To,

From,
Dr. AKSAHY PATEL
1st Year Resident
Department of Radio-diagnosis Parul Institute of Medical Sciences & Research (PIMSR), Limda.
E Mail: akshaynpatel780@gamil.com
Mobile No: 8758099400
Date:06/04/2024

Parul University Institutional Ethics Committee for Human Research (PUIECHR), Parul Institute of Medical Sciences & Research (PIMSR).
Limda, Gujarat, India.

Subject: Application for getting permission to carry out research work as a M.D.(Radio-diagnosis) PG Resident

Sir/Madam,

I, undersigned **Dr. Akshay Patel,** currently working as a 1st Year Resident in Department of Radio-diagnosis Faculty of Medicine under Parul Institute of Medical Sciences & Research (PIMSR). I am applying for M.D. Dissertation permission in the Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR), Limda. I want to carry out research study entitled **" DIAGNOSTIC ACCURACY OF CONTRAST ENHANCED FLAIR IN VARIOUS INTRACRANIAL PATHOLOGIES."** Under guidance of **Dr. Anil Rathva Sir**, Professor and Head Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR),

Limda.

I am submitting proposal for the study in the prescribed format along with necessary reference papers, and assurance letter from the guide. This Study will be conducted strictly as per the ethical guidelines with due consideration of prevention of plagiarism.

Thanking You,

Yours Sincerely,

Dr. Akshay Patel

Enclosures

1. Application Form
2. Assurance Letter of Guide
3. Study Protocol with Study Related Documents
4. Case Report Form, Patient Information Sheet & Informed Consent Form.
5. Permission of Dean, Parul Institute of Medical Sciences & Research (PIMSR) Limda.
6. Permission of Medical Superintendent, Parul Sevashram Hospital, Limda.
7. Minutes of Presentation at Department Meeting with Signed Attendance Sheet

Forwarded through Head of the Department

APPLICATIONFORM

Title of The Study	**"DIAGNOSTIC ACCURACY OF CONTRAST ENHANCED FLAIR IN VARIOUS INTRACRANIAL PATHOLOGIES"**
Name of The Student	**Dr. Akshay Patel** **M.B.B.S.**
PG Admission Month and Year Branch Name	**e.g. October2023** **M.D.(Radio-diagnosis)**
Name of the Guide & Department	**Dr. Anil Rathva** **Designation: -** **Professor and Head of Department of Radio diagnosis,** **Parul Institute of Medical Sciences & Research.**
Source of funding if any	**No**
Type of Study	**Cross sectional observational study**
Ethical Issues Involved In The Study	

	Invasive Procedure: no
ProposalEnclosedIn8Copies.	**Yes**
Whether Consent Forms In English & Vernacular Language is Enclosed.	**Yes**
Is this special research?	**Animal Experiment: No** **Clinical Trial: No** **Research on Patented Product: No** **Research on Herbal Extract: No**

Signature of the PG Resident:
Dr. Akshay Patel

Signature of the guide:
Dr. Anil Rathva

To,
The Dean,

From:
Dr. Akshay Patel
1st YearResident
Department of Radio-diagnosis
Parul Institute of Medical Sciences & Research(PIMSR)
Limda.
Date:06/04/2024

Parul Institute of Medical Sciences & Research (PIMSR), Limda, Gujarat, India.

Subject: **Application for getting permission to carry out research work as a M.D.(Radio-diagnosis) PG Student**

Respected Sir,

I, undersigned **Dr. Akshay Patel,** applying for study in the Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR.I want to carry out research study entitled **"DIAGNOSTIC ACCURACY OF CONTRAST ENHANCED FLAIR IN VARIOUS INTRACRANIAL PATHOLOGIES"** under guidance of **Dr. Anil Rathva** Professor and Head in Department of Radio diagnosis, Parul Institute of Medical Sciences & Research (PIMSR), Limda. Kindly give me permission to carry out above mentioned research work.

Thanking You,

Yours Sincerely,

Dr. Dr. Akshay Patel

To,
The Medical Superintendent,

From:
Dr. Akshay Patel
Department of Radio-diagnosis

Parul Institute of Medical Sciences & Research
(PIMSR) Limda.
Date: 06/ 04 /2024

PSH & Parul Institute of Medical Sciences
& Research (PIMSR), Limda, Gujarat, India.

Subject: **Application for getting permission to carry out research work as a M.D. (Radio-diagnosis) PG Resident**

Respected Sir/Madam,

I, undersigned **Dr. Akshay Patel** applying for study in the Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research. I want to carry out research study entitled **"DIAGNOSTIC ACCURACY OF CONTRAST ENHANCED FLAIR IN VARIOUS INTRACRANIAL PATHOLOGIES**" under guidance of **Dr. Anil Rathva** Professor and Head in Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR), Limda.

Kindly give me permission to carry out above mentioned research work.

Thanking You,

Yours Sincerely,

Dr. Akshay Patel

Date: 06/ 04 /2024

To,
Parul University Institutional Ethics Committee for
Human Research (PUIECHR), Parul Institute of

Medical Sciences & Research (PIMSR), Limda.

Subject: **Assurance for mentoring of Dr. Akshay Patel for M.D. Study in Department of Radio-diagnosis.**

Sir/Madam,

This is to inform you that the research work entitled "**DIAGNOSTIC ACCURACY OF CONTRAST ENHANCED FLAIR IN VARIOUS INTRACRANIAL PATHOLOGIES**" will be carried out by **Dr. Akshay Patel** in the Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR) Limda, under our guidance and observation.

We assure you in this regard that the work will be done strictly as per the ethical guidelines with due consideration of prevention of plagiarism.

Yours Truly,

Dr. Anil Rathva
Designation: -Professor
and Head of department
Department of Radio-diagnosis
Parul Institute of
Medical Sciences &
Research (PIMSR),
Limda

THESIS PROTOCOL SUBMISSION FORM

A. GENERAL INFORMATION

1. Name (in full):
DR. AKSHAY NAGINBHAI

2. Father's Name:
NAGINBHAI MANIBHAI PATEL

3. Correspondence Address:
Department of Radio-diagnosis
Parul Institute of Medical Sciences & Research (PIMSR), Limda

4. Permanent Address:
AT & POST: KESHARGANJ, TA: VADALI,
DIST: SABSARKANTHA, GUJARAT
PIN:383235
Mobile- 9825825780
E-mail- akshaynpatel780@gamil.com

Correspondence Address of the Institute:
Department of Radio-diagnosis, Parul Sevashram hospital
Parul Institute of Medical Sciences & Research (PIMSR), Limda

d) Information about Thesis Protocol

Title- DIAGNOSTIC ACCURACY OF CONTRAST ENHANCED FLAIR IN VARIOUS INTRACRANIAL PATHOLOGIES.

Area of Specialty- RADIODIAGNOSIS

Thesis Guide-

Dr. Anil Rathva
Designation: -Professor and Head of department
Department of Radio-diagnosis
Parul Institute of Medical Sciences & Research (PIMSR), Limda

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THESIS PROTOCOL

1.1 INTRODUCTION:

Magnetic Resonance Imaging (MRI) is a rather novel technique in the realm of diagnostic imaging. It is based on the electromagnetic activity of atomic nuclei when placed in a magnetic field to provide non-invasive, multiplanar, cross sectional depictions of healthy and diseased anatomy in exquisite detail.

In the wide taxonomy of sequences used in MRI, the essential sequences in the field of neuroradiology are T1W, T2W, Fluid Attenuation Inversion Recovery (FLAIR), Diffusion Weighted Imaging (DWI) and Susceptibility Weighted Imaging (SWI). In addition to these sequences contrast media are used in neuroimaging which are compounds of gadolinium, forming paramagnetic ion complexes which shorten the T1 or T2 relaxation times of tissues they accumulate in and result in increased signal intensity on T1-weighted images and reduced signal intensity on T2-weighted images.

Contrast enhanced T1W imaging is the preferred sequence at most institutions. FLAIR is essentially a T2W based imaging method with suppressed cerebrospinal fluid, it is also known to show mild T1-weighted contrast effects, resulting in perceivable enhancement. Intra and extra-axial lesions demonstrate contrast enhancement closely associated with the

specific disease processes occurring at the molecular level which is due to the disruption of the blood brain barrier (BBB) in intra-axial and due to their prolific vascular supply or due to the leakage across leaky vessels into the CSF spaces. Advantages of contrast-enhanced FLAIR over contrast enhanced T1W imaging are due to decreased enhancement of blood vessels and dural sinuses leading to decreased phase shift artefacts, nullification of CSF signals, better detection of edema and hence peritumoral edema.

This study targets at providing insights to the post contrast effects on T1W and FLAIR imaging and the understanding the efficacy of post contrast T1W and FLAIR imaging in the detection of intracranial pathologies following the administration of intravenous gadolinium contrast material. The study also aims at discussing the desired approach in the detection and characterization of lesions using these techniques with increased diagnostic confidence thus improving the overall patient outcome.

1.2 REVIEW OF LITERATURE:

- Gadolinium enhanced FLAIR sequences have been compared to contrast enhanced T1 sequences and post contrast FLAIR sequences have increased diagnostic value in leptomeningeal diseases and tumors.[1,2,3,4,5,6]

- Delayed post contrast FLAIR have increased accuracy in detection of meningeal carcinomatosis as compared to post contrast T1.[7]

- On CE-T1WI, it is easier to detect enhancing lesions surrounded by a hypointense edematous area. In addition, large Gadolinium accumulated lesion may not demonstrate enhancement on CE-FLAIR images because the signal-reducing T2 effects obscure the signal-enhancing T1 effects. Hence, for intraparenchymal tumors, CE-T1WI can be superior to CE-FLAIR imaging for detecting the breakdown of the BBB.[8]

- Post-operative changes in patients, who have undergone intracranial surgery, in the form of dural enhancement is seen better with post contrast FLAIR sequence.[9,10,11]

- Traumatic brain injury missed on routine non-contrast MR studies can be detected easily on post contrast FLAIR.[12]

- Cranial nerve lesions like facial nerve neuritis are better seen on post contrast FLAIR because there is no prominent enhancement of arteriovenous plexus

surrounding normal facial nerve which is seen in contrast enhanced T1 sequence.[13,14]

➢ Metastasis from tumors like breast cancer, lymphoma, lung cancer and prostate cancer to the dura can be detected with diagnostic efficiency similar to that of contrast enhanced T1WI (T1 weighted image).[15]

➢ CE- FLAIR and CE-T1WI have shown to complement each other in detection of intracranial tumors.[16]

➢ Traumatic meningeal injury is a novel imaging marker of traumatic brain injury, which appears as enhancement of the dura on post-contrast T2-weighted FLAIR images, and is likely associated with inflammation of the meninges. Dynamic Contrast Enhanced MRI provides a better discrimination of abnormally perfused regions.[17]

1.3 Aims and Objectives:

AIMS: To illustrate the diagnostic importance of CE-FLAIR imaging in various intracranial pathologic conditions.

OBJECTIVES:

1. To understand normal patterns of enhancement of intracranial structures on Contrast enhanced FLAIR.

2. To understand the differences in enhancement patterns between CE-FLAIR and CE-T1WI in various intracranial pathologies.

1.4 Material and methods:

Study Area: The study will be conducted in the Department of Radio-diagnosis, Parul Sevashram hospital, Parul Institute of Medical Sciences & Research (PIMSR), Limda
Study Population: All patients with plain and contrast MRI having findings suggestive of intracranial pathologies.

Study Design: The study is prospective. It is an Observational, Analytical type of study.

Sample Size:
The sample size was calculated on the basis of" SAMPLE SIZE CALCULATOR-THE SURVEY SYSTEM"
Total no of cases per month: 6
Duration of the enrolment: 12 months
Therefore, population under study (N) = 72
Considering
Confidence level: 95%
Z= 1.96 for 95% CI
Margin of error (c): 10%
Response distribution (P): 50%

Predicted sample size n = 96 by the following formula:
$n= (Z^2 X P (1-P))/c^2$

$n= (1.96^{2 X} 0.5 (1-0.5))/0.1^2$
= (3.8 X 0.5 X 0.5)/0.01
=3.8 x 0.25/0.01
=96
For finite population correction, n is adjusted.
n (adjusted)= (NX n)/(N+n)
= (72 x 96)/ (72+96)
= 6912/168
=41

Study Time Frame
Duration of study is from date of approval by ethic committee till 1 year.
The data will be collected from the MRI scans done in from date of approval by ethic committee till 1 year.

Inclusion criteria:
All patients with intracranial pathologies undergoing MRI brain with contrast.

Exclusion criteria:

1) Patients with renal failure
2) Patients with claustrophobia.
3) Patients with contraindications to undergo MRI.
4) Patients with allergy to gadolinium

Methodology
Prospective MR Imaging studies with gadolinium contrast will be performed with 1.5T MRI scanner GE healthcare (GE healthcare technologies, Chicago, Illinois).
The sequences included were,

T1

T2

FLAIR

DWI

ADC

SWI

T1-post contrast

FLAIR- post contrast

Statistical methods:
Study is prospective in nature. Collected data will be analyzed by student t test, chi-square test or/and others as applicable. Statistician's help will be taken for this purpose.

1.5 References:

1) Ercan N, Gultekin S, Celik H, Tali T, Oner Y, Erbas G. Diagnostic value of contrast-enhanced fluid-attenuated inversion recovery MR imaging of intracranial metastases. *Am J Neuroradiol* 2004; *25:* 761-765.
2) Goo H, Choi C. Post-contrast FLAIR MR imaging of the brain in children: normal and abnormal intracranial enhancement. Pediatric Radiology. 2003;33(12):843-849.
3) Griffiths P, Coley S, Romanowski C, Hodgson T, Wilkinson I. Contrast-enhanced fluid-attenuated inversion recovery imaging for leptomeningeal disease in children. *Am J Neuroradiol* 2003; *24:* 719-723.
4) Mathews V, Caldemeyer K, Lowe M, Greenspan S, Weber D, Ulmer J. Brain: Gadolinium-enhanced Fast Fluid-attenuated Inversion-Recovery MR Imaging. Radiology. 1999;211(1):257-263.

5) Splendiani A, Puglielli E, Amicis R, Necozione S, Masciocchi C, Gallucci M. Contrast-enhanced FLAIR in the early diagnosis of infectious meningitis. Neuroradiology. 2005;47(8):591-598.

6) Tsuchiya K, Katase S, Yoshino A, Hachiya J. FLAIR MR Imaging for Diagnosing Intracranial Meningeal Carcinomatosis. American Journal of Roentgenology. 2001;176(6):1585-1588.

7)Hirota T, Ishihara K, Akazawa K, Kubota T, Yamada K, Nishimura T. Delayed post-contrast fluid-attenuated inversion recovery image for depicting meningeal carcinomatosis. The British Journal of Radiology. 2004;77(918):528-531.

8) Melhem E, Bert R, Walker R. Usefulness of optimized gadolinium-enhanced fast fluid-attenuated inversion recovery MR imaging in revealing lesions of the brain. American Journal of Roentgenology. 1998;171(3):803-807.

9) Smirniotopoulos J, Murphy F, Rushing E, Rees J, Schroeder J. Patterns of Contrast Enhancement in the Brain and Meninges. RadioGraphics. 2007;27(2):525-551.
10) Elster A, DiPersio D. Cranial postoperative site: assessment with contrast-enhanced MR imaging. Radiology. 1990;174(1):93-98.
11) Sinclair A, Scoffings D. Imaging of the Post-operative Cranium. RadioGraphics. 2010;30(2):461-482.

12) Kim S, Park S, Ryoo I, Jung S, Yun T, Choi S et al. Contrast-Enhanced FLAIR (Fluid-Attenuated Inversion Recovery) for Evaluating Mild Traumatic Brain Injury. PLoS ONE. 2014;9(7):e102229.

13) Hong H, Yi B, Cha J, Park S, Kim D, Lee H et al. Enhancement pattern of the normal facial nerve at 3.0 T temporal MRI. The British Journal of Radiology. 2010;83(986):118-121.

14) Lim H, Lee J, Hyun D, Park J, Kim J, Lee H et al. MR Diagnosis of Facial Neuritis: Diagnostic Performance of Contrast-Enhanced 3D-FLAIR Technique Compared with Contrast-Enhanced 3D-T1-Fast-Field Echo with Fat Suppression. American Journal of Neuroradiology. 2011;33(4):779-783.

15) Tsuchiya K, Katase S, Yoshino A, Hachiya J. Pre- and postcontrast FLAIR MR imaging in the diagnosis of intracranial meningeal pathology. Radiat Med. 2000 Nov-Dec; 18(6):363-8.

16) Zhou ZR, Shen TZ, Chen XR, Peng WJ.Diagnostic value of contrast-enhanced fluid-attenuated inversion-recovery MRI for intracranial tumors in comparison with post-contrast T1W spin-echo MRI.Department of Diagnostic Radiology, Cancer Hospital, Fudan University, Shanghai 200032, China.

17) Castro M, Williford J, Cota M, MacLaren J, Dardzinski B, Latour L et al. Quantification of traumatic meningeal injury using dynamic contrast enhanced (DCE) fluid-attenuated inversion recovery (FLAIR) imaging. Medical Imaging 2016: Biomedical Applications in Molecular, Structural, and Functional Imaging. 2016;.

1.6 Study Proforma:

1. Case No :

2. UHID :

3. Date :

4. Name :

5. Age/Sex :

6. Clinical Symptoms/signs : Headache/giddiness/neurological deficits/vomiting/syncope/TIA/neck rigidity

7 Past history: Trauma/Diabetes/HTN/primary/others

8. Lab findings if any:

7. MRI Findings :

A. Location of the lesion:

1. Supratentorial/infratentorial
2. Intra-axial /extra-axial

B. Size of the lesion

C. T1

T2

FLAIR

DWI

ADC

SWI

T1C+

FLAIR C+

D. Vasogenic edema

E. Meningeal enhancement: Leptomeningeal/pachymeningeal

Uniform smooth/nodular

F. Midline shift

G. Hydrocephalus

H. Brainstem

I. Other associated findings:

J. Radiological diagnosis:

K. Histopathological findings:

PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

INFORMATION SHEET
INTRODUCTION:

I, **Dr. Akshay N Patel**, resident doctor in the Department of Radio-diagnosis, Parul Sevashram hospital, Parul Institute of Medical Sciences & Research (PIMSR), Limda working on my post-graduation dissertation titled **"DIAGNOSTIC ACCURACY OF CONTRAST ENHANCED FLAIR IN VARIOUS INTRACRANIAL PATHOLOGIES"**

I am going to give you information and invite you to be part of this research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them and get yourself clarified.

Purpose of the research: -
To determine the role of contrast enhanced FLAIR in various intracranial pathologies.

Type of Research Intervention:
MRI brain with contrast.

Procedures and Protocol:
MRI brain with contrast done for all the participants will be used for research purpose.

Voluntary Participation:
Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

Benefits
Personally you may be or may not be benefited in any way directly from the research. But by taking part in this research, you will be helping the scientific community to learn more about the **"DIAGNOSTIC ACCURACY OF CONTRAST ENHANCED FLAIR IN VARIOUS INTRACRANIAL PATHOLOGIES"** and increasing the definitive therapy and reducing the burden for other invasive and higher costly mode of imaging to the other population

Reimbursements
You won't be given any monetary incentives or gifts for being a part of this research.

Confidentiality
The information that we collect from this research project will be kept confidential. Information about the patient that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about the patient will have a number on it instead of your name.

Sharing the Results
The knowledge that we get from doing this research will be shared with you. Confidential information will not be shared. We will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Who to Contact
if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should contact Dr. Akshay N Patel (9825825780 / akshaynpatel780@gmail.com)

INFORMED CONSENT FORM (Parul University Institutional Ethics Committee for Human Research)

Subject identification number for this trial _____

Title of the Project: _____

_____

Name of the Principal Investigator _____ Tel. No._____

I have received the information sheet on the above study and have read and / or understood the written information.

I have been given the chance to discuss the study and ask questions.

I consent to take part in the study and I am aware that my participation is voluntary.

I understand that I may withdraw at any time without this affecting my future care.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible persons (ethics committee members / regulatory authorities). I give access to these individuals to have access to my records.

I understand I will receive a copy of the patient information sheet and the informed consent form.

☐

_____
Signature / Thumb Impression of subject

_____
_____
Printed name of the subject in capitals Date of signature

_____
Signature / Thumb Impression of legally

_____
Date of signature

10

<<The legally acceptable representative signature should be added if the subject is a minor or is unable to sign for themselves. The relationship between the subject and the legally acceptable representative should be stated. The impartial witness signature should be added if the subject / legally acceptable representative is unable to read or write and consent should be obtained in his presence.>>

_____

Printed name of legally acceptable representative in capitals

_____
Relationship of legally accepted representative to subject in capitals

_____ _____ ____
Signature of the person conducting the informed consent discussion Date of Signature

_____
Printed name of the person conducting the Informed consent discussion in capitals

_____ _____
Signature of impartial witness Date of signature

_____
Printed name of the impartial witness in capitals

PATIENT INFORMATION FORM
MRI

Name of the patient: _____ Date: _____
UHID No: _____ IP/OP Bed No: _____ Ref by Dr. _____
Age: _____ Sex: _____ Weight: _____ Contact No: _____
MR Imaging study to be done: _____
Clinical Information: _____
_____
_____
_____
Please mention any disease you have like HIGH BP, DIABETES, ASTHMA, etc. _____
Previous investigations: _____
Previous history: _____
_____
S. Creatinine: _____ Creatinine clearance: _____
Allergies, if any: _____
For female patients: Date of last LMP: _____ Are you pregnant or breast feeding: _____

Please indicate if you have any of the following:

Yes….. No….. Aneurysm clip(s)
Yes….. No….. Cardiac pacemaker
Yes….. No….. Electronic implant or device
Yes….. No….. Neurostimulation system
Yes….. No….. Internal electrodes or wires
Yes….. No….. Cochlear, otologic, or other ear implant
Yes….. No….. Insulin or other infusion pump
Yes….. No….. Implanted drug infusion device
Yes….. No….. Any type of prosthesis (eye, penile, etc.)
Yes….. No….. Eyelid spring or wire
Yes….. No….. Metallic stent, filter, or coil
Yes….. No….. Radiation seeds or implants
Yes….. No….. Medication patch (Nicotine, Nitroglycerine)
Yes….. No….. Any metallic implant, fragment or foreign bo
Yes….. No….. Wire mesh implant
Yes….. No….. Dentures or partial plates

Instructions for the Patient

1. Remove all jewellery (e.g., necklaces, pins, rings), all hair pins, bobby pins, barrettes, clips, etc.
2. Remove all dentures, false teeth, partial dental plates, eyeglasses / hearing aids.
3. Remove your watch, cell phone, credit and bank cards and all other cards with a magnetic strip.

4. Remove body piercing objects.

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

Name of Patient: Date:

Signature of patient/relative: Relationship to Patient:

Name of Radiologist: Signature of Radiologist:

Name of Nurse:

Signature of Nurse: Name of Technician:

Signature of Technician:

CONSENT FOR THE MRI EXAMINATION USING GADOLINIUM.

CONSENT FORM FOR MAGNETIC RESONANCE IMAGING USING GADOLINIUM

I understand that I am being given information about Gadolinium Based Magnetic Resonance Contrast Agents, their risks and alternatives to help me make an informed decision whether to voluntarily and freely undergo the procedure. It not only makes the identification of abnormalities more accurate, but may also provide additional information that might otherwise have gone undetected.

It is felt to be a safe contrast agent. On rare occasions, allergic-type reactions (usually minor, such as hives and itching) have occurred. A few more serious reactions (for example: drop in blood pressure or difficulty breathing) have also been reported.

People who have severe kidney disease, advanced liver disease or are on dialysis who are given a gadolinium based MR contrast agent may have a small risk of developing a disease called, Nephrogenic Systemic Fibrosis (NSF). Inform the technologist if you have been diagnosed as having one of these disorders.

The safety of its use in children less than two years of age, pregnant women, and nursing mothers has not yet been determined.

Our staff is available to answer any questions you may have regarding the use of gadolinium.

HAVING READ AND UNDERSTOOD THIS INFORMATION, I HEREBY FREELY GIVE MY CONSENT FOR THE MRI EXAMINATION USING GADOLINIUM.

Name of Patient:
Date:

Signature of patient/relative:
Relationship to Patient:

SIGNATURE OF CANDIDATE :

SIGNATURE OF GUIDE :

SIGNATURE OF HOD :

SIGNATURE OF HEAD OF INSTITUTION :

CONSENTFORM

(Parul University Institutional Ethics Committee for Human Research)

I ‘ ‘have been explained there search project and also my role in the same.

I have been explained that the information provided by me shall be kept confidential and will in no way influence my receiving services from hospital. I also understand that I can withdraw from the study at any point time of the interview.

I agree to participate in the above research project voluntarily.

Witness signature: (Signature/Thumb impression)

Name: Date:

Place:

We give one copy information sheet to our client (consent must be in local language)

सहमतिपत्र

(पारुल यूनिवर्सिटी इंस्टीट्यूशनल एथिक्स कमेटी फॉरह्यूमन रिसर्च)

मुझे_'_____'_को अनुसंधान परियोजना और उसमें मेरी भूमिका के बारे में भी समझाया गया है।

मुझे समझाया गया है कि मेरे द्वारा प्रदान की गई जानकारी गोपनीय रखी जाएगी और किसी भी तरह से अस्पताल से मेरी सेवाओं को प्रभावित नहीं करेगी। मैं यह भी समझता हूं कि मैं साक्षात्कार के किसी भी समय अध्ययनसे हट सकता हूं।

मैं उपरोक्त शोध परियोजना में स्वेच्छा से भाग लेने केलिए सहमत हूं।

गवाहकेहस्ताक्षर : (हस्ताक्षर/अंगूठेकानिशान)

नामतारीख :

जगह :

हमअपनेग्राहककोसूचनापत्रकीएकप्रतिदेतेहैं (सहमतिस्थानीयभाषामेंहोनीचाहिए)

સંમતિ ફોર્મ

(પારુલ યુનિવર્સિટી ઇન્સ્ટિટ્યુશનલ એથિક્સ કમિટી ફોર હ્યુમન રિસર્ચ)

મને _____સંશોધન પ્રોજેક્ટ અને તેમાં મારી ભૂમિકા પણ સમજાવવામાં આવી છે.
મને સમજાવવામાં આવ્યું છે કે મારા દ્વારા આપવામાં આવેલી માહિતી ગોપનીય રાખવામાં આવશે અને તે કોઈ પણ રીતે હોસ્પિટલમાંથી મારી સેવાઓને પ્રભાવિત કરશે નહીં. હું એ પણ સમજું છું કે ઇન્ટરવ્યુના કોઈપણ સમયે હું અભ્યાસમાંથી ખસી શકું છું.
હું ઉપરના શોધ પ્રોજેક્ટમાં સ્વૈચ્છિક રીતે સહભાગી છું.

સાક્ષી હસ્તાક્ષર:
(સહી/અંગૂઠાની છાપ)

નામ:
તારીખ:

સ્થળ:

અમે અમારા ક્લાયન્ટને માહિતી શીટની એક નકલ આપીએ છીએ
(સ્થાનિક ભાષામાં સંમતિ હોવી જોઈએ)