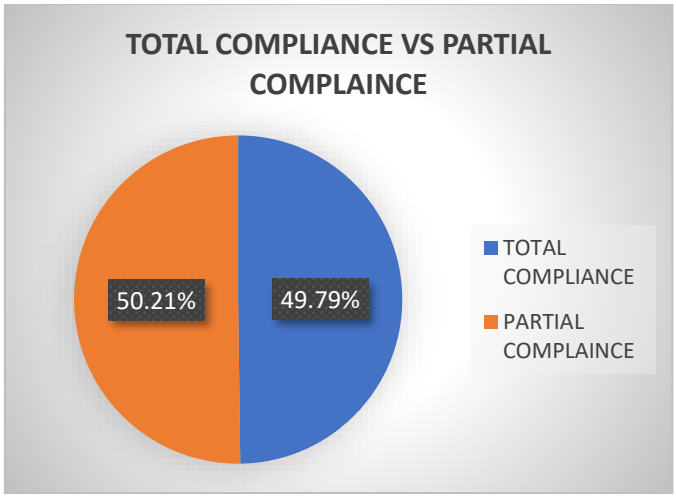
During the period of the study, files of all the patients admitted in the ward and all the ICUs were analyzed for three different types of informed consents. Compliance of the various consents were assessed for 5 different variables such as patient details, date of issue, patient declaration after counselling regarding the procedure/surgery, risk/ alternative/ benefits, and doctors' declaration, the completeness and appropriateness were checked in context to these variables.

Out of the IP case files audited for 480 informed consents it was observed that 239 [49.79%] consents were found to be totally compliant in all the five aspects and 241[50.21%] were partially compliant i.e., non-compliant in 1 or more aspects [1,2 or 3] but no consent was found to be totally non-compliant [or non-compliant in 4 or 5 aspects].

TABLE 1: OVERALL COMPLIANCE

Total Consents	**480**	**Percentage**
Overall compliance in all five respects	239	49.79%
Partial Compliance in all five respects	241	50.21%

FIGURE 1: OVERALL COMPLIANCE



Compliance in individual aspects

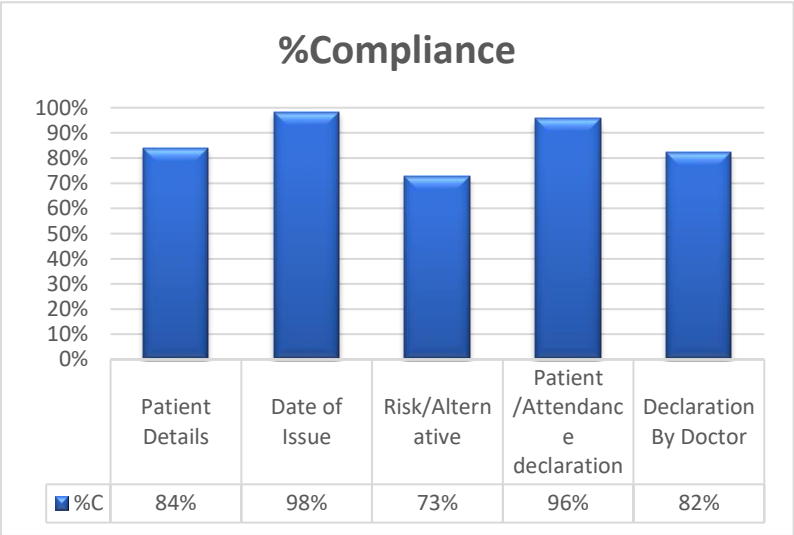
The compliance analysis of consents was done in accordance to the following 5 parameters

1. Patient details.
2. Date of issue.
3. Patient declaration after proper counselling without using any abbreviations.
4. Risks, alternatives explained if any or struck off if not required [JCI Policy]
5. Doctors' declaration.

TABLE 2: AREAS OF COMPLIANCE IN INDIVIDUAL ASPECT

Total	**480**	**Percentage**
Patient details	403	84%
Date of issue	472	98%
Risks, alternatives explained if any or struck off if not required	460	73%
Patient declaration after proper counselling.	349	96%
Doctors' declaration	395	82%

FIGURE 2: AREAS OF COMPLIANCE IN INDIVIDUAL ASPECT



On analysis of the various parameters that were incomplete in the consents, the following results came up:

TABLE 3: AREAS OF NON-COMPLIANCE IN INDIVIDUAL ASPECTS

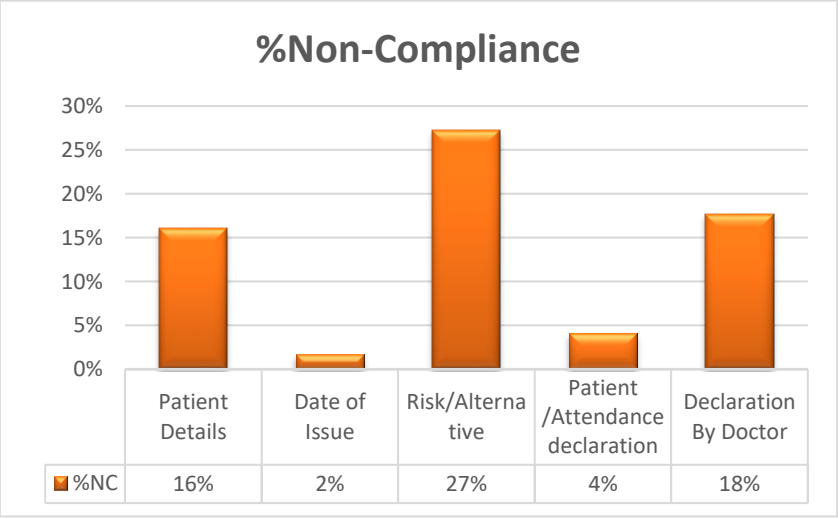
Parameter	No. of Consents	Percentage
Patient details	77	16%
Date of issue	8	2%
Risks, alternatives explained if any or struck off if not required	131	27%
Patient declaration after proper counselling.	20	4%
Doctors' declaration	85	18%

As is clear from the table above, maximum number of consents had non-compliance in risks and alternatives [27%], doctors declaration either date, time, countersign missing [18%] and 16% did not bear the complete patient details.

However, the most important parameters such date of issue, patient declaration were not recorded in 2% and 4% cases respectively

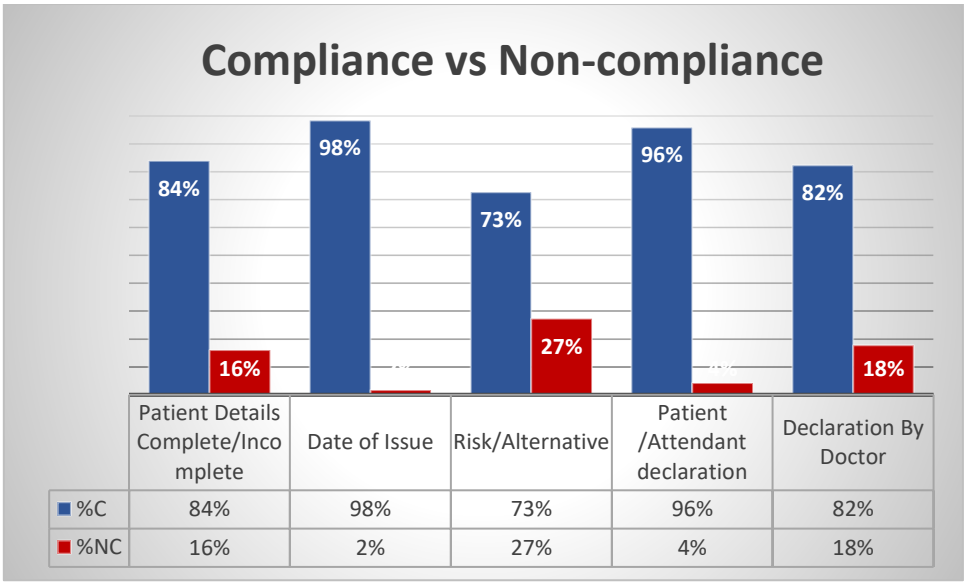
The following graph shows the results as enumerated above:

FIGURE 3: AREAS OF NON-COMPLIANCE IN INDIVIDUAL ASPECTS



The following graph shows the illustration of percentage compliance vs non-compliance in different aspects of the 480 consents audited;

FIGURE 4: COMPLAINCE VS NON-COMPLIANCE



	Patient Details Complete/Incomplete	Date of Issue	Risk/Alternative	Patient /Attendant declaration	Declaration By Doctor
%C	84%	98%	73%	96%	82%
%NC	16%	2%	27%	4%	18%

As is clear from the table and graph above, maximum compliance is seen is date of issue [98%] and patient/ attendants declaration [96%] were complete in all respects. However, in 27% consent forms the risk and alternatives and patient details in 16% consents were not completely filled in, also incomplete doctors declaration in 18% consents were recorded.

DATA INTERPRETATION

Out of the 480 informed consents studied, maximum compliance was seen in recording the date of issue (98%) followed by patient/ attendant declaration (96%) and patient details (84%) with last declaration of doctor (82%), the least compliant when compared to other parameters was risks/ alternatives (73%) which showed only partial compliance with room for improvement.

CONCLUSION

From the above data collected and the results which we got from the study we can say that:

1. The informed consent has to be taken in all the major or minor procedures, high risk procedures, anesthesia induction, investigations like MRI, stress test, etc. and treatment like blood transfusion etc. and it's the responsibility of Personnel conducting the procedure / investigation including visiting doctors to take proper consent from the patient.

2. At Alexis multi-specialty hospital there is a consent for almost every procedure or surgery and every consent has these common five parameters, they are Patient details, Date of issue, Patient declaration after proper counselling without using any abbreviations, Risks/ alternatives explained if any or struck off if not required [JCI Policy] and Doctors' declaration. (As shown in annexure)

3. Theres the policy at Alexis hospital that all the risks alternatives and benefits are in the printed format in all the consents, it is just needed to be explained to the patient, and the patient needs to be counselled regarding the procedure properly and if there are any chances of any risks or alternatives present then that is needed to be explained and written manually or ticked in the boxes given, but if this is not the case then no blank space is to be left and spaces should be struck otherwise it would be audited as non- compliance.

4. After assessing the compliance in 480 consents in the five aspects, the following conclusions can be made:

- The overall compliance is good and no consent was found to be totally non-compliant.
- The first aspect that was assessed was patient details and it was found to be 84% compliant i.e. all the parameters in patient details (as shown in annexure) such as Patients name, age, sex, PIN number, Nationality is been mentioned in all the 403 consents, and in 16% consents (77 consents) the parameters were not recorded completely. If abbreviation M or F used for male or female respectively or even one or more parameter is missing from the patient details section then it was counted as non-compliance. It can be concluded that the doctors/ RMO are not very careful while filling in all the parameters.
- The second aspect was date of issue, this portion to be filled in by the doctors was found to be complete in most of the forms, it was 98% compliance (472 consents) and only 2% non-compliance. only 8 consents had date of issue missing.
- The third aspect was risk/ alternatives which was found to be least compliant (73%) among all the other aspects audited, in 131 consents (27%) all the blank spaces for risks/ alternative were not struck (according the policy) it was audited as non-compliance. It can be concluded that the doctors/ RMOs are not so well-versed with the standard protocols regarding the consents.
- The fourth aspect audited was the section of patient's declaration in the form, only 4% (20 consents) had incomplete patient's declaration i.e., either patients name, signature or date or time missing, any parameter (out of these 3) found missing from the patient declaration section then it was considered as non- compliance. It can be said that the doctors are responsible while taking

patients declaration as none of the consent was found to be completely non-compliant in this aspect, this section showed 96% compliance (460 consents) with proper patient declaration and 4% partial compliance.

- The fifth aspect audited was doctors' declaration, this section consisted of doctor's name, signature, date and time and any parameter missing from this aspect was audited as non-compliant, in 18% i.e., in 85 consents partial compliance was seen and maximum time doctor's signature was missing. Overall compliance was 82% (395 consents) with all the parameters filled with consultant's name, date, time, signature and stamp of the consultants.

The results of the periodic review showed room for improvement in terms of a standardized checklist and training for the use of the same. All the non-compliances were escalated to the admin department, and the doctors were given training accordingly and when the consents were periodically reviewed after the training there was improvement seen and the rate of compliance was better than before.

LIMITATIONS

- The period of the study was limited to only two months due to time constraints.
- The time period from which the data was collected was limited to 1.5 months.
- Lack of knowledge of the staff about the policies of the hospital. This limited the accurateness of data as the staff was still unclear on the way consents had to be filled.

RECOMMENDATIONS

Informed consent is a critical process in the field of healthcare and is directly linked to the quality of patient care. Thus, in order to provide improved healthcare value, the issues mentioned before must be solved. The proposed solutions are long-term approaches that are considered to be better than the short-term options that only mask the problems for a short time, delaying the crisis and need for long-term solutions.

Following recommendations are proposed in order to enhance the compliance of the informed consent process:

- The person under whose supervision the informed consent is been taken should be more vigilant regarding the completeness of the form and should ensure that all details are completed alongside.
- After taking the consent the form should be re-checked and counter signed by the designated employee/ doctor.
- Compliance of all the consent forms should be checked on a periodic basis by a review of a limited sample of files.
- Regular training should be conducted for the doctors regarding the proper filling of the consents and about the policies too.
- There should be a box for patient sticker to avoid writing the patient details each time such as manual writing of the pin could lead to mistakes or missing of some digits and also it saves time.
- To increase the compliance of the doctors a checklist is recommended. The checklist is designed with inputs from the audit and based on policies of the hospital.
  The checklist can be implemented and compliance can be measured on a periodic basis.

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ANNEXURE

CONSENT FOR BLOOD AND BLOOD COMPONENT TRANSFUSION

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ALEXIS
PARTNERS IN GOOD HEALTH

***Abbreviations and symbols usage is not permitted in this consent form**

Patient's Name: _____ Age:_____ Sex: _____

PIN: _____ Nationality: _____

Date of issue: _____

I (Name)_____, self / Attendant

(relation to patient_____) willingly consent as under towards

the treatment of _____(Name of patient / Self).

Description of Procedure: Dr. ……., my physician, has explained to me that a blood/blood component transfusion may be necessary part of my medical treatment. I understand that multiple blood/blood component transfusions on multiple occasions may be necessary. In a blood/blood component transfusion, blood/blood component is introduced into the vein using a sterilized, disposable needle. Usually only one part of the blood, such a as the red blood cells, platelets, plasma, is needed at one time, but occasionally whole blood is required.

Risk of Blood//Blood Component Transfusion: the doctor has explained a risk of blood/blood component transfusion, and I understand the following: Blood/blood component transfusion is normally a procedure of low risk. Reactions to blood/blood component are uncommon, but do occur. The reactions may include chills or hives (itchy rash). Other risks include iron overload and transmission of an infection. Even with testing of blood donors, there is a small risk of hepatitis infection from the blood/blood component transfusion. The risk of Acquired Immune Deficiency Syndrome (AIDS) and other unavoidable complications may occur. I understand the risks, including the risks that are specific to me, approximate duration of hospital stay and other problems related to recovery (including but not limited to possibility of admission to intensive care units including the possibility of life support measures and the expenses incurred therein and the risk to life in case of request for discharge of patient against medical advice

Risk of Refusal of Blood/Blood Component Transfusion: The refusal of a blood/blood component transfusion may result in adverse outcomes, including death.

I understand that no guarantees have been made to me about the outcome of the transfusion(s).
The source of the blood /blood component to be given to me may be from volunteer, community donors or directed donors (family of friends who donate specifically for me). I understand that some patients may be able to donate blood for themselves (autologous blood) and those units will be given first, when appropriate.

Extension of Consent: I/We understand that in the course of performing the above Procedure(s), my physician may discover other or different conditions which may require additional or different Procedure(s) than those planned. I/We authorize my physician and his/her associates, designees, technical assistants, and other health care providers to perform other Procedure(s) which they deem necessary and advisable in their professional judgment.

Patient's/Attendant's Initial: …… Doctor's Initial: ……

Photography: I/We consent to the observing, photographing or televising of the procedure to be performed, including appropriate portions of my / our patient's body for medical or educational purposes provided my / our patient's identity is not revealed by the pictures or by descriptive text accompanying them. If any staff member is injured or exposed to my blood or other body fluid then I give my consent to a sample of my blood being collected for the purpose of testing for infectious diseases, such as Hepatitis B, C and HIV (Human Immunodeficiency Virus). I understand that no testing of the blood sample will be carried out without prior discussion and my explicit consent.

Validity: This consent covers single or multiple blood/blood component(s) alone or in combination: Packed Red Blood Cells (PRBC), Fresh Frozen Plasma (FFP), Platelet, and Apheresis products which are administered during the current hospital stay only.

☐ **I consent to blood/blood component transfusion(s) as part of my medical treatment at Alexis Multispeciality Hospital.**

I certify that this form has been fully explained to me in the language I understand , that I have read it or have had it read to me, that the blank spaces have been filled in, I understand its contents and I believe that I have sufficient information to give this informed consent.

Name	Signature	Date & Time
Patient.....	.....	.....
Attendant.....	.....	.....
(Relation with patient)		
Witness.....	.....	.....
Translator..... (If applicable)	.....	.....

☐ **I refuse any and all blood/blood component transfusions. (Blood Bank MUST be notified)**

Name	Signature	Date & Time
Patient.....	.....	.....
Attendant.....	.....	.....
(Relation with patient)		
Witness.....	.....	.....
Translator..... (If applicable)	.....	.....

Declaration by Doctor:

I certify that I have explained to the Patient (or Legally Responsible Agent) his / her Condition, the Proposed Operation(s) or Procedure(s), Attendant Risks and Possible Discomforts involved Other Methods of Treatment, and the Possibility of Complications.

Name & signature of Doctor: _____

Date:_____ Time:_____

INFORMED CONSENT FOR MEDICAL & SURGICAL PROCEDURE

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ALEXIS
PARTNERS IN GOOD HEALTH

***Abbreviations and symbols usage is not permitted in this consent form**

Patient's Name: _____ Age: _____ Sex: _____

PIN: _____ Nationality: _____

Date of issue: _____

I (Name)_____, self / Attendant (relation to patient_____) willingly consent as under towards the treatment of _____(Name of patient / Self),residence of _____

A) **Consent**: I/We authorize and voluntarily request Dr……..…… as my physician and team of Alexis other persons (such as colleagues, technical assistants, and other health care providers as my physician may select), to treat (including further diagnosis of) my clinical condition……

B) **Procedure/Surgery**: I / We agree that the physician has explained to me type of the (se) procedure(s) treatment(s) and service(s) (called "Procedure"), the purpose and duration of the Procedures, reasonable alternative Procedure(s) If any, Option of not receiving the procedure. I/We voluntarily consent to have the Procedure(s) listed below performed on me:
……
……
……

C) **Risks**: While not getting treatment has risks, I/We realize that the Procedure(s) planned for me also has risks. I/We understand that the complications of the Procedure(s) could require corrective surgery and/or other procedures. I/We understand the risks associated with the proposed Procedure(s), including but not limited to, those listed below, and have had an opportunity to ask questions about the risks : (Please enter where relevant or Not applicable)

- ☐ Infection
- ☐ Blood clots in veins or lungs
- ☐ Allergic reactions
- ☐ Blood vessel and/or nerve injury to other tissue
- ☐ Wound healing problem/ delayed wound healing
- ☐ Intraoperative fracture
- ☐ Possibility of/ need of second repeat surgery
- ☐ Bleeding/hematoma
- ☐ Pain
- ☐ Separation of the wound
- ☐ Worsening and/or recurrence of symptoms
- ☐ Brain, spine and/or other nervous system damage
- ☐ Death

Patient's/Attendant's Initial: ……..…. Doctor's Initial: ……..

Additional Risk

a. Patient related ……..

……..……..……..……..……..……..……..……..……..……..……..……..……..……..……..……..

b. Procedure related..……..……..……..……..……..……..……..……..……..……..……..……

……..……..……..……..……..……..……..……..……..……..……..……..……..……..……..

The practice of medicine and surgery are not exact sciences and the results of procedure may not cure the disease completely.

Blood: The doctor has explained the risks of blood transfusion and I understand the following:
Blood transfusion is normally a procedure of low risk. Reactions to blood are uncommon, but do occur. The reactions may include fever, chills or hives (itchy rash). Other risks include iron overload and transmission of an infection. Even with testing of blood donors, there is a small risk of hepatitis infection from the blood transfusion. The risk of AIDS and other unavoidable complications may also occur.

Extension of Consent: I/We understand that in the course of performing the above Procedure(s), my physician may discover other or different conditions which may require additional or different Procedure(s) than those planned. I/We authorize my physician and his/her associates, designees, technical assistants, and other health care providers to perform other Procedure(s) which they deem necessary and advisable in their professional judgment.

Photography: I/We consent to the observing, photographing or televising of the procedure to be performed, including appropriate portions of my / our patient's body for medical or educational purposes provided my / our patient's identity is not revealed by the pictures or by descriptive text accompanying them.

If any staff member is injured or exposed to my blood or other body fluid then I give my consent to a sample of my blood being collected for the purpose of testing for infectious diseases, such as Hepatitis B, C and HIV. I understand that no testing of the blood sample will be carried out without prior discussion and my explicit consent

Validity: This consent is valid for 15 days from date of signing or till the completion of procedure (whichever is earlier) provided there is no change in clinical condition, addition or change of procedure or change in treating doctor

I/We, am/are legally competent and have sufficient knowledge to give this voluntary and informed consent. I/We have read and fully understood this consent form.

	Name	Signature/ Stamp	Date & Time
Patient	……..	……..	……...
Attendant (Relation to patient)	……..	……..	……..
Doctor	……..	……..	……...
Translator (If applicable)	……..	……..	……..

I certify that I have explained to the Patient (or Legally Responsible Agent) his / her Condition, the Proposed Operation(s) or Procedure(s), Attendant Risks and Possible Discomforts involved, Other Methods of Treatment, and the Possibility of Complications

Name of Doctor: …… Signature: ……

Date…… Time: ……

CHECKLIST USED FOR THE AUDIT

Sr.No	PIN No.	Consultant Name	Consent Name	Patient Details Complete/Incomplete (C/NC)	Date of Issue(C/NC)	Risk/Alternative (C/NC)	Patient /Attendance initial (C/NC)	Declaration By Doctor (C/NC)	Any Remarks