RESEARCH PROPOSAL

1. **TITLE:** Effect of web based learning module on knowledge related to drug calculations among staff nurses in teaching hospital; a quasi-experimental study.
2. **INTRODUCTION:**

"Web based learning is any purposeful application of web technologies to the task of educating a human being." –Norton, 2000

An important aspect of providing patient care is administrating medication in correct calculated dose. Registered nurses' good knowledge and skills in practicing drug calculation are an important indicator of adherence of safety protocols. Nurses are trained during their course period for calculating correct dose and administrating them. It is argued that the staff nurses' medication calculation ability is vital and has been associated with quick & prompt recovery among patients. Therefore, registered nurses' good knowledge and skills are an important indicator of adherence of safety protocols. The main reason for this research was to fill in the gap in the knowledge and skills related to drug calculation as there is little known locally about the significance of this concern and its impact on public health and well-being.

B.2 BACKGROUND:

Web based learning is a self-directed learning which can be a useful educational strategy for busy clinical nurses. It helps to improve knowledge, enhance the skill, improve the critical thinking & staff nurse will be able to provide effective care in the clinical area with confidence. Quality care implies appropriate drug dose calculation that helps to provide optimum therapeutic care and management.

2.2 NEED OF THE STUDY:

Web based learning can help clinical nurses to continue their learning even while working. In-service education is promoted by MNC to develop quality care services. Number of medication error reported due to calculation mistake are rapidly rising. To overcome this it is imperative to assess the knowledge regarding drug calculation among staff nurses working in teaching

hospitals. As a researcher's experience in the medical surgical clinical postings felt the need to enhance staff nurses' knowledge regarding drug calculation. Web bas ed learning module will provide all the necessary formula required for drug calculation along with conversion table. After teaching the staff nurses through the means of insert learning and wiki pages their knowledge will be assessed to make sure the method used was effective.

3. **Research question:** How does web based learning assist the nursing staff in enhancing their knowledge of drug calculations to avoid medication errors?

4. HYPOSTHESIS

Primary hypothesis

Null hypothesis

H_0: There is no significant difference in the knowledge score regarding drug calculation among staff nurses before and after learning through web based learning module.

Alternative hypothesis

Research hypothesis

H_1: There is significant difference in the knowledge score regarding drug calculations among staff nurses before and after learning through web based learning module.

5. REVIEW OF LITERATURE

A. Studies related to knowledge regarding drug dose calculation:

Abdul Rahim Mangrio, Pir Bux Jokhio and Saif Ullah Mahar conducted a cross sectional study to evaluate nurses knowledge regarding drug dose calculation in civil hospital. It helped to determine the knowledge regarding drug dose calculation among staff nurses. A pre-test post-test interventional study was conducted at civil hospital over 50 staff nurses working in different departments. The data was collected using assessment tool. The result revealed that majority of nurses have inadequate knowledge regarding drug dose calculation.[1]

An evaluation of drug dosage calculation knowledge and proficiency among newly hired nurses in private tertiary care hospital, Islamabad, Pakistan. Participatory action research (PAR) approach was selected using pre and post-test to assess the newly hired nurses

knowledge and proficiency related to drug dosage calculation. Data was collected after IRB approval at private tertiary hospital, Islamabad, Pakistan. Purposive sampling technique was adopted (n=135) all nurses on their commencement of employment from July 2016 to October 2016 participated The study concluded in the light of pre-test and post-test results that there is an intense need to review the nurse's drug dosage calculation knowledge and proficiency at the time of employment as nurses are key player in drug preparation and administration.[2]

B. Studies related to web based learning module:

Evaluation of Swedish nursing student's experience of a web-based platform for drug calculation. A cross-sectional comparative study was conducted to evaluate nursing student's skills about drug calculations. A web based learning platform was created. A questionnaire was used to evaluate the nursing student's experience of web based learning platform for drug calculation in terms of usage and learning support. The majority of participants evaluated the platform positively.[3]

Web based training for readiness and perception of nurses. A descriptive study was conducted in order to determine the views of nurses working at university hospital on web-based training. It was found out that nurses use computer at the moderate level (46.5 %), they benefit from Internet at a good level (46.5 %), almost all of them use Internet to make searches about professional issues (94.6%), they want to update their professional knowledge (90.1%) and they find it difficult to reach information on such grounds as time constraint (81.1 %) and lack of appropriate environment (62.1 %) and they want to receive a web-based training (87.1 %). It is important that web-based training programmes be generalised in the field of nursing where there exists a time problem, studies as regards to how to integrate these programmes into continuing education be increased and their results be reflected on the practices.[4]

6. OBJECTIVES OF THE STUDY

Primary objective:

- To assess the knowledge related to drug calculation among staff nurses.
- To compare the knowledge related to drug calculation among staff nurses before and after web based learning module.

Secondary objective:

- To analyse the feedback regarding web based learning module on knowledge related to drug calculation among staff nurses.

7. RESEARCH METHODOLOGY

7.1 Research approach: Quantitative approach

7.2 Research design: one group pre-test post-test design.

Parameters for self-learning module:

The parameters for self-learning module include title, target audience, behavioural objectives, instructions, educational content, and learner activity and learner feedback.

Title: Drug dose calculation

Target audience: Staff nurse working in teaching hospital

Instructions: To access all the available content on web page.

Learn all the necessary formulas required for drug calculation

Solve and practice the module questions

Educational Content: Formulas for drug dose calculation

Sums to practice on drug dose calculation

Pdf to save for further use, Modules to learn drug dose calculation, Wiki pages for solved examples of drug dose calculation and Quiz to solve and practice drug dose calculation.

Learner activity: To access the web page and solve the practice sums.

Learner's feedback: Gather learners feedback on google forms to know how effective is the used learning method.

7.3 Setting : Teaching hospitals in Navi Mumbai

7.4 Population: All staff nurses working in teaching hospital of Navi Mumbai.

7.5 Sample size : Using Yamane formula

Yamane formula is used for sample size estimation. This formula is applicable when we have finite population size but we don't have any information on the parameters under study in literature. Since the total number of staff nurses under MGM Hospital are 250, while 120 nurses work in shift duties. Hence, we estimate the optimum sample size for the study given by Yamane formula as follows,

$$n = \frac{N}{(1+Ne^2)}$$

N=total population; e=level of acceptable sampling error

N= 120 and e=0.05

$$n = \frac{120}{1+120(0.05\times0.05)}$$

n = 120/1.3

n = 92

7.6 Sampling technique: Non-probability purposive sampling technique.

7.7 Sampling criteria :

Inclusion criteria: All staff nurses willing to participate in study.

Exclusion criteria: ANM staff nurses.

7.8 Operational definition :

1. Effect:

In this study, effect is the change in knowledge in relation to drug calculation of medication as elicited as response by using a Structured Questionnaire.

2. Web-based learning:

In this study, web based learning module through the means of insert learning and wiki pages on drug calculation prepared by the researcher and provided access to all staff nurses working at teaching hospital.

3. Knowledge:

In this study, knowledge refers to the understanding of drug calculation practiced by staff nurses while administrating medication as prescribed.

7. Drug calculation:

In this study, drug calculation refers to math calculation done for preparing appropriate medication doses by making use of conversion factors.

8. Staff Nurses:

In this study, staff nurses refers to nurses working at MGM hospital Navi Mumbai.

7.9 Methods of measurement variable:

Interval scale to assess knowledge regarding drug dose calculation.

Ordinal scale to obtain feedback regarding effectiveness of web based learning module.

7.10 Interventional details:

Develop web based learning module regarding drug dose calculation for staff nurses.

Provide access to web page for staff nurses.

Conduct post-test after 7 days.

7.11 Data collection tool: Structured questionnaire.

Section A: demographic data

Section B: conversion of metric units

Section C: dilution and strengths of solution

Section D: drug dose calculation for measuring oral and intravenous medication.

7.12 Data collection technique:

Questionnaire to assess knowledge regarding drug dose calculation.

7.13 Plan for data collection:

A pre-test will be conducted to assess the knowledge of staff nurses regarding drug dose calculation.

A web based module will be prepared.

After providing access to web based learning module a post-test will be conducted after 6 days to evaluate the effectiveness.

7.14 Plan for data analysis and method: The questionnaire will be distributed among the respondents with a request to answer the questionnaire and return it as soon as possible to collect data.

8. Expected outcome and future plan bases on expected outcome :

There would be significant change in knowledge related to drug calculation among staff nurses after learning from web based module.

9. TIME FRAME

Duration:

S. No	Activity	Month & Year											
		Jan 22	Feb 22	Mar 22	Apr 22	May22	June 22	July 22	Aug 22	Sept 22	Oct 22	Nov 22	Dec 22
1	Literature Review												
2	Preparation of Proposal												
3	Ethical Approval												
4	Tool Validation &Pretesting												
5	Pilot study												
6	Data collection												
7	Data Analysis												
8	Project Report Submission												

10.BUDGET

Research Project Budget Format

Sr. No	Materials to be utilized for research	Available in the Institute (Yes)	Not available outsourced	Total cost of Research	Amount waiver to be availed from the Institute	Remarks
1	**Animals**	NA	NA	NA	NA	
2	**Plants**	NA	NA	NA	NA	
3	**Drugs**	NA	NA	NA	NA	
4	**Chemicals**	NA	NA	NA	NA	
5	**Investigations**	NA	NA	NA	NA	
a	Radiological	NA	NA	NA	NA	
b	Biochemistry	NA	NA	NA	NA	
c	Histopathology	NA	NA	NA	NA	
d	Any other investigation other than the above	NA	NA	NA	NA	
6.	**Lab. Equipment**	NA	NA	NA	NA	
a	Name of equipment	NA	NA	NA	NA	
b	Instruments	NA	NA	NA	NA	
c	Glassware	NA	NA	NA	NA	
d	Any other	NA	NA	NA	NA	
7.	**Stationary**					
a	Xerox	NA	2000	2000		
b	Data collection form	NA	1000	1000		
c	Computer	NA	500	500		
d	Soft wear for data analysis/ Statistical analysis	NA	5000	5000		

8	**Travel expenses**					
a	Researcher	NA	1000	1000		
b	Patients	NA				
9	**Stationary**					
a	Computer use/data storage (pen drive/hard drive) etc.	NA	1000	1000		
b	Xerox of reports	NA				
10	**Miscellaneous**					
a	Publication cost	NA	5,000	5,000		
b	Service contracts	NA				
c	Data analysis / Statistical analysis	NA	8,000	8,000		
d	Purchase of software, books periodicals	NA	3,000	3,000		
c	Patient reimbursement /Hospitalization					
5	Technicians if to be appointed					
	Total		Rs. 27,200/-	Rs. 27,200/-		

1. Signature of the researcher

2. Signature of the Guide

3. Signature of the Co- Guide

4. Signature of the secretary SAC/ Ethics Committee

11.REFERENCES

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11. Heczková J, Bulava A. Nurses' knowledge of the medication management at intensive care units. Pielegniarstwo XXI wieku/Nursing in the 21st Century. 2018;17(1):18-23.

12.Annexures

13. MGM INSTITUTE OF HEALTH SCIENCES
14. (Deemed University u/s 3 of UGC Act, 1956)
15. Grade 'A' Accredited by NAAC
16. MGM NEW BOMBAY COLLEGE OF NURSING
17. 5th Floor, MGM Educational Campus, Plot No. 1& 2, Sector-1
18. Kamothe, Navi Mumbai – 410 209.

12.1 PARTICPANT / PATIENT INFORMED CONSENT FORM

Study title: Effect of web based learning module on knowledge related to drug calculations among staff nurses in teaching hospital; a quasi-experimental study.

Study Number:

Participant's Initials: _____ Participant's Name: _____

Date of Birth/Age: _____

Address of the Participant
_____

Qualification _____

Occupation: Student or Self-Employed or Service or Housewife or Others (Please click as appropriate).

Annual Income of the
Participant:_____

Name and address of the nominees and his relation to the Participant (for the purpose of compensation in case of trial related death).:
_____

Place Initial box (Participant)

S.No	Item	Tick the box
1.	I confirm that I have read and understood the information sheet dated ------ -- for the above study and have had the opportunity to ask questions.	

2.	I understand that my participants in the study is voluntary and that I am free to with draw at any time , without giving reason without any my medical care or legal rights being affected	
3.	I understand that the study team member, Ethics committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to even if I with draw from the trial. I agree to this access. However, I understand that my identity will not be revealed, in nay information released to third parties or published.	
4.	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes	
5.	I agree to take part in the above study	

S.No	**Name**		**Signature/Thumb impression with date**
1	Participant		
2	Legally accepted Representative		
3	Investigator		
4.	Witness		

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12.2 PARTICIPANT / PATIENT INFORMATION SHEET

Protocol Number	
Principal investigator	Ms. Mansi Kambli
Designation	First year MSc nursing student
Address	MGMNBCON
Phone number	8422021859
Email id	mansikambli50@gmail.com

I. Project Title: Effect of web based learning module on knowledge related to drug calculations among staff nurses in teaching hospital; a quasi-experimental study.

II. Introduction: You are invited to participate in a research study. It is important that you read the description of the study and understand your role in it including the nature and risks of participation. Please give your consent to participate in this study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant

III. Why am I being requested to participate in this study?

You are being requested to participate in the study because

IV. Purpose of the study

Purpose of the study is to assess the effect of web based learning module on knowledge regarding drug calculation among staff nurses working in teaching hospitals in Navi Mumbai to minimize the medication error occurring due to wrong calculation.

V. Expected duration of this study and number of participants

You will be one of many number of participants who will participate in this study. You will be part of this research study for about 2 years duration.

VI. Description of the procedure to be followed

If you agree to participate in this study, you will be taught drug dose metric conversion, dilution and strength calculation and drug dose calculation for administering accurate prescribed dose.

VII. Risks and discomforts of participating in this study

There is no associated risk and discomfort of participants in this study.

VIII. Possible benefit of this study

This study will help to improve knowledge of drug dose calculation which will minimize the medication error happening while administering drugs to the patients.

IX. Specific alternative procedures or therapies available to the participant

NA

X. Schedule of interventions if any and allocation of participant in randomized controlled trail study.

NA

XI. Possibility of failure of investigational product to provide intended therapeutic effect in case of RCT

NA

XII. Confidentiality:

All study records will be kept confidential at all times. Your identity will not be revealed except as required by law. The results may be published for scientific reasons. Your identity will not be revealed in these articles

XIII. What happens when the study stops?

NA

XIV. Compensation for participation

No compensation will be provided for your participation. Payment for things such as lost wages is not available.

XV. Compensation for study related injury:

You will be provided medical care at this institute for any physical Injury or illness that occurs as a direct result of your participation of the study. This medical care will be at no cost to you. You will not give up any of your legal rights by signing this form.

XVI. Voluntary participation and right to withdraw

Participation in the study is entirely voluntary. You may choose not to take part or you may leave the study at any time

XVII. Responsibilities of participant if decided to participate

Learn and practice drug dose calculation as provided on web based learning modules.

XVIII. Contact for further information:

We thank you for taking the time to read the information about this study. Before you sign this document, you should ask questions about anything that you do not understand. The study staff will answer questions before, during &after the study.

If you have questions about this study, contact investigator: Name, address, contact no., email id

For any research related Information: Principal investigator: (Refer first Page)

For your rights related Information contact: Dr. Shilpa Patel, IEC Member Secretary, MGM Dental College Hospital, MGM educational campus, Kamothe, Navi Mumbai. Contact No. : 9987696594

Content of Drug Calculation

Introduction: An important part of nurse's role is to ensure that drug dose is calculated and administered appropriately

Converting metric units:

- 1 gram = 1000 milligram
- 1 milligram = 1000 micrograms
- 1 litre = 1000 millilitres
- 1 megaunit = 1,000,000 units
- 2.2 Ibs = 1 kg
- 30 ml = 1 oz
- 1 tsp = 5 ml
- 1 tbsp = 15 ml
- 2 tbsp = 1 oz

Dilution and strengths of solutions:

A drug when dissolved in a solution and the strength of the solution may be expressed as:

- grams per liter
- mg/ml
- ratio strength
- percentage

Drug dose calculation formula:

a) Volume or number of tablets to be given.
b) Calculating drops per minute
c) Calculating time required to complete an infusion
d) Calculating the rate of infusion
e) Drug calculation by weight

Practice Questions:

a) Convert the following
b) Calculate the rate

12.3 Data collection tool

Section A

Demographic Data:

1. Age:
    a) 21-30 years
    b) 31-40 years
    c) 41-50 years
2. Gender:
    a) Male
    b) Female
3. Years of experience:
    a) 1-3 years
    b) 4-6 years
    c) 7-9 years
    d) >10 years
4. Qualification:
    a) GNM
    b) BSc
    c) MSc
    d) NPcc
5. Designation:
    a) Staff nurse
    b) Senior staff nurse
    c) Team leader
6. When calculating drug doses, is it necessary to double-check your own calculations?

Section B

Conversion of metric unit

1. How much mcg constitute 5mg:
    a) 2000 mcg
    b) 500 mcg
    c) 5000 mcg
    d) 5500 mcg
2. How many microliters constitute 8 mL of drug solution?
    a) 8 microlitre
    b) 80 microlitre
    c) 800 microlitre
    d) 8000 microlitre
3. How much ml is 1 teaspoon??
    a) 10 ml
    b) 15 ml

c) 5 ml
d) 30 ml

4. How much ml is 1 oz?
    a) 10 ml
    b) 15 ml
    c) 5 ml
    d) 30 ml
5. How much ml are there in 1 tablespoon?
    a) 10 ml
    b) 15 ml
    c) 5 ml
    d) 30 ml
6. How much gram constitute 7500 mg?
    a) 75 gram
    b) 7.5 gram
    c) 750 gram
    d) 0.75 gram
7. How much gram does 4000 mcg constitute?
    a) 0.04 gram
    b) 0.004 gram
    c) 0.4 gram
    d) 0.0004 gram

Section C

Dilution and strengths of solutions.

1. How much sodium (in grams) is there in 500 ml of solution of sodium chloride 0.9% of solution:
    a) 2.5 gram
    b) 9 gram
    c) 4.5 gram
    d) 1.5 gram
2. 10 ml ampoule of adrenaline 1 in 1000, how much adrenaline in milligrams does the ampoule contains:
    a) 10 mg
    b) 30 mg
    c) 40 mg
    d) 50 mg
3. A 80kg patient is planned for suture. Maximum dose of lignocaine administered is 3mg/kg what is the maximum safe volume in ml of 2% lignocaine solution that can be given:
    a) 14 ml
    b) 12 ml
    c) 10 ml

d) 8 ml

4. Sodium hypochlorite solution is available as 10% solution in 1 litre. How much water can be added to make its concentration 2%:
    a) 4000 ml
    b) 3000 ml
    c) 2000 ml
    d) 1000 ml
5. Atropine is available as 1mg in 10ml. How much mg/ml it forms?
    a) 0.01 mg/ml
    b) 0.1 mg/ml
    c) 1 mg/ml
    d) 10 mg/ml
6. 1% of dopexamine is available in 5ml ampoule. How many milligrams of dopexamine does that ampoule contains?
    a) 20 mg
    b) 30 mg
    c) 40 mg
    d) 50 mg
7. Injection epinephrine 1:1000 is the ampoule strength, how much mg of epinephrine is in 1 ml?
    a) 10 mg
    b) 100 mg
    c) 1 mg
    d) 15 mg

Section D

Drug dose calculation for measuring oral and intravenous medication.

1. A 45 kg female client arrives in emergency department with symptomatic bradycardia. Drug of choice is Atropine 20 microgram/kg which is given intravenously. How much atropine is required if 10ml contains 1 mg?
    a) 3 ml
    b) 6 ml
    c) 9 ml
    d) 12 ml
2. 375 mg of cefuroxime is prescribed however the drug is available in 750 mg dose. If diluted in 10 ml sterile water how much can be administered?
    a) 5 ml
    b) 7 ml
    c) 6 ml
    d) 8 ml
3. 130 mg of Paracetamol syrup is to be administered to a paediatric patient. The available dose is 250 mg per 5 ml. How much ml will you administer?
    a) 1.6 ml

b) 2.6 ml
c) 3.6 ml
d) 4.6 ml

4. 125 microgram digoxin is prescribed orally. Available is digoxin elixir 50 microgram/ml with a pipette dropper. How many ml is required for this patient?
    a) 1 ml
    b) 1.5 ml
    c) 2 ml
    d) 2.5 ml
5. 1 gram of erythromycin orally is ordered. Available suspension is 250 mg in 5 ml. How many ml will you administer?
    a) 20 ml
    b) 30 ml
    c) 40 ml
    d) 50 ml
6. Gentamycin injection is available in 40mg/ml in 2ml ampoule. Prescribed dose is 4mg/kg for 60 kg patient. How many ampoules will be required?
    a) 6 ampoules
    b) 8 ampoules
    c) 10 ampoules
    d) 12 ampoules

Answer Key

Section B

Q.1: C

Q.2: D

Q.3: C

Q.4: D

Q.5: B

Q.6: B

Q.7: B

Section C

Q.1: C

Q.2: A

Q.3: B

Q.4: A

Q.5: B

Q.6: D

Q.7: C

Section D

Q.1: C

Q.2: A

Q.3: B

Q.4: D

Q.5: A

Q.6: A

Scoring Criteria

Based on UGC criteria the scoring is divided into good, moderate and poor knowledge.

Level of knowledge	**Score**
Excellent knowledge:	>75%
Good knowledge:	60-75%
Moderate knowledge:	50-60%
Poor knowledge:	<50%

Feedback Form

Your feedback will be greatly appreciated.

Kindly answer all the statements on the scale of 1 to 5.

1= Disagree (D)

2= Strongly Disagree (SD)

3= Uncertain (U)

4= Agree (A)

5= Strongly Agree (SA)

Select among 1 to 5 to indicate your response in accordance to your experience.

Sr. No.	Content	D	SD	U	A	SA
1.	The content was appropriate					
2.	The content was relevant					
3.	The content was easy to understand					
4.	Introduction was clear to the subject					
5.	The aims and objectives were clearly stated					
6.	The material was well organised					
7.	Modules were easy to understand					
8.	Web page was easily accessible					
9.	It helped to improve your knowledge					
10.	Quiz aided in stimulating practice of problems					
11.	It was convenient to save pdf for further use					
12.	There was a clear summary and conclusion					

12.4 Curriculum Vitae

Personal information of investigator:

Name: Ms Mansi Kamalakar Kambli

Age: 23 years **D.O.B:** 20/11/1998

Marital status: Single

Name of post working as: Staff Nurse

Area of experience: Intensive Care Unit, Emergency Department.

State: Maharashtra

Gender: Female

Phone number: 8422021859

Highest qualification attained: B.sc Nursing

Years of experience: 1 year

Email Id: mansikambli50@gmail.com

Certified courses : C and C++ programming, BLS

Personal information of Guide:

Name: Ms. Sivakamasundari.P

Date of Birth: 11/04/1982

Marital Status: Married

Address: MGM New Bombay College of Nursing, Kamothe, Navi Mumbai

Contact No: 7208755782

Email id : Sivasundari822019@gmail.com

Academic Background : M.Sc Nursing

Year of Passing (Last qualification) : 2010

Work Experience: 13 years in Nursing

Professional Organization Membership : Nil

Conferences Seminar Attended: 15

Dissertation: 1

Personal information of Co-Guide:

Name: Dr. Ashok Kanthe

Date of Birth 04/04/1973

Marital status: Married

Address: Plot No C-3, A 206, Millenium Orchid, Sector 12, Kharghar, Navi Mumbai

Contact No: 9322583542

Email id ashokkanthe@gmail.com

Academic Background: Teaching

Year of passing (Last qualification). PhD 2015

Work experience : 25 Years

Professional Organization membership: Computer Society of India, Indian Society for Technical Education

Conferences Seminars attended: 25

Papers /Posters Presented: 20

Research Topics currently undertaken: Solving cyber security issue using Machine Learning

Dissertation: Secure Routing Protocol for Mobile Adhoc Networks

Workshops /Pre conference:10

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Check List of Documents

Sr. No.	Document	Yes	No
1	IERC MGMDCH application form	✓	
2	Summary of protocol		✓
3	Protocol	✓	
4	Amendments to protocol		✓
5	Informed consent document in English	✓	
6	Informed consent documents in Regional languages (Total No.:)		✓
7	Back translations of Informed consent documents		✓
8	Amendments to the informed consent document		✓
9	Case Record Form / Questionnaire	✓	
10	Principal investigators Current Curriculum Vitae	✓	
10	Subject recruitment procedures: advertisement, letters to doctors, notices		✓
11	Investigator Brochure		✓
12	Ethics Committee clearance of other centres (Total No.)		
13	Insurance policy if any		✓
14	Drugs Controller General (India) [DCG(I)] clearance if applicable		✓
15	Investigator's agreement with sponsor if applicable		✓
16	Investigator's undertaking to DCG(I) if applicable		✓
17	Health Ministry Screening Committee (HMSC)approval if applicable		✓
18	Bhabha Atomic Research Centre (BARC) approval if applicable		✓
19	Genetic Engineering Advisory Committee (GEAC)approval if applicable		✓
20	Director General of Foreign Trade (DGFT) approval if applicable		✓
21	FDA marketing/manufacturing license for herbal drugs. if applicable		✓
22	Other Documents		✓