Standard Operating Procedure (SOP)
Institutional Review Board
[Human Ethics Committee]

Email: irb_gmcb@yahoo.com

Government Medical College,
Bhavnagar-364001,Gujarat, India.

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Objective

The objective of this Standard Operating Procedure (SOP) is to ensure quality and consistency in review of research proposals as prescribed by the Ethical guidelines for biomedical research on human subjects.

Functions of IRB

- IRB provides independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies until and after completion of the study.
- The IEC takes care that all the cardinal principles of research ethics viz.
  Autonomy, Beneficence, Non-malfeasance and Justice are taken care of in planning, conduct and reporting of the proposed research.
- IRB reviews all research projects involving human subjects to be conducted at Government Medical College, Bhavnagar, Gujarat, irrespective of the funding agency.

Application Procedure to IRB

All applications should be forwarded by the head of the departments to the IRB in prescribed format in 10 copies.

Documents to be submitted are:

- IRB proposal form
- Protocol of the proposed research
- Case report forms and follow - up cards
- Questionnaires if any
- Informed consent form in vernacular language (Gujarati or Hindi) and English
- Patient information sheet in vernacular language (Gujarati or Hindi) and English
- Approval of the Head of the Department
- For any new drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers, if available.
- Financial requirements for the project and its source.
- Statement of conflicts of interest, if any.
- C.V. of all the investigators(dated and signed) with relevant publications in last five years.
- Agreement to comply with the relevant national and applicable international guidelines.
- A statement describing any compensation or insurance coverage for study participation, if applicable.

- All significant previous decisions by same or other IRBs or regulatory authorities for the proposed study. The reasons for negative decisions should be provided.
- Plans for publication of results.
- **IRB processing fee**: Post graduate students have to pay Rs. 300/- to Rogi Kalyan Samiti, Sir T General Hospital, Bhavnagar and Rs. 200/- to IRB and for industrial trial Rs. 5000/- to Rogi Kalyan Samiti, Sir T General Hospital, Bhavnagar and Rs. 1000/- to IRB as processing fee.

Quorum requirement for meeting

For review of each protocol the quorum of Ethics Committee has at least 5 members with the following representations:

(a) Basic medical scientists (preferably one pharmacologist).

(b) Clinicians

(c) Legal expert

(d) Social scientist/ representation of non-governmental voluntary agency philosopher/ethicist/ theologian or similar person

(e) Common man from the society.

IRB meeting schedule

- IRB (HEC) meeting will be held on the last Thursday of every 2 month.
- Researchers/Students should submit their research / Dissertation proposal at least 3 weeks before the meeting.
- Dates can be changed if the possibility of quorum formation will not be there.

IRB Review Procedure

- The proposals are sent to members at least 2 weeks in advance.
- Decisions are taken by consensus after discussions, and whenever needed voting is done.
- Researchers are invited to offer clarifications if needed.
- Independent consultants/Experts are invited to offer their opinion on specific research proposals if needed.

Decision Making Process of IRB

- Members discuss the various issues before arriving at a consensus decision.

- A member withdraws from the meeting during the decision procedure concerning an application where a conflict of interest arises and this is indicated to the chairperson prior to the review of the application and recorded in the minutes.
- Decisions will be taken only in meetings when quorum is complete.
- Only members can make the decision. The expert consultants only offer their opinions.
- Decision may be to approve, reject or revise the proposal.
- Modified proposals may be reviewed by an expedited review through identified members.

Communicating the Decision of IRB

- Decisions are communicated by the member secretary in writing in prescribed format.
- Specific suggestions for modifications and reasons for rejection are given by IRB.

Follow up Procedures of IRB

- The ongoing researches are reviewed at regular intervals. (3 months)
- The IRB reviews approved projects for continuation, new information, adverse event monitoring, follow-up and later after completion if needed.
- Final report should be submitted at the end of study.

IRB Record Keeping

Documents to be preserved are

- The constitution and composition of the IRB.
- Signed and dated copies of the latest the curriculum vitae of all IRB members with records of training if any.
- Standard operating procedure of the IRB.
- National and International guidelines.
- Copies of protocols submitted for review.
- All correspondence with IRB members and investigators regarding application, decision and follow up.
- Agenda of all IRB meetings.
- Minutes of all IRB meetings with signature of the Chairperson.
- Copies of decisions communicated to the applicants.
- Record of all notification issued for premature termination of a study with a summary of the reasons.
- Final report of the study.
- All documents related to research project are preserved for a period of at least 3 years after completion of study.

Institutional Review Board (IRB)/ [Human Ethics Committee (HEC)]

સરકારી તબીબી મહાવિદ્યાલય, ભાવનગર. **Govt. Medical College, Bhavnagar-364001**

એસ.ટી સ્ટેન્ડ પાછળ, જેલ રોડ, ભાવનગર - ૩૬૪૦૦૧ (ગુજરાત),

Behind S.T. Stand , Jail Road, Bhavnagar 364001 (Gujarat) India.

Phone no (0278) 2430808 Web site: www.bvnmedicol.org Fax no.(0278) 2422011

No. GMCB / ……IRB (HEC) / . . . ./ 2011.

Form to be filled by the Principal Investigator (PI) for submission to Institutional Review Board (IRB)/[Human Ethics Committee (HEC)]

(Attach with each copy of the proposal)

For Office Use:
Received Date:
Received after scrutinization:
IRB Approval Date:
IRB (HEC) No.. . . . . / 2011
. . . . . no. …/2011 (... . . . .)

Govt. Medical College, Bhavnagar.

Date: / /2011

Affix Passport size recent photograph only in two copies of proposal

Office of the Dean,
Govt. Medical College,
Bhavnagar 364001(Gujarat)
Date: / /2011

Research / Dissertation Proposal Submission Proforma :

Before submitting the proposal to Institutional Review Board (IRB) / [Human Ethics Committee (HEC)] please discuss it in the department's scientific meeting and produce a attendance sheet of that meeting.

Research Proposal Title: (In Times New Roman fonts, size:16, in capital letters)

	Name, Designation & Qualifications	Address Tel no. & Fax Nos. Email ID	Signature
PI			
Co-PI / Collaborators 1.			
2.			
3.			

Please attach detailed Curriculum Vitae of all Investigators dated and signed by the investigators (with subject specific publications limited to previous 5 years).

Sponsor Information :

1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐

b) Private ☐

2. International Government ☐ Private ☐ UN agencies ☐

3. Industry National ☐ Multinational ☐

Contact Address of Sponsor: . . . . . .

Total Budget: **In Indian Currency: Rs. (In number) . . . . . .**

Rs. (In Words) . . . . . .

1.Type of Study : Epidemiological ☐ Basic Sciences ☐ Animal studies ☐

Clinical: Single center ☐ Multicentric ☐ Behavioral ☐

2. Status of Review: New ☐ Revised ☐

3. Clinical Trials:
Drug /Vaccines/Device/Herbal Remedies :

i. Does the study involve use of :
Drug ☐ Devices ☐ Vaccines ☐

Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ NA ☐

ii. Is it approved and marketed
In India ☐ UK & Europe ☐ USA ☐

Other countries, specify ☐

iii. Does it involve a change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No

d). **Clinical Study is** : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐

e). Are you aware if this study/similar study is being done elswhere ? **If Yes**, attach details	Yes	No

4. Brief description of the proposal (In Times New Roman fonts double spacing, size: 14) – in following points :

a .Introduction,
b. Review of literature - submit hard copy of few published papers.
c. Aim(s) & objectives,
d. Justification for study,
e. Methodology describing the potential risks & benefits,
f. Outcome measures,
g. Statistical analysis and
h. Whether it is of national / State of Gujarat significance with rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i.	Number of Subjects :		
ii.	Duration of study :		
iii.	Will subjects from both sexes be recruited	Yes	No

iv.	Inclusion / exclusion criteria given				Yes	No
v.	Type of subjects	Volunteers	☐	Patients	☐	
vi.	Vulnerable subjects (Tick the appropriate boxes)	Yes	☐	No	☐	
	pregnant women	☐	children	☐	elderly	☐
	fetus	☐	illiterate	☐	handicapped	☐
	terminally ill	☐	seriously ill	☐	mentally challenged	☐
	economically & socially backward	☐	any other	☐		
vii.	Special group subjects (Tick the appropriate boxes)	Yes	☐	No	☐	
	captives	☐	institutionalized	☐	employees	☐
	students	☐	nurses/dependent	☐	armed	☐
	any other	☐	staff	☐	forces	☐

6. Privacy and confidentiality

i.	Study involves -	Direct Identifiers	☐
		Indirect Identifiers/coded	☐
		Completely anonymised/ delinked	☐
ii.	Confidential handling of data by staff	Yes	No

7. Use of biological/ hazardous materials

i.	Use of fetal tissue or abortus	Yes	No
ii.	Use of organs or body fluids	Yes	No
iii.	Use of recombinant/gene therapy	Yes	No
	If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iv.	Use of pre-existing/stored/left over samples	Yes	No
v.	Collection for banking/future research	Yes	No
vi.	Use of ionizing radiation/radioisotopes	Yes	No
	If yes,has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii.	Use of Infectious/ bio hazardous specimens	Yes	No
viii.	Proper disposal of material	Yes	No
ix.	Will any sample collected from the patients be sent abroad ?	Yes	No
If Yes, justify with details of collaborators			
	a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriate box):

- Facility not available in India ☐
- Facility in India inaccessible ☐
- Facility available but not being accessed. ☐

If so, reasons…

8. Consent : *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization eg. genetic basis for drug development	☐
Compensation for study related injury	☐		

*If written consent is not obtained, give reasons: -

- - - -- - - - - -- - - -- - - - - - -- - - - -- - - - -- - -- - - - - - - - -- - - - - - - -- - - - -- - - - -- - -- -- - - - -

ii. Who will obtain consent ? PI/Co-PI ☐ Research staff ☐ Nurse/Counsellor ☐ Any other ☐

9. Will any advertising be done for recruitment of Subjects ? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No

Iii.Is there a benefit a) to the subject ?

Direct ☐ Indirect ☐

b) Benefit to society ☐

11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No

ii. **Is there a plan for reporting of adverse events** ? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long ?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by Insurance ☐ by any other company ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify**	Yes	No

Checklist for attached documents:

1. Project proposal (IRB form) – in 10 Copies[#] ☐
2. Curriculum Vitae of all the Investigators ☐
3. Brief description of proposal ☐
4. Patient information sheet * in vernacular language & in English ☐
5. Informed Consent form ** in vernacular language & in English ☐
6. Investigator's brochure for recruiting subjects ☐
7. Copy of advertisements / Information brochures, if any. ☐
8. Copy of clinical trial protocol and / or questionnaire ☐
9. Case Record Form ☐
10. Attendance sheet of departmental scientific meeting. ☐
11. If any HMSC/DCGI/DBT/BARC clearance if obtained ☐
12. Investigator's undertaking ☐
13. Copy of Insurence Policy obtained for the present research work ☐
14. Agreements between PI and Sponsor ☐

[#] Submit one soft copy of above check listed documents to irb_gmcb@yahoo.com with copy to cbrtripathi@yahoo.co.in

* Dardi Mahiti Patrak ** Dardi Sahmati Patrak

Note: 1) Everytime as per the sugessions from the respected IRB members, we update the IRB proforma. So, ask your younger collegues, collegues and other staff members to use the updated proposal form and procure it from Dept. Of Pharmacology, Govt. Medical College, Bhavngar for submission for next IRB meeting.

2) Please maintain one copy of all your IRB documents for your reference.

Date: Name, Signature & Designation of PI

FOR FURTHER COMMUNICATION AND SUBMISSION OF FILLED IN FORM KINDLY CONTACT:
Secretary IRB, Prof. & Head, Department of Pharmacology

Investigator's declaration

Department of _____,

Government Medical College & Sir Takhatsinhji General Hospital Bhavnagar-364001

For the research proposal entitled (In Times New Roman fonts, size: 12, capital letters**)**

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1. We certify that, we have determined that the proposal herein is not unnecessarily duplicative of previously reported research.
2. We certify that, we are qualified and have enough experience to do such a study /and do the study under guidance of my P.G. guide .
3. For procedures listed under proposal, we certify that we have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress to the patient.
4. We certified that, study will be initiated only upon review and approval of scientific intent by IRB, Govt. Medical College, Bhavnagar and getting a certificate from IRB.
5. We will do necessary changes in our study protocol as per the suggestions given by respected IRB members during meeting before getting approval letter and bound to submit the changes to IRB. We will obtain approval from the IRB, Govt. Medical College, Bhavnagar, before making any significant changes in this study. Institutional Bio safety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents of human pathogens).
6. We will do our study according to ICH-GCP guidelines and maintain all the study related records. Whenever asked, we are bound to produce to IRB, Govt. Medical College, Bhavnagar.
7. We will report adverse drug reaction to Pharmacovigilance cell and IRB whenever, we come across the adverse drug reaction while doing research work. (If applicable)
8. We certify that, we will follow the recommendations of IRB and Govt. of Gujarat rules and regulation issued from time to time.
9. We certify that, record of all premature termination of a study with a summary of the reasons / final report after completion of the study including microfilms, CDs and Video recordings, will submit to the IRB, Govt. Medical College, Bhavnagar.
10. At the time of submission of dissertation to Bhavnagar University, Bhavnagar, we will also submit (If applicable- for PG students only) our work to any indexed journal and as a proof copy will be submitted to the IRB office, Dept. of Pharmacology, Govt. Medical College, Bhavnagar.
11. We will also submit the detailed summary of our work in two copies to IRB office after completing the work.

Signature & Name of

1. ----------	2. ----------	3. ----------
_____	_____	_____
Principal Investigator Dept. of _____	P.G. Guide Dept. of _____ (If applicable)	Professor and Head, Dept. of _____ (If applicable)

Date: . . . . . .

Place: Bhavnagar - 364001

FORMAT FOR COMMUNICATION TO THE PRINCIPAL INVESTIGATOR BY THE MEMBER SECRETARY, INTITUTIONAL REVIEW BOARD

Institutional Review Board (Human Ethics Committee)

સરકારી તબીબી મહાવિદ્યાલય, ભાવનગર Govt. Medical College, Bhavnagar-364001

એસ.ટી સ્ટેન્ડ પાછળ ,જેલ રોડ ,ભાવનગર - ૩૬૪૦૦૧) ગુજરાત,(

Behind S.T. Stand, Jail Road, Bhavnagar 364001 (Gujarat) India.
Phone no (0278) 2430808 Web site: www.bvnmedicol.org Fax no.(0278) 2422011

No. Pharma / GMCB /… IRB (HEC) Meeting / . . . . . / 2010

For Office Use:
IRB (HEC) no._____.
Subject no. _____
Government Medical College,
Bhavnagar-364001(Gujarat).
Date:

Department of Pharmacology,
Government Medical College,
Bhavnagar -364001(Gujarat).
Date:

To,
Dr._____
_____
Department of _____
Government Medical College,
&
Sir Takhtsinghji General Hospital,
Bhavnagar- 364001. (Gujarat), India.

Dear Dr. _____

The Institutional Review Board of Government Medical College, Bhavnagar has reviewed and discussed your application dated_____to conduct the research work entitled "_____" on _____.

Following documents were reviewed:

1. **IRB (IEC) filled up form.**
2. **Principal Investigator and Co-investigator's current Curriculum Vitae (CV).**
3. **Brief description of Proposal.**
4. **Patient / Volunteer's information sheet in vernacular language and English.**
5. **Informed consent form in vernacular language and English.**
6. **Pre - tested questioners. (Not applicable).**

The following members of the ethics committee were present in the meeting held on

Day & Date : _____
Time : _____
Place : Dean Office, Government Medical College, Bhavnagar, Gujarat.

1. **Dr. V.H. Bhavsar, M.D. Pharmacology,**
   Chairman, Institutional Review Board, Senior Professor & Head Department of Pharmacology, College of Medical sciences & K.J. Mehta General Hospital, Jithari, Amargarh,
2. **Dr. B.D. Parmar, M.D. Medicine,**
   Co-chairman, Institutional Review Board, Dean, Government Medical College, Bhavnagar.
3. **Dr. M.P. Singh, M.D., Preventive & Social Medicine.**
   Member of the Institutional Review Board. Medical Superintendent, Professor & Head, Department of PSM, Sir T. General Hospital, Government Medical College, Bhavnagar.
4. **Mr. Navinbhai Rajyaguru, L. L.B.,**
   Member, Institutional Review Board, **Advocate & Socially active member**.
5. **Dr. P.R. Jha, M.D. Medicine**
   Member, Institutional Review Board. **(Clinician)**. Professor and Head, Department of Medicine, Government Medical College & Sir T. General Hospital, Bhavnagar-364001.
6. **Dr.Bharat Panchal, M.D. Psychiatry-** leave of absence
   Member, Institutional Review Board. **(Philosopher)**. Professor and Head, Department of Psychiatry, Government Medical College & Sir T. General Hospital, Bhavnagar- 364001.
7. **Dr. H.B. Mehta, M.D. Physiology**
   Member, Institutional Review Board. (**Scientist from Institution**). Professor and Head, Department of Physiology, Government Medical College, Bhavnagar- 364001.
8. **Dr. Pramila Jha, M.D. Anesthesiology-**
   Member, Institutional Review Board, Associate Professor, Department of Anesthesiology, Government Medical College & Sir T. General Hospital, Bhavnagar-364001
9. **Mr. Manbhabhai Mori,**
   Member, Institutional Review Board, Member from the Society, Bhavnagar Seva Sadan, Bhavnagar.
10. **Dr. C. B. Tripathi, M.D. Pharmacology,**
    Member Secretary, Institutional Review Board **(Pharmacologist)**. Professor and Head, Department of Pharmacology and Dean, Faculty of Medicine, Government Medical College and Bhavnagar University, Bhavnagar – 364001. (M): 9825951678, e-mail: cbrtripathi@yahoo.co.in

We approve the above mentioned study in the present form to be conducted by
Principal Investigator - Dr_____
Co – Investigator - Dr. _____

The IRB (IEC) reference number for future correspondence is IRB (HEC) no. _____Subject no._____, Dated: _____.

The Institutional Review Board expects to be informed about the progress of the study, any changes in the protocol and pre tested questioners (if applicable) and receive copy of the final report in duplicate.

Yours Sincerely

Member Secretary,
Institutional Review Board,
Government Medical College,
Bhavnagar-364001(Gujarat).

INTIMATION OF START OF STUDY

1. Project Trial Code Number:

2. Title of study/ trial:

3. Principal Investigator (Name & Department):

4. Sponsor:

5. Date of approval from IRB:

6. Date of start of study:

Date:

Name & Signature of PI	Name & Signature of Guide (If applicable)	Name &Signature of Head of the Department

PROGRESS REPORT (Annual)/FINAL REPORT

1. Project IRB no.

2. Title of project

3. Principal Investigator(PI) (Name and Department)

4. Sponsor

5. Date of approval form IRB

6. Date of start

7. Objectives of the study

8. Progress report as per objectives(in separate page)

9. Serious Adverse Event if any with details

10. Protocol deviation if any with reasons justification

11. Report publication conference presentation

12. Awards (if any)

Date:

Name & Signature of PI	**Name & Signature of Guide (If applicable)**	**Name &Signature of Head of the Department**

GUIDELINES FOR PATIENT INFORMATION SHEET

Potential recruits to your research/trial study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate, and preferably in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

1. **Study Title**
   Is the title self explanatory to a lay person? If not, an additional simplified title may also be included.

2. **Invitation Paragraph**
   You should explain that the patient is being asked to take part in a research/trial study. The following is an example:

   "You are being invited to take part in a research trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clew- or if you would like more information. Take time to decide whether or not you wish to take part.

3. **What is the purpose of the study?**
   The background and aim of the study should be given here.

4. **Why have I been chosen?**
   You should explain how and why the patient was chosen and how many other patients will be studied.

5. **Do I have to take part?**
   You should explain that taking part in the research/trial is entirely voluntary. You could use the following paragraph:-
   "It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be puked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

6. **What will happen to me if I take part?**
   You should say how long the patient will be involved in the research/trial, how long the research/trial trial will last (if this is different), how often they will need to visit the hospital or a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit the doctor (or clinic) more often than for usual treatment and if travel expense are available. What are the patient's responsibilities set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 8.00 am without

having eaten anything/on empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to use - the following simple definitions may help:-

Randomized Trial: Sometimes. because we do not know which way of treating patients is best. we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer. which has no intimation about the individual -- by chance. Patients in each group then have a different treatment and these are compared. This way. the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the patients what chance they have of getting the study drug treatment: e.g. a one in four chance.

Blind trial: In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you not your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result form knowing which group you are in, which can adversely affect the results.

Cross-over Trial: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.

Placebo: A placebo is a dummy treatment such as a pill. which looks like the real thing but is not. It contains no active drug. chemical or ingredient.

7. What do 1 have to do?

Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions. Can the patient drive? Drink? Take pail in sport? Can the patient continue b take his/her regular medication? Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if appropriate) that the patient should take the medication regularly.

8. What is the drug or procedure that is being tested?

You should include a short description of the drug or device and give the stage of Development. You should also state the dosage of the drug and method of administration. Patients entered into drug trials should preferably be given a card /(similar to an identity-card) with details of the trial they are in. They should be asked to carry it at all times.

9. What are the alternatives for diagnosis or treatment?

For therapeutic research trial the patient should be told what other treatment options are available.

10. What a v the side effects of taking part?

For any new drug or procedure von should explain to the patients the possible side effects. II

they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side Meets should be listed in kilns the patient will clearly understand *(e.g* ‘damage to the heart' rather than 'cardiotoxicity% 'abnormalities of liver tests' rather than 'raised liver enzymes·). For any relatively new drug it should be explained that them may be unknown side effects.

11. What are the possible disadvantages and risks of taking part?

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, the following (or similar) should be said:

"It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for man if the treatment could damage sperm which might therefore lead to a risk of foetal damage.

If' future insurance status. e.g. for life insurance or private medical insurance, could be affected by taking part this should he stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with the company before agreeing to take pan in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should clearly state what will happen if you detect or find a condition of which the patient was unaware. It is treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure? HIV status)?

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the patient from taking part in the trial this should he stated clearly.

It is important not to exaggerate the possible benefits to the patient during the course of the study. e.g. saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

"We hope that both (all) the treatments will help you. However, this cannot he guaranteed. The

information we get from this study may help us to treat future patients with (name of condition) better".

13. What if new information becomes available?

If additional information becomes available during the course of the research/trial you will need to tell the patient about this. You could use the following:

'Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens. your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form.

Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you form the study. He/she will explain the reason and arrange for your care to continue."

14. What happens when the research/trial study stops?

If the treatment will not be available alter the research trial finishes this should be explained to the patient. You should also explain to them what treatment will be available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the patient.

15. What if something goes wrong?

You should inform patients how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of stall (doctors. nurses *etc)* and something serious happening during or following their participation in the trial. i.e. a reportable serious adverse event.

16. Will my taking part in this study he kept confidential?

You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research/trial is:

"If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"

"All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory w ill have your name and address removed so that you cannot be recognized from it."

17. What will happen to the results of the research/trial study?

You should be able to tell the patients what will happen to the results of the research/trial. You might add that they will not be identified in any report/publication.

18. Who is organizing and funding the research/trial?

The answer should include the organization or company sponsoring or funding the research/trial (e.g. (Govt. agency. pharmaceutical company. NGO, academic institution).The patient should be told whether the doctor conducting the research/trial is being paid for including and looking after the patient in the study. This means payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the casts of a research nurse.

19. Who has reviewed the Study?

You may wish to mention that IEC has reviewed and approved the study' (you should not however list the members of the Committee)

20. Contact for further information

You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **(Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers)**

Remember to thank your patient for taking part in the study. The patient information sheet should be dated and given a version number. The Patient Information Sheet should state that the patient will be given a copy of the information sheet and the signed consent form.

Date **Signature of PI**

ડિપાર્ટમેન્ટ ઓફ .....,

સરકારી મેડિકલ કોલેજ, ભાવનગર.

દર્દી માહિતી પત્રક નો નમુનો (Model Patient Information Sheet)

અભ્યાસ વિગત :- ડીપ્રેશનના દર્દીઓમા હળદરના સત્વની અસરની ફ્લુઓક્સેટીન નામની દવા સાથે સરખામણી કરવી તેમજ ઉપરોકત બન્ને દવાની એકસાથે થતી અસરનો અભ્યાસ કરવો.

પ્રિય દર્દી,

પ્રસ્તાવના :-

તબીબે તમને આ અભ્યાસ માં ભાગ લેવાનુ કહ્યુ કારણકે તમને ડીપ્રેશન છે. આ બીમારીમા બાયોકુર્કુમેક્ષ(હળદરમાથી બનાવેલ દવા)થી સુધારો થતો હોવાનુ સાબિત થયેલ છે તેમજ આ દવાની આડઅસર પણ ઓછી છે.

દવાઓ વિશે મહિતી:-

ફ્લુઓક્સેટીન નામની દવા ડીપ્રેશનમા વપરાતી જુની દવા છે. જ્યારે બાયોકુર્કુમેક્ષ નવી દવા છે જેનાથી ડીપ્રેશનની બીમારીમા સુધારો થતો હોવાનુ અભ્યાસમા માલૂમ પડ્યુ છે.

તબીબી અભ્યાસ પદ્ધતિ :-

આ અભ્યાસમાં કુલ ૫૪ દર્દીઓ ને સામેલ કરવામાં આવશે કે જેમને ડીપ્રેશનની બીમારી હશે.તમે આ અભ્યાસ માં ભાગ લઇ શક્શો કે નહિ તે પ્રાથમિક તબીબી તપાસ અને લેબોરેટોરી તપાસ થી નક્કી થશે.જે દર્દીઓ આ અભ્યાસ માં ભાગ લેવા સક્ષમ છે એવુ જણાશે તે દર્દીઓ ને ત્યાર બાદ ત્રણવિભાગમાં આડીઅવળી રીતે વહેંચી દેવામાં આવશે.જેમાંથી પહેલા વિભાગ ના દર્દીઓને ફ્લુઓક્સેટીન નામની દવા આપવામા આવશે, બીજા વિભાગ ના દર્દીઓને હળદરમાથી બનાવેલ દવા આપવામાં આવશે અને ત્રીજા વિભાગના દર્દીઓને ઉપરોક્ત બન્ને દવા એકસાથે આપવામા આવશે જે તેમને તબીબે સમજાવેલ સમયાનુસાર છ અઠવાડીઆ સુધી લેવાની રહેશે. આ અભ્યાસ દરમિયાન દર્દી દાક્તરની રજા સિવાય કોઈ વધારાની દવા લઈ શકશે નહી.

અભ્યાસ માં ભાગ લીધેલ વ્યક્તિ માટે દવા ની માત્રા :-

પહેલા વિભાગ ના દર્દીઓને ફ્લુઓક્સેટીન નામની દવા ૨૦ મિલીગ્રામ દિવસમા એકવાર લેવાની રહેશે, બીજા વિભાગ ના દર્દીઓને બાયોકુર્કુમેક્ષ દવા ૫૦૦ મિલીગ્રામ દિવસમા બે વાર લેવાની રહેશે જ્યારે ત્રીજા વિભાગના દર્દીઓને ઉપરોક્ત બન્ને દવા એક સાથે ઉપરોક્ત માત્રામા લેવાની રહેશે.

અન્ય દવા :-

આ અભ્યાસ દરમિયાન દર્દી દાક્તરની રજા સિવાય કોઈ વધારાની દવા લઈ શકશે નહી.આ તબક્કા દરમ્યાન અભ્યાસમાં અપાતી દવા સિવાયની કોઇ અન્ય દવા લેવાની તમારે જરૂર હશે તો તમને અભ્યાસ માં ચાલુ રાખવા કે નહિ તે નક્કી કરવાનો હક્ક એના પ્રમુખ સંશોધક પાસે રહેશે.

બચાવ સારવાર :-

ઉપરોક્ત દવાથી દર્દીની તકલીફમા જો સુધારો નહી જણાય તો દર્દીને રાબેતા મુજબની ડીપ્રેશનની સારવાર આપવામા આવશે.

છુટા થવા બાબતે :-

તમે અભ્યાસમાં સ્વૈચ્છિક રીતે ભાગ લઇ રહ્યા છો માટે તમે અભ્યાસ દરમ્યાન ગમે ત્યારે છુટા થવા ઇચ્છતા હોય ત્યારે છુટા થઇ શકો છો.જેની તમારી તબીબી સારવાર પર કોઇ અસર થશે નહિ અને તમારા તબીબ તમને વૈકલ્પિક ઉપચાર પુરો પાડશે.જયારે તબીબ ને જાણ થશે કે ઉપરોક્ત સારવાર તમારા માટે ફાયદાકારક નથી અથવા તમે તેમણે આપેલા સુચન અનુસાર અભ્યાસ ની પદ્ધતિનું પાલન નથી કરી રહ્યા તો તબીબ તમને અભ્યાસ માંથી છુટા કરી શકશે.ઉપરોક્ત કોઇ પણ સંજોગો અનુસાર તમારી તબીબી સારવાર પર કોઇ અસર થશે નહિ અને તમારા તબીબ તમને વૈકલ્પિક ઉપચાર પુરો પાડતા રહેશે.

નવી તત્કાળ માહિતી :-

તમારા અભ્યાસ માં ભાગ લેવા ની સાથે સંકળાયેલી નવી મહિતી જાણવા મળશે તો તેની તમને તુરંત જાણ કરવામાં આવશે.

અભ્યાસ દરમ્યાન તમારી જવાબદારીઓ :-

તમારે તબીબના સુચનોનું પાલન કરવાનુ રહેશે અને તમને જણાવ્યા અનુસાર દવા લેવાની રહેશે.તમારે અભ્યાસ દરમ્યાન તમને અનુભવાતી કોઇપણ પ્રકારની અસુવિધા કે ખરાબ અનુભવ તબીબને જણાવવાનાં રહેશે.જો તમે સ્ત્રી દર્દી હોવ તો તમારે અભ્યાસ દરમ્યાન કે અભ્યાસ પુર્ણ થયા ના ૩૦ દિવસ દરમ્યાન ગર્ભ ધારણ કરવો નહિ.

નવી માહિતી ના ઉપયોગ બાબત :-

આ અભ્યાસ દ્વારા જે પરિણામ મળશે તેનો ઉપયોગ નવી મહિતી તરીકે છાપવા કે વૈજ્ઞાનીક શોધો ને લગતી સભાઓમાં દર્શાવા માટે થશે.

જો તમને તમારી સારવાર ને લગતો કોઇપણ પ્રશ્ન હોય તો તમે કોઇપણ સમયે તમારા તબીબ નો સમ્પર્ક સાધી શકો છો.તમે જ્યારે અભ્યાસ માં ભાગ લઇ રહ્યા હશો અ દરમ્યાન તમારા સ્વાથ્યને લગતી કોઇપણ નવી માહિતી તમારા તબીબને મળશે તો તેઓ તમને તેની જાણ કરશે.

Department of _____,
Government Medical College & Sir Takhatsinhji General Hospital Bhavnagar-364001

MODEL INFORMED CONSENT FORM IN ENGLISH

Study Title:
Study Number:
Subject's Initials: _____ Subject's Name:_____
Date of Birth / Age: _____

Please do initial in box (Subject)

(i) I confirm that I have read and understood the information sheet dated ___ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the 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 it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) 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 purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____ Date: _____/_____/_____

Study Investigator's Name: _____

Signature of the Witness _____ Date:_____/_____/_____

Name of the Witness: _____

ડિપાર્ટમેન્ટ ઓફ .....,

સરકારી મેડિકલ કોલેજ, ભાવનગર.

દર્દી સંમતી પત્રક નો નમુનો (Model Informed Consent Form)

અભ્યાસ વિગત :- _____

સહભાગીનું ટુકાક્ષરી નામ _____ સહભાગીનું નામ:_____

જન્મ તારીખ: __/__/_____ /અથવા ઉંમર:___

કૃપા કરી બોક્સમાં ટૂંકી સહી કરો (સહભાગી)

(૧) હું બહાલ રાખું છું કે મેં ઉપરોક્ત અભ્યાસ માટે તારીખ_____ નો કાગળ વાંચ્યો અને સમજ્યો છે અને પ્રશ્નો પૂછવાની તક મને મળી હતી. [ ]

(૨) હું સમજું છું કે અભ્યાસ માં મારો સહભાગ મરજીયાત છે અને કે મારી તબીબી સંભાળ અથવા કાયદેસર હકોને અસર પહોંચ્યા વગર, કંઈપણ કારણ આપ્યા વગર, કોઈપણ સમયે ખસી જવા હું મુક્ત છું. [ ]

(૩) હું સમજું છું કે ચિકિત્સાલક્ષી અજમાયશનાં પ્રાયોજક ની વતી કાર્ય કરતા અન્યો, નિતિમત્તા સમિતિ અને નિયમનકર્તા સત્તાવાળાઓને, હું અજમાયશમાંથી ખસી જાઉં તેમ છતાં વર્તામાન અભ્યાસ અને તેની સાથેના સંબંધમાં જેનું સંચાલન કરવામાં આવે તેવા કોઈપણ વધુ સંશોધન, બંનેની બાબતમાં મારા આરોગ્યનાં રેકોર્ડ જોવા માટે મારી પરવાનગી જોઈશે નહિં. આ પહોંચ અંગે હું સંમત થાઉં છું. તેમ છતાં, હું સમજું છું કે મારી ઓળખ ત્રીજા પક્ષો માટે મુક્ત કરાયેલી અથવા પ્રસિધ્ધ કરાયેલી કોઈપણ માહિતીમાં જાહેર કરવામાં આવશે નહિં. [ ]

(૪) હું સંમત થાઉં છું કે આ અભ્યાસ માંથી જે ઉપસ્થિત થાય તેવાં કોઈપણ પરિણામોના ઉપયોગ પર, જો તેવો ઉપયોગ ફક્ત વૈજ્ઞાનિક હેતુ માટે હોય, તો તે નિયંત્રણ કરીશ નહિં. [ ]

(૫) હું ઉપરનાં અભ્યાસ માં ભાગ લેવા સંમત થાઉં છું. [ ]

સહભાગીની સહી (અથવા અંગુઠાનું નિશાન): તારીખ:_____

સહીકર્તાનું નામ:_____

સહભાગીના કાયદેસર સ્વીકાર્ય પ્રતિનિધિ ની સહી:

_____ તારીખ:____ _____

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1. Name (Dr./Kum/Smt./Shri):

First name Surname

2. Designation:

3. **Complete Postal Addresses & PIN:**

Address :

Telephone Number : (O)
(R)
(M)

Fax :

E-mail :

4. Date of birth:

5. Educational Qualification: Degrees obtained (Begin with Bachelor's Degree)

Degree	Institution	Field(s)Year

Date of Internship completion :

Registration number with date U.G.
P.G. (If applicable)

Registration no. of PG at University: (If applicable)

6. Research/Training Experience

Duration	Institution	Particulars of work done

7. Life membership of Subjects professional bodies:

8. Research specialization (major scientific fields of interest)

9. Recent publications (last 5 years, with: titles and references), also Papers in press:

Books :

Research: 1)

2)

10. Financial support received:

a) From the Ministry of Health & Family Welfare
Past
Present
Pending

b) From other organizations
Past
Present
Pending

Signature and Date

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