EVALUATING CONSENT FORM COMPLIANCE PRACTICES TO ENHANCE LEGAL AND ETHICAL STANDARDS IN A MULTISPECIALTY HEALTHCARE INSTITUTION

Dissertation Submitted to

The IIHMR University, Jaipur

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Master of Business Administration (MBA)

in

Hospital and Health Management

by

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Under the Supervision and Guidance of

Dr. Sarthak Sengupta

2025

Grant Medical Foundation
Ruby Hall Clinic

National Accreditation Board For Hospitals & Healthcare Providers

CERTIFICATE

This is to certify that Mr. **Telsang Sumedh Girish** in partial fulfillment of the requirements for the award of the degree of **MBA Hospital and Health Management** from the **IIHMR University, Jaipur** has successfully completed his internship at **Ruby Hall Clinic Hospitals**, Pune, India during **Mar 10, 2025 to May 31, 2025**.

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Date: 31st May 2025

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CERTIFICATE

This is to certify that dissertation titled "**Evaluating Consent Form Compliance Practices To Enhance Legal And Ethical Standards In A Multispecialty Healthcare Institution"** is a record of the research work undertaken by **Telsang Sumedh Girish** in partial fulfillment of the requirements for the award of the degree of MBA Hospital and Health Management from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

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IIHMR University, Jaipur

Date- 16th June, 2025

Dr. Sanjay Gupta

IIHMR University, Jaipur

Date- 16th June, 2025

DECLARATION BY STUDENT

I hereby declare that this dissertation titled **"Evaluating Consent Form Compliance Practices to Enhance Legal and Ethical Standards in a Multispecialty Healthcare Institution"** is the Bona fide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Telsang Sumedh Girish

Date- 16/06/2025

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List Of Abbreviations

Abbreviation	Full Form
OPD	Outpatient Department
NABH	National Accreditation Board for Hospitals
DR	Doctor
%	Percentage
etc.	Et cetera (and so on)

"EVALUATING CONSENT FORM COMPLIANCE PRACTICES TO ENHANCE LEGAL AND ETHICAL STANDARDS IN A MULTISPECIALTY HEALTHCARE INSTITUTION"

Submitted By- Telsang Sumedh Girish

Submitted to – Dr Sarthak Sengupta

ABSTRACT

Abstract

Study Objectives:
The primary objective of this study was to evaluate the compliance of consent form practices in a multispecialty hospital setting, with the aim of enhancing legal and ethical standards in patient care. Specific goals included assessing the extent to which consent forms adhered to institutional policies, identifying gaps in documentation, and recommending strategies to improve compliance and ensure legal validity of these forms.

Methodology:
This research was carried out at a 600-bedded multispecialty hospital in Pune over a 30-day period. A total of 100 consent forms across various departments—surgery, anesthesia, oncology, gynecology, and general medicine—were randomly selected using simple random sampling. A structured checklist was developed to evaluate key elements such as doctor's name and signature, patient and relative details, witness information, date and time entries, and bilingual availability. Data was collected and analyzed using descriptive statistical methods to determine compliance rates.

Key Results:
The analysis showed considerable non-compliance across various parameters. Doctor's name and signature were compliant in 91% and 79% of forms, respectively. Patient name compliance was 77%, and signature compliance was only 67%. Witness details showed the lowest compliance rates, with only 30% for name and 46% for signature. Time entry compliance was 55%, and a full 100% of forms had at least one incomplete area, rendering them legally non-compliant. Additionally, 34% of forms had entries in improper sections. However, 100% of the forms were found to be in bilingual format, aiding patient comprehension. Compliance also varied by specialty—for example, gynecologists had 0% sign compliance, whereas oncologists and general medicine practitioners had 100%.

Conclusion:
The findings reveal systemic gaps in consent documentation, which could expose healthcare providers to legal and ethical risks. Despite institutional policies, inadequate training, poor awareness, and lack of accountability contribute to widespread non-compliance. The study recommends implementing structured staff training, assigning clear responsibility for form oversight, and considering digital consent systems to enhance accuracy and traceability. Improving consent form compliance is essential not only for legal indemnity but also for fostering trust and ethical patient care practices.

Keywords: Consent Form, Legal Compliance, Hospital Ethics, Informed Consent, Healthcare Documentation

INTRODUCTION

Introduction

Consent is the willingness of a party to undergo examination/procedure / treatment by a healthcare provider. It may be implied (i.e.; patient registering in OPD) or expressed (which may be written or verbal). As a legal document, it is one of the most important parts of communication in medical field. In many of the medico legal cases, court decisions are with the remark “no proper consent”. Consent means understanding treatment options and making the right decisions on the information provided. Legally the patient is required to agree to the procedure or treatment suggested by the doctor for the medical condition.

Incomplete information about the patient diagnosis, therapeutic plan etc. is a commission rather than an omission. Unfortunately, due to many reasons this part is underestimated and missed by the treating doctors. Hence the consent form compliance becomes a very powerful tool to ensure higher degree of indemnity for the concerned hospital. This is the reason why I chose to do my project on Consent form Compliance.

My project work would help in assessing the current situation pertaining to practices and process involved in ensuring the required compliance for consent forms. It would also throw light on the shortcomings if any and also to identify areas of improvement. My project work was at a multispecialty hospital near Pune Station. The hospital has 600 beds and over 1500 paramedical staff in employment.

AIM & OBJECTIVES

AIM & OBJECTIVES

Aim

To study the compliance rate of consent policies in a multispecialty hospital and recommend improvements.

Objectives

1. To study the types of consent forms and understand the hospital's consent policy.
2. To evaluate the current compliance rate with respect to form completion.
3. To identify gaps and suggest strategies for improving compliance.

RESEARCH METHODOLOGY

RESEARCH METHODOLOGY

Research Location:

Multispecialty Hospital

Dhole Patil road,

Pune, Maharashtra.

Research Period and Sample Size:

- Research term/Period: From 17 Jan to 16th February 2024 (30 days)
- Sample size: Total 100 consent forms covering different departments
- Sampling technique: simple random sampling

While surveying ethical considerations like confidentiality has been prioritized throughout the study period.

Data Collection Tool's

- Consent completion checklist

OBSERVATIONS
&
RESULTS

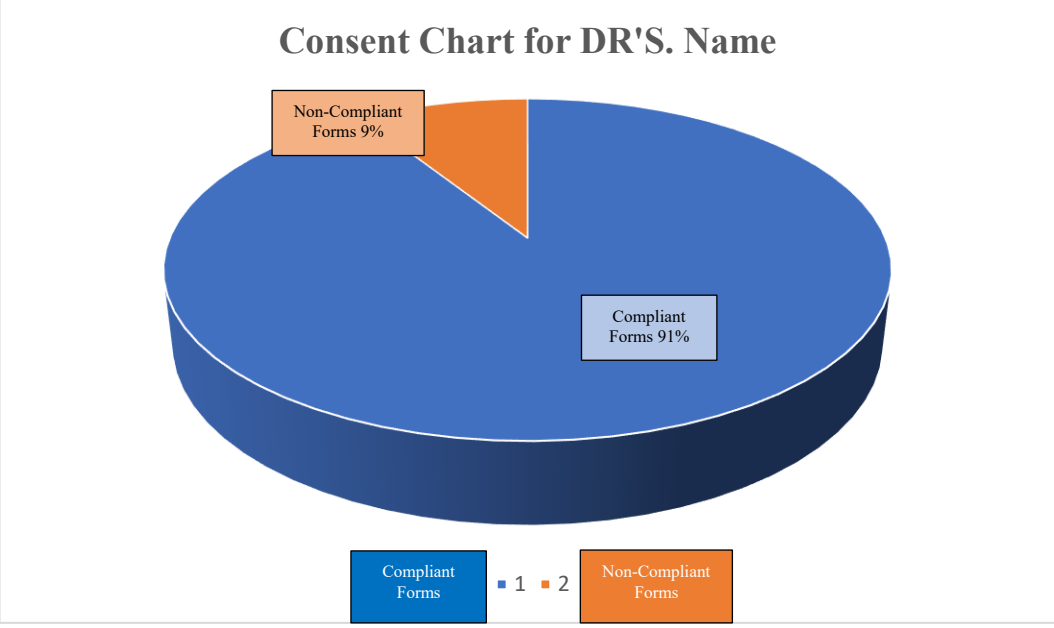
OBSERVATIONS & RESULTS

Table no: 01

Consent Data for DR's Name Entries

	DR's NAME
Applicable forms	100
Compliance	91
Compliance Rate %	91%
Non-Compliance Rate%	9%

Chart no: 01



91 % of the forms had Doctor's name compliance

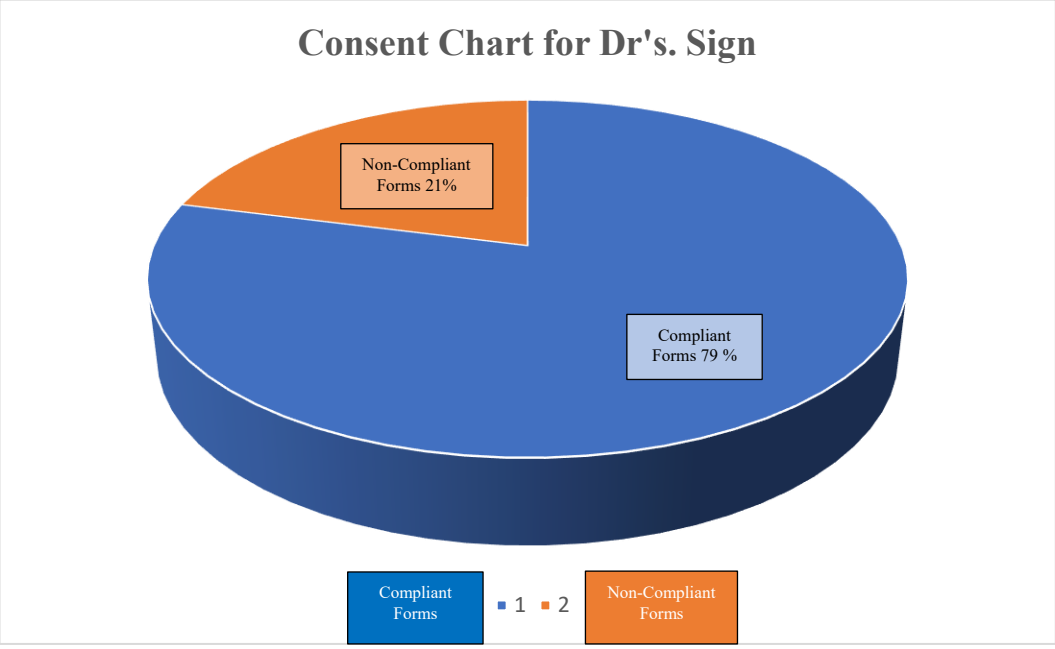
9 % of the forms were non-compliant as Doctor's name was not mentioned

Table no: 02

Consent Data for DR'S Signature

	DR'S SIGN
Applicable forms	100
Compliance	79
Compliance Rate %	79%
Non-Compliance Rate%	21%

Chart no: 02



79 % of the forms had Doctor's sign compliance

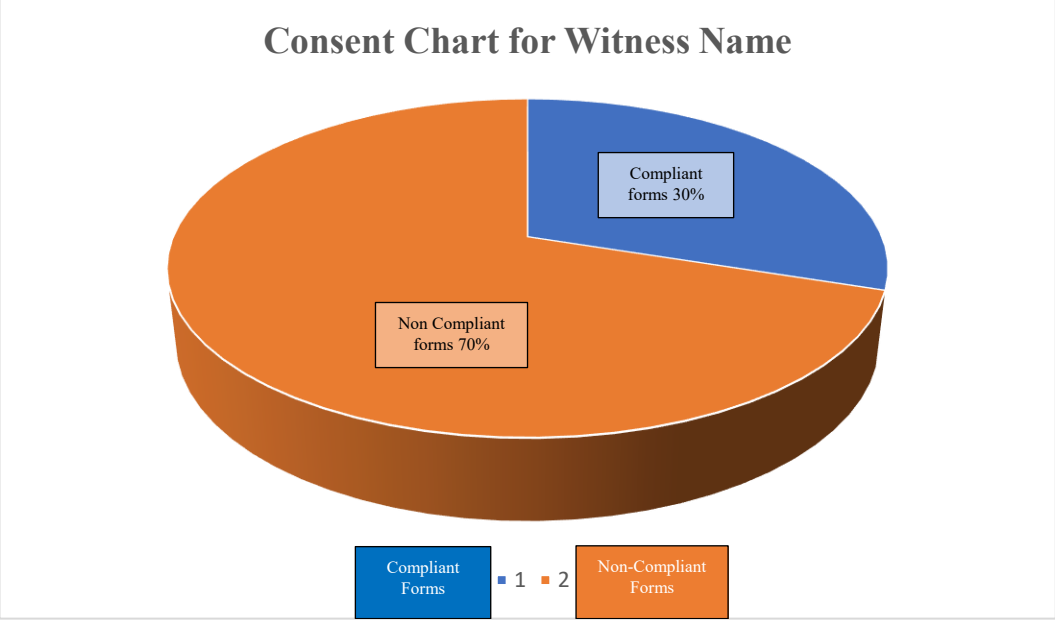
21 % of the forms were non-compliant as Doctor's sign was missing.

Table no: 03

Consent Data for Witness Name Entries

	WITNESS NAME
Applicable forms	84
Compliance	25
Compliance Rate %	30%
Non-Compliance Rate%	70%

Chart no: 03



30% of the forms had witness name compliance

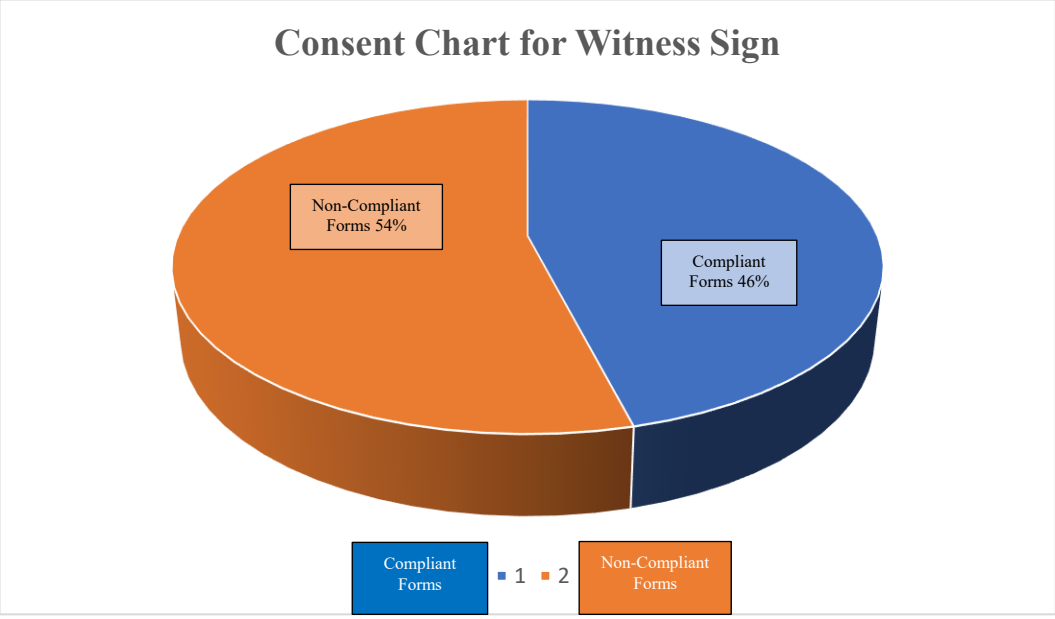
70% of the forms were non-compliant as witness name was not there

Table no: 04

Consent Data for Witness Signature

	WITNESS SIGN
Applicable forms	84
Compliance	39
Compliance Rate %	46%
Non-Compliance Rate%	54%

Chart no: 04



46% of the consent forms had witness sign compliance

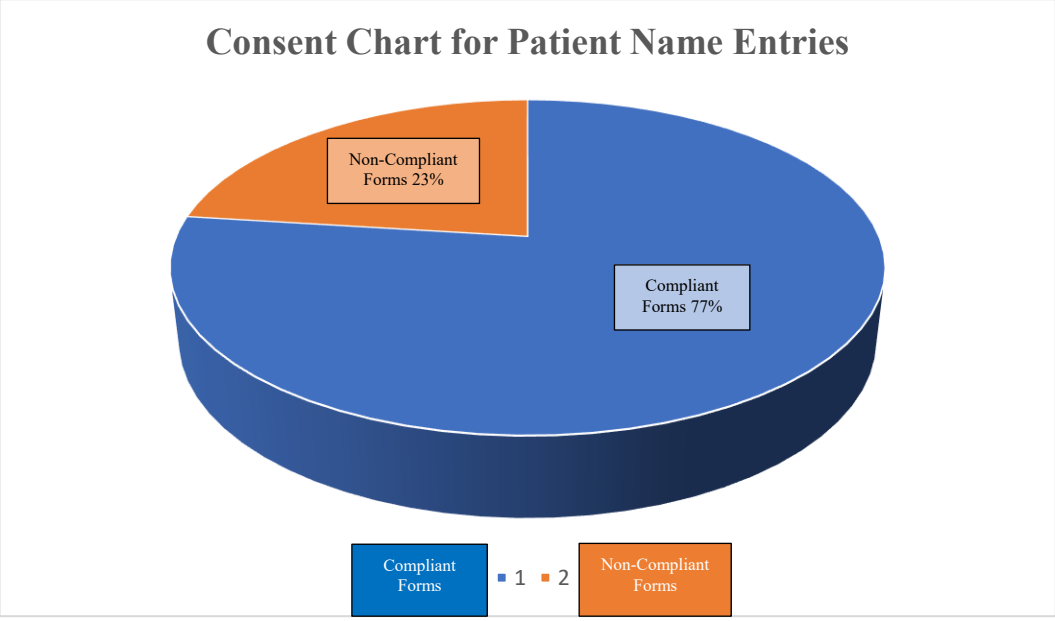
54 % of the consent forms were non-compliant as witness sign was missing

Table no: 05

Consent Data for Patient Name Entries

	PATIENT NAME
Applicable forms	48
Compliance	37
Compliance Rate %	77%
Non-Compliance Rate%	23%

Chart no: 05



77 % of the forms had Patient name compliance

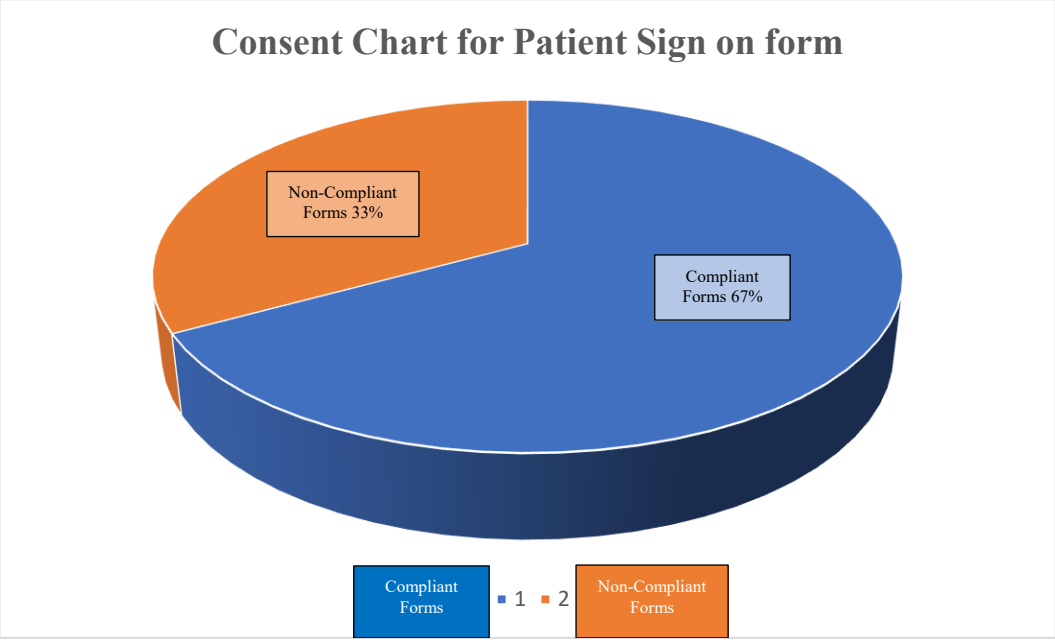
23 % of the forms were non-compliant as patient name was not there

Table no: 06

Consent Data for Patient Signature

	PATIENT SIGN
Applicable forms	48
Compliance	32
Compliance Rate %	67%
Non-Compliance Rate%	33%

Chart no: 06



67 % of the forms had Patient's sign compliance

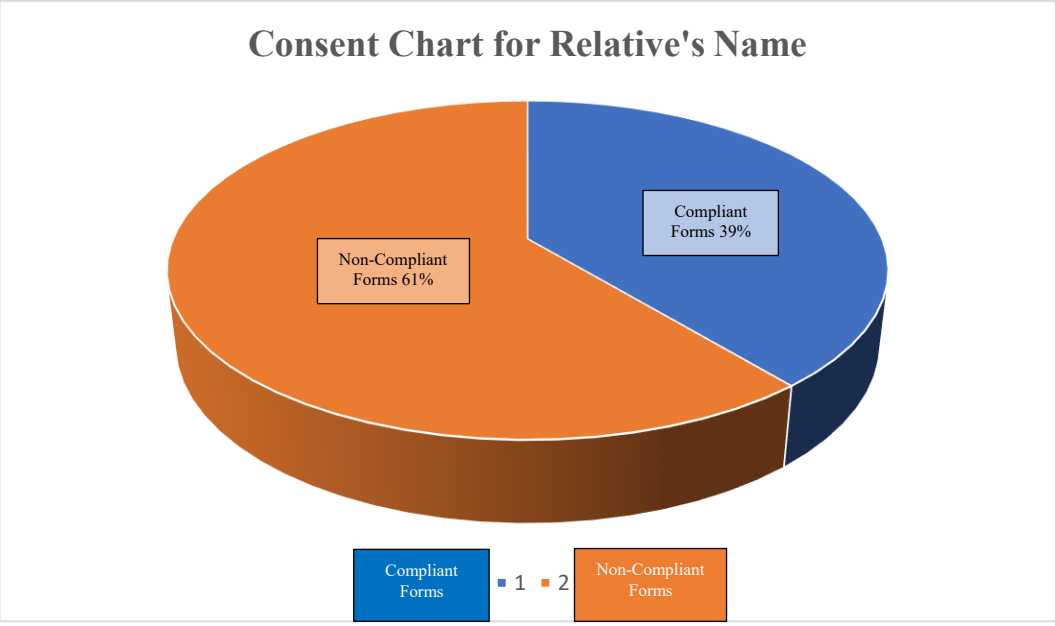
33 % of the forms were non-compliant due to missing patient's sign

Table no: 07

Consent Data for Relative's Name

	RELATIVE'S NAME
Applicable forms	59
Compliance	23
Compliance Rate %	39%
Non-Compliance Rate%	61%

Chart no: 07



39% of the forms had Relative's name compliance

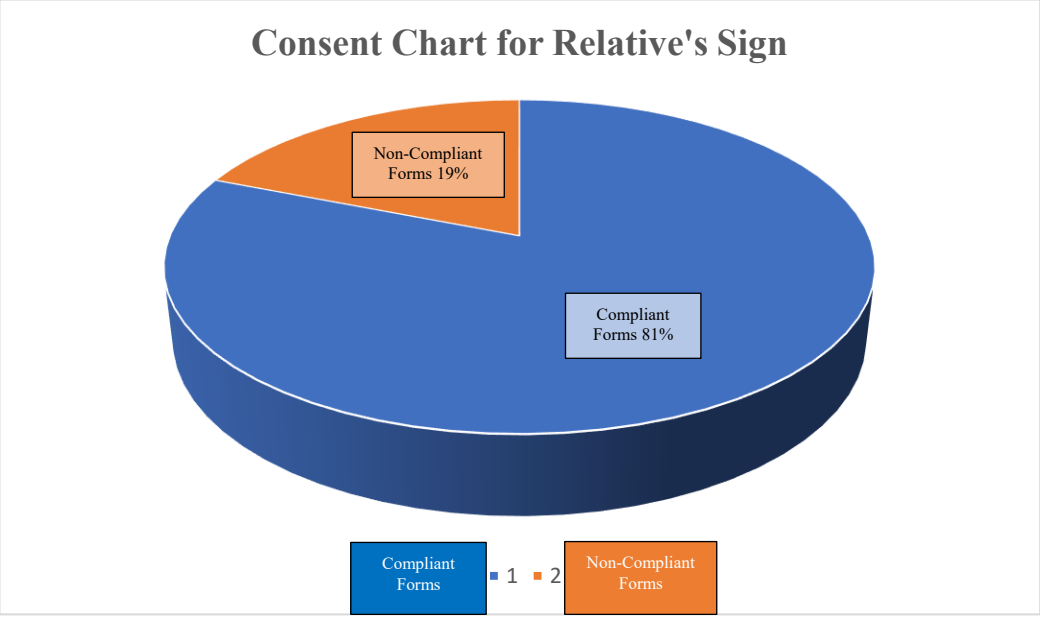
61 % of the forms was non-compliant as relative's name was missing

Table no: 08

Consent Data for Relative's Signature

	RELATIVE'S SIGN
Applicable forms	59
Compliance	48
Compliance Rate %	81%
Non-Compliance Rate%	19%

Chart no: 08



81% of the forms had Relative's Sign compliance

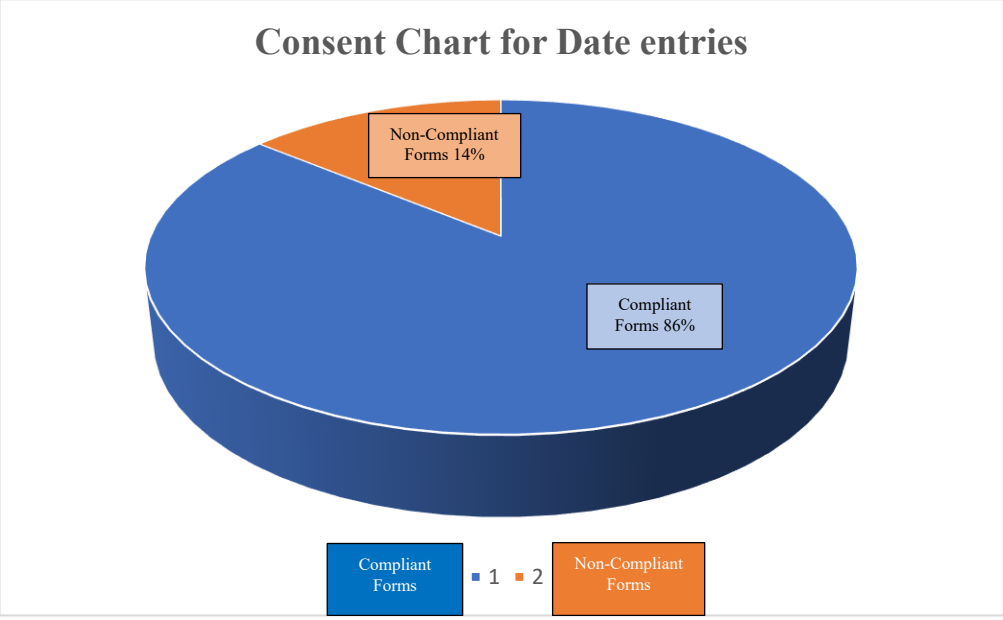
19 % of the forms were non-compliant as there was no sign of Relative

Table no: 09

Consent Data for Date Entries

	DATE
Applicable forms	100
Compliance	86
Compliance Rate %	86%
Non-Compliance Rate%	14%

Chart no: 09



86 % of the forms has Date entry compliance

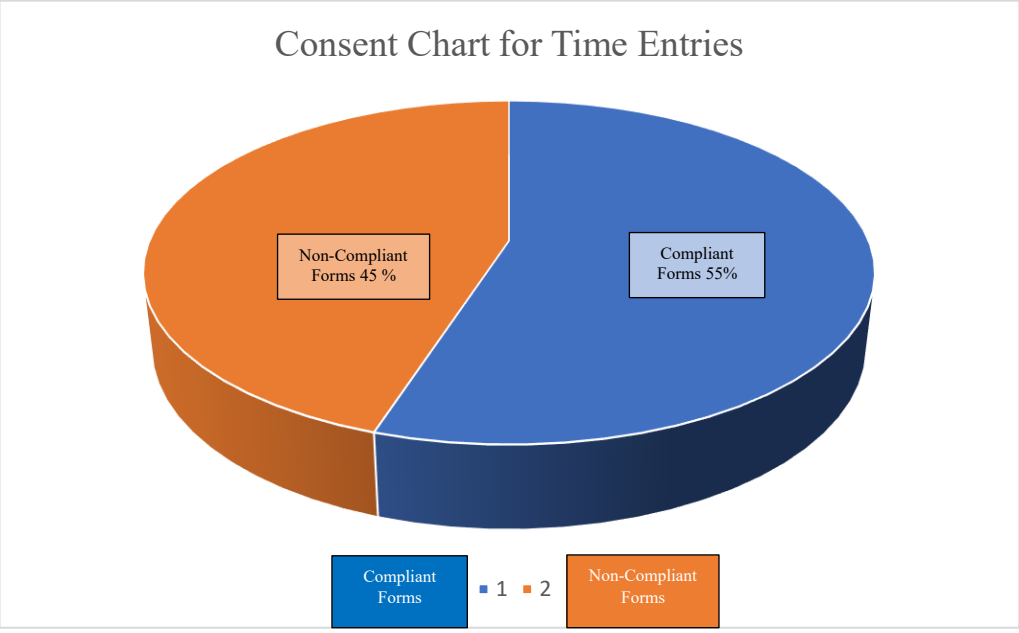
14 % of the forms were non-compliant due to missing Date on form

Table no: 10

Consent Data for Time Entries

	TIME
Applicable forms	100
Compliance	55
Compliance Rate %	55%
Non-Compliance Rate%	45%

Chart no: 10



55 % of the forms were compliant for Time entry

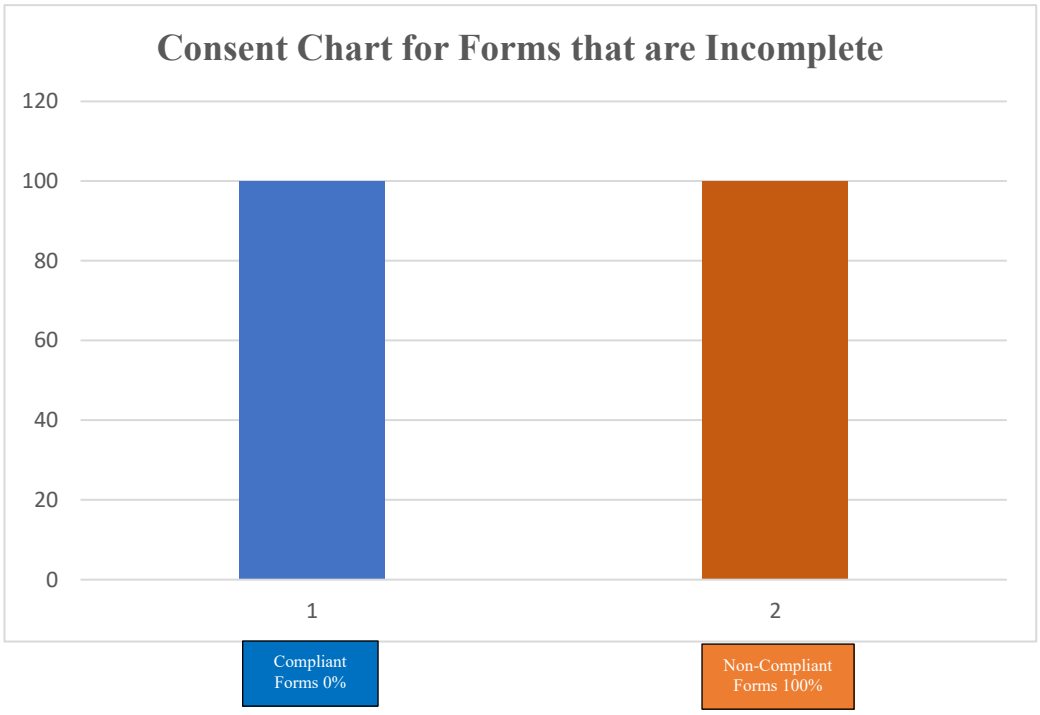
45 % of the forms were non-compliant for Time entry

Table no: 11

Consent Data for Incomplete Areas in the form

	INCOMPLETE AREAS
Applicable forms	100
Compliance	100
Compliance Rate %	0%
Non-Compliance Rate%	100%

Graph no: 11



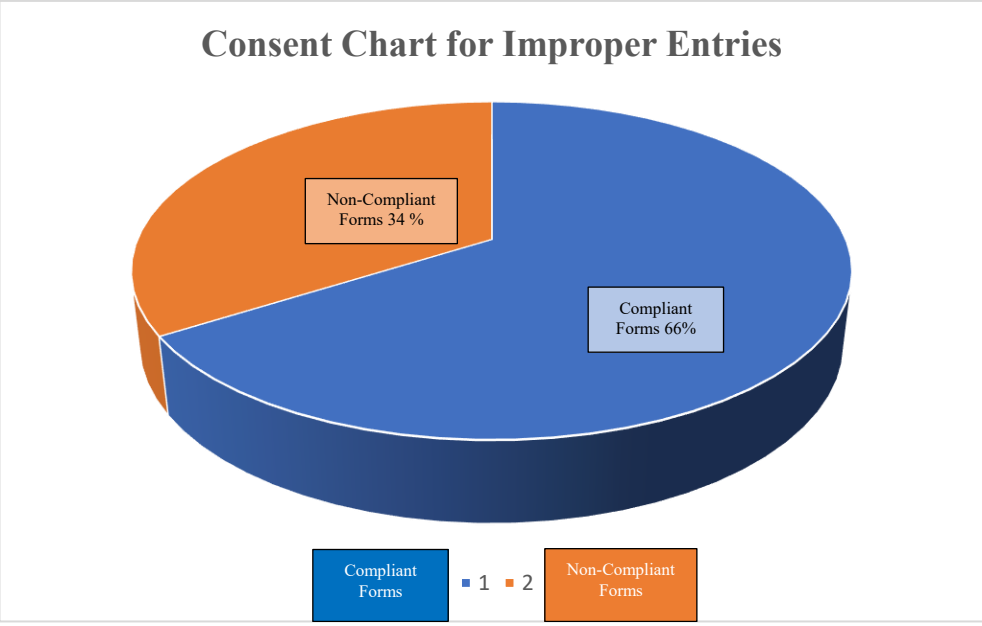
All 100 consent forms were found to be non-compliant due to incomplete entries

Table no: 12

Consent Data for Entries in Improper Areas

	IMPROPER AREAS
Applicable forms	100
Compliance	66
Compliance Rate %	66%
Non-Compliance Rate%	34%

Chart no: 12



34 % of the forms were having Improper entry compliance,

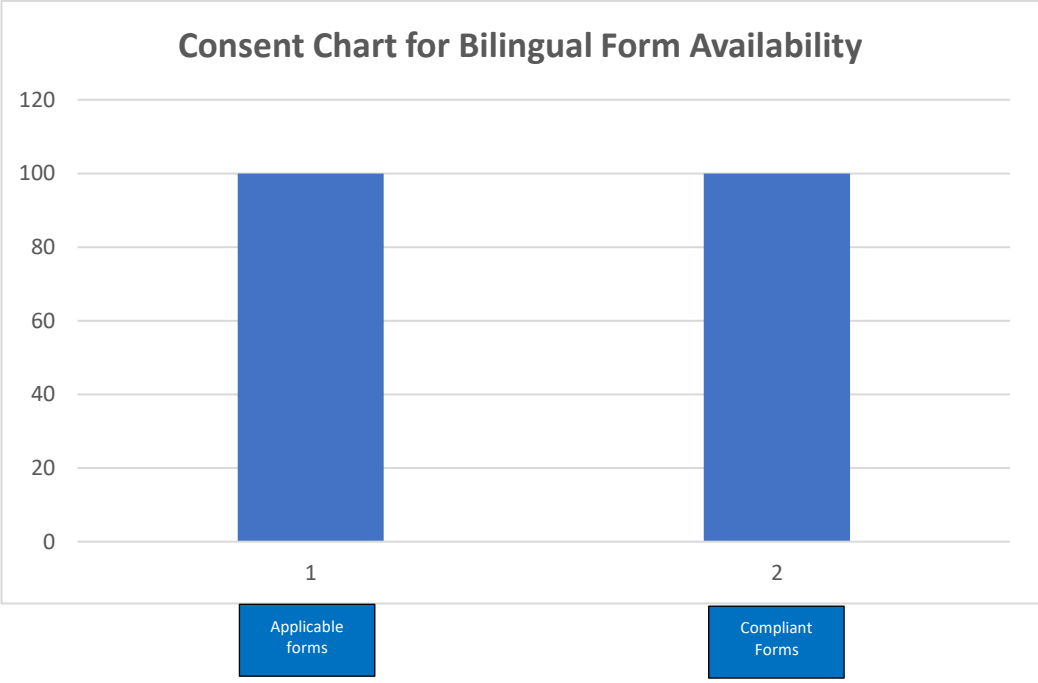
66 % of the consent forms were found to be non-compliant due to entries in improper areas / space.

Table no: 13

Data for Consent Form availability in Bilingual format

	BILINGUAL FORMAT
Applicable forms	100
Compliance	100
Compliance Rate %	100%

Graph no: 13



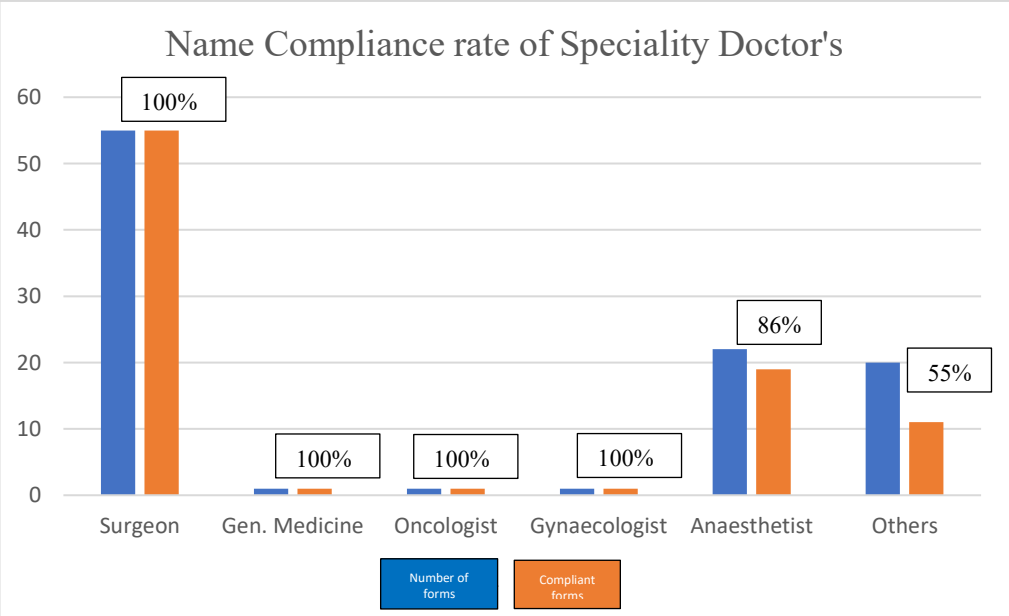
All the Consent forms were in Bilingual format having English and Marathi versions. Hence the compliance for Bilingual form requirement is 100 %

Table no: 14

Specialist Doctor's Name Compliance on consent form (OUT OF 100 TOTAL FORMS)

Consent Type	Specialization	No of Forms	Name Compliance	Name Compliance Rate
Surgery	Surgeon	55	55	100%
Blood Transf.	Gen. Medicine	1	1	100%
High Risk	Oncologist	1	1	100%
Blood Transf.	Gynecologist	1	1	100%
Anesthesia	Anesthetist	22	19	86%
Others	Others	20	11	55%
	TOTAL FORMS	100		

Graph no 14:



In the analysis of Name Compliance of Specialist Doctor's in the consent form

- Surgeons had 100 % compliance with all 55 forms having names
- General medicine Practitioners had a Name compliance rate of 100 %
- Oncologists had 100 % Name compliance
- Gynecologists had 100% Name compliance

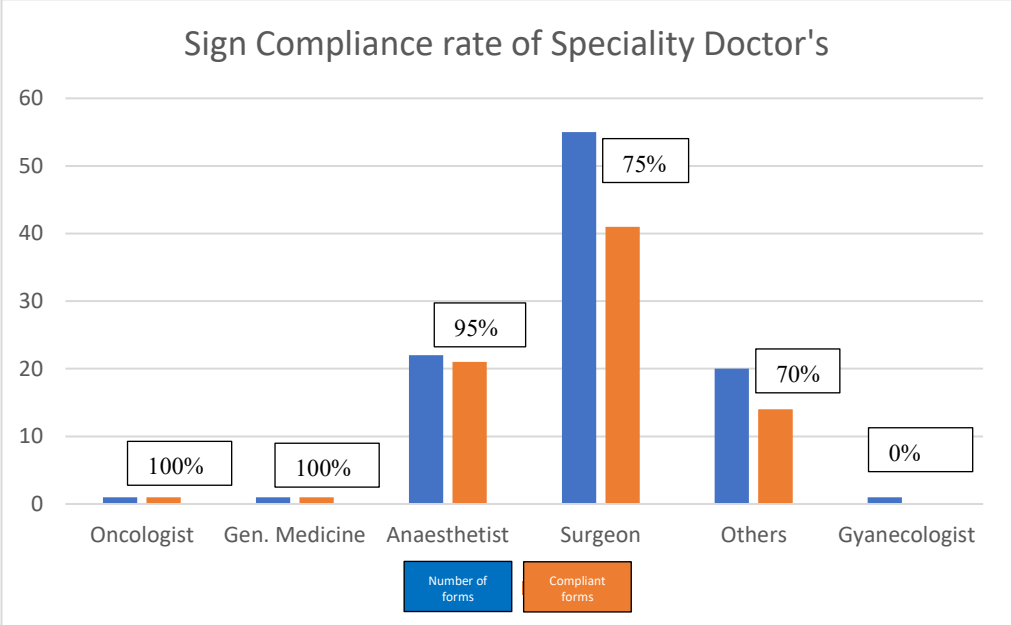
- Anesthetists had 19 forms out of 22 as compliant, this is 86 % Compliance rate
- Other Doctor's Category had 11 out of 20 forms having Name compliance resulting in 55 % Name compliance rate

Table no: 15

Compliance of the Specialist Dr's Sign Compliance on consent form

Consent Type	Specialization	No of Forms	Sign Compliance	Sign Compliance Rate
High Risk	Oncologist	1	1	100%
Blood Transf.	Gen. Medicine	1	1	100%
Anesthesia	Anesthetist	22	21	95%
Surgery	Surgeon	55	41	75%
Others	Others	20	14	70%
Blood Transf.	Gynecologist	1	0	0%
	TOTAL FORMS	100		

Graph no 15:



In the analysis of Sign compliance of Specialist Doctor's in the consent form.

- Oncologists had 100% Sign compliance
- General Medicine practitioners had 100% Sign compliance
- Anesthetists had 21 forms out of 22 as Sign compliant, this resulted in 95% Sign compliance.

- Surgeons had 41 out of 55 forms as Sign compliant, resulting in 75% Sign Compliance
- Other Doctor's category had 14 out of 20 forms as compliant resulting in 70% compliance rate.
- Gynecologists had 0 % sign compliance as the form had no sign

ANALYSIS
&
DISCUSSION

ANALYSIS & DISCUSSION

The sampling and analysis of consent form compliance in Hospital was done with the objective of understanding the degree of compliance while filling the consent forms, keeping in mind the legal validity and significance of compliant consent forms and the practices involved towards this compliance in the hospital.

100 consent forms sampling was done covering 5 specialties including Anesthesia, Surgery, High Risk Consents.

It was found that from the legal perspective all the 100 samples of the consent forms were non-compliant.

In the analysis of the Project, following were the notable points:

- From the technical side, the anomaly involving Doctor's Name and Sign on the consent forms which were entered in wrong space in the form or it was missing from the form. This makes the consent form invalid.

- On the administrative side anomalies concerning entry of date and time, patient name and sign, relative name and sign, witness name and sign where applicable, incomplete areas and entries in improper areas / Spaces renders the consent forms invalid as a legal document.

- In cases where signatures have been done in Marathi, the consent forms should have been filled on the Marathi version of the consent forms, else this might be seen as a situation where the patient or relative signing the form might not have been able to read and understand the form. To better indemnify the hospital, this can be rectified easily.

- There have been some consent forms where critical information like “benefits of the surgery”, “alternatives to the surgery”, “specific risks related to anesthesia” etc., has not been explained to the patient / relative.

- One of the flaws which can be easily and immediately corrected is the entry of “name and sign” in its appropriate space. It was found that 36 forms were having entries in the wrong space which rendered the forms non-compliant.

CONCLUSIONS

CONCLUSIONS

In the study of 100 sample of consent forms compliance in the hospital all the 100 forms were found to be non-complaint from the legal requirements for a consent form that can be categorized as compliant.

In each criterion like Doctor's entries, Date & Time entries, required details of Patient, Relative, Witness names and signatures entries etc., had discrepancies

Entries made in appropriate spaces negated the validity of the consent forms in some cases.

Compliance for Doctor's "Name & Sign" space:

- 91% of the forms had the Doctor's name compliance, 9 % did not have Doctor's name on the form's so they were non-compliant.
- 79% of the forms had Doctor's sign Compliance, 21% did not have the Doctor's sign hence they were non-compliant.

Compliance of "Date & Time" Space:

- 86% of the forms had the date compliance, 14 % of the forms did not have the date so they were non-compliant.
- 55% of the forms had the time compliance, 45% of the forms did not have the time mentioned hence they were non-compliant.

Compliance of "Patient, Relative, Witness "Name & Sign":

- 77% compliance for patient name, 23% patient name non-compliant.
- 67% Compliance for patient sign, 33% of the forms were found to be non-compliant for patient sign.
- 39% of the Relative's name entries were as per the required compliance, 61% were found to be non-compliant due to missing entries or due to entries in improper spaces.
- 81% compliance for Relative's sign, 19 % non-compliant for Relative's sign.
- 30% Witness name compliance, 70 % non-compliant.
- 46% Witness sign compliance, 54% non-compliant

Non-Compliance due to entries in improper areas:

- 66% of the consent forms were invalid due to entries done in improper areas.

Bilingual forms:

- 100% of forms were found to be having the option of Bilingual (English & Marathi) thereby making it easy for a non-English speaking person to understand the consent form and sign it based on a clear and well-informed manner.

Specialist Doctor's Name Compliance in the consent forms:

- Out of the total 100 forms, Surgeons had 100 % compliance with all 55 forms having names. General medicine Practitioners had a Name compliance rate of 100 %. Oncologists had 100 % Name compliance, Gynecologists had 100% Name compliance, Anesthetists had had 86 % Name compliance rate with 19 forms out of 22 as compliant. and Other Doctor's Category had 11 out of 20 forms having Name compliance resulting in 55 % Name compliance rate

Specialist Doctor's Sign compliance in the consent form:

- Oncologists had 100% Sign compliance; General Medicine practitioners had 100% Sign compliance. Anesthetists had 95 % Sign compliance with 21 forms out of 22 as Sign compliant. Surgeons had 41 out of 55 forms as Sign compliant, resulting in 75% Sign Compliance. Other Doctor's category had 14 out of 20 forms as compliant resulting in 70% compliance rate.

  Gynecologists had 0 % sign compliance as the form had no sign.

RECOMMENDATIONS

RECOMMENDATIONS

It was concluded after study of 100 samples of consent forms, as per the requirements needed to categorize the consent forms as compliant, all the 100 samples were found to be non-compliant. Following are the recommendations to help rectify the anomalies as mentioned in the conclusion

1. **Recommendation for "Doctor's name & Sign" Compliance:**

- For the doctor's Name & Sign Compliance, the coordinator or admin in charge of the consent form must personally ensure that the doctor's name is entered in the correct space along with the sign
- Doctor may also take a portion of the responsibility to cross check if the form is filled as per its requirements as the consent form is a legal document.

2. **Recommendation for "Date & Time" Compliance:**

- The responsibility for entry of date and time has to be in the hands of the coordinator / admin in charge handling that particular consent form

3. **Recommendation for "Patient Name & Sign" Compliance:**

- The spaces which require patient name and sign, relative name and sign, witness name and sign, should be ideally guided by the admin in charge or the respective coordinator responsible for that particular form.

- It is also recommended that the Patient / Relatives are explained about the importance of the consent form requirements and its fulfillment before commencing the process and procedures for the medical treatment and/or Surgeries.

4. **Additional Recommendations:**

- It is recommended to bring about a clause that, only one coordinator/admin in charge/ hospital staff shall be responsible for that particular consent form. This shall fix a clear responsibility and accountability for each consent forms on one responsible staff

- For all signatures which is in Marathi or in case of thumb print, the Marathi side of the form is filled, and all the relevant entries and signatures are also on the Marathi version of the form

A valid consent form helps to improve the degree of legal indemnity of the concerned hospital; therefore, it is very important that each consent form must be completed in a legally valid and acceptable manner, thereby ensuring the interests of the hospital. The above recommendations will enable the hospital to ensure its indemnity.

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