Cerebral Palsy describes a group of disorders of the development of movement and posture, causing activity limitation that is attributed to non-progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of Cerebral Palsy are often accompanied by disturbances of sensation, cognition, communication, perception, and/or behaviour and/or by a seizure disorder. Indian research shows that the incidence of Cerebral Palsy is 2-2.5 cases per 1000 live births and over 40-60% of children with Cerebral Palsy have some visual problem in India. Various studies have documented vision impairment in children with Cerebral Palsy; especially that they are at a greater risk of reduced visual acuity, disorders of ocular posture, and significant refractive errors. Efficient visual functioning is very important for learning and development of children. In India, there is no scientifically developed framework to assess the visual functions in children with Cerebral Palsy. Therefore, this study would focus on assessing the visual functions in children with Cerebral Palsy.

Our team is trying to study the visual impairment in children with Cerebral Palsy. We would like to invite you to take part in this study and this brochure will give you the details about the additional investigations. Please read this brochure carefully and discuss with any member of our research team to clarify your doubts. If you agree to allow your child to take part in the study, we will perform a series
of visual tests like cycloplegic refraction and prescribe visual aid in the form of spectacles.

In children and young adults, the action of the muscles in the eye may be very strong and can hinder the proper evaluation of their refractive errors. Refraction for children less than 18 years is done using cycloplegic agents and this type of refraction is called Cycloplegic refraction.

**Benefits of cycloplegic refraction:**

It helps in dilating the pupil and arrests accommodation which hinders the evaluation of refractive error in the eye. Therefore, a cycloplegic refraction is a must for children and young adults especially with complaints of headache.

**What is done in cycloplegic refraction?**

Cycloplegic like Cyclopentolate Hcl a drops (0.5%) is instilled in the eyes with subsequent intervals of 5 minutes. Then patient is asked to sit with his eyes closed for half an hour. When the pupils become large (dilated), the static retinoscopy is done to obtain the total refractive error of the subject.

**The ocular effects of cycloplegics:**

- Difficulty in seeing bright light
- Irritation and watering
- Blurred vision
- Can increase Intra ocular pressure on instilling for glaucomatous patients.
The effect of cycloplegic drops may last for 24-48 hours, with sufficient recovery of accommodative amplitude in 6-12 hours.

**The systemic effects of cycloplegics:**

- Visual hallucinations
- Drowsiness
- Disorientation
- Restlessness

**Contraindication:**

The use of concentrations higher than two drops (0.5%) or one drop (1%) is not recommended in children with spastic paralysis or brain damage.

**Precaution:**

There might be difficulty in performing near work for 24 hours after cycloplegic refraction. All other reactions usually subside within 4 to 6 hours without permanent sequelae, after which the subject can resume back to daily routine.

If your candidate takes part, the participation may help to discover new diagnostic tests or new treatment options. This will help the researchers to learn and understand the visual impairment in children with Cerebral Palsy. There may not be any direct benefit to your candidate for taking part in this study however the results will help people in future. For this you need not pay anything and at the same time your refusal will not affect the future medical care of your candidate in
any way. If you no longer wish to continue you may withdraw at any stage from the study.

The data obtained will be kept confidential. This study is approved by the Scientific and Human Research Ethics Committees set out by Sri Ramachandra University, Chennai.
I have read this Information Brochure carefully / this form has been read to me. I understand the consequences involved in participation in this research study that are explained to me. I have had an opportunity to ask questions and I am satisfied with the answers I have been given.

I, mother/father/guardian of ____________________ (please write the name), hereby voluntarily consent to participate my (son/daughter) _______________ in the study on “Visual issues among children with Cerebral Palsy” as described in the Information Brochure. My child may undergo the series of visual tests and also would participate in the follow-up visit to ensure the benefit of the spectacle prescribed for daily activities. I wish to be contacted if findings are made that have implications for the child or my family.

In making my candidate participate I understand that:

- The data collected will remain confidential and will not be released within legal limit.
- There will be no cost, nor financial benefit to my candidate for participating in this study. If the data lead to the development of a commercial product in future we will not receive payment for this.
- I may at anytime withdraw my candidate from participating in this study. This will not affect future medical treatment.
Annexures

- I may be approached again to participate in future studies but I am under no compulsion to do so.
- My signature below acknowledges voluntary participation of my candidate in this study, but in no way releases the staff from their professional and ethical responsibility to me.
Refractive and Accommodative status among the children with Cerebral Palsy in three special schools of Chennai and the impact of the optical intervention on the visual acuity and accommodative response
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Refractive and Accommodative status among the children with Cerebral Palsy in three special schools of Chennai and the impact of the optical intervention on the visual acuity and accommodative response
PROFORMA (Children with CP)

S.NO:
NAME:
AGE:
SEX:

CEREBRAL PALSY CLASSIFICATION

➢ Motor abnormalities

1. Nature and typology of the motor disorder
   • Spastic
   • Dystonia
   • Athetosis
   • Ataxic

2. Functional motor abilities: limited motor functions in all the body areas oromotor speech functions

➢ Associated impairments

• Seizures
• Hearing/Vision impairments
• Attentional, behavioural
• Communicative & cognitive deficits
Anatomic and radiological findings

1. Parts of the body affected
   - Limbs
   - Trunk
   - Bulbar region

2. Radiological findings based on CT Scan & MRI
   1. Ventricular enlargement
   2. White matter loss
   3. Brain anomaly

4. Causation and timing
   Postnatal CEREBRAL PALSY
   - Meningitis
   - Head injury

LEVEL OF MOTOR ABILITY

- VERY MILD
- MILD
- MODERATE
- SEVERE
- UNCLASSIFIED
Annexures

**OCULAR DISORDERS**

- **STRABISMUS**
  - * EXO-
  - * ESO-

- **NYSTAGMUS**

**I VISIT**

**PAST GLASS PRESCRIPTION**

**DISTANCE:**

**OD:**

**OS:**

**NEAR:**

**OD:**

**OS:**

**SCREENING TEST:**

BCVA (Distance):

**OD:** with PH **OD:**

**OS:** **OS:**
Annexures

BCVA (Near):

OD:

OS:

Visual field test:

OD:

OS:

Eye movements (Saccades): PRESENT/ABSENT

DIAGNOSTIC TEST

STATIC RETINOSCOPY-

OD:

OS:

CYCLOPLEGIC RETINOSCOPY-

OD:

OS:

TREATMENT:

Prescription: OD:

OS:

II VISIT

PGP (Present glass prescription)

OD:

OS:
Annexures

BCVA (Distance)

OD:

OS:

BCVA (Near)

OD:

OS:

**DYNAMIC RETINOSCOPY (MEM METHOD)**

*OD:*

*OS:*

**TREATMENT:**

Change of Rx

- YES

If yes Rx-

- OD:

- OS:

- NO
Vision being one of the most important senses for the humans, undergoes many changes in the first months after birth. Infants have peripheral vision i.e., the ability to see to the sides and in the first weeks of life gradually develop the ability to focus on an object or point in front of them. At one month, a child would be able to focus briefly on objects up to three feet away. By two months, infants would be able to track moving objects, as their visual coordination and depth perception improves. By three months they would have the hand/arm control needed to reach the nearby moving objects. Distance vision continues to develop. Colour vision matures about the same rate as the other visual abilities in children. Most children are naturally somewhat farsighted (hyperopic) but can see well at other distances. More pronounced myopia (nearsightedness) and astigmatism are thought to be inherited. Refractive error is one of the most common causes of visual impairment around the world and the second leading cause of treatable blindness. Limited population-based refractive status data are available from India, these data are inadequate for planning cost-effective interventions in India. Therefore our study is designed to assess the age- and sex-specific normative data for visual functions in our country which would not only help us to learn about the visual development in children with special needs but also to manage effectively with appropriate visual devices. We would like to invite you to take part in this study and this brochure will give you the details about the additional investigations. Please read this
brochure carefully and discuss with any member of our research team to clarify your doubts. If you agree to allow your child to take part in the study, we will perform a series of visual tests like cycloplegic refraction and prescribe visual aid in the form of spectacles. In children and young adults, the action of the muscles in the eye may be very strong and can hinder the proper evaluation of their refractive errors. Refraction for children less than 18 years is done using cycloplegic agents and this type of refraction is called Cycloplegic refraction.

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• Visual hallucinations

• Drowsiness

• Disorientation

• Restlessness

Contraindication:

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Precaution:

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CONSENT FOR RESEARCH (PARTICIPANT COPY)

I have read this Information Brochure carefully / this form has been read to me. I understand the consequences involved in participation in this research study that are explained to me. I have had an opportunity to ask questions and I am satisfied with the answers I have been given.

I, mother/father/guardian of ____________________ (please write the name) hereby voluntarily consent to participate my (son/daughter) _____________ in the study on “Visual functions in normal children- normative data analysis in hospital based population” as described in the Information Brochure. My child may undergo the series of visual tests and also would participate in the follow-up visit to ensure the benefit of the spectacle prescribed for daily activities. I wish to be contacted if findings are made that have implications for the child or my family.

In making my candidate participate I understand that:

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My signature below acknowledges voluntary participation of my candidate in this study, but in no way releases the staff from their professional and ethical responsibility to me.

I have read this consent form (or it has been read to me) and I fully understand the contents of this document and voluntarily consent to participate in the study. All of my questions concerning this study have been answered. If I have any questions in the future about this study they will be answered by the investigators listed below. I understand that this consent ends at the conclusion of the study.

Contact address with phone number:

Ms JayaRajini Vasanth
Assistant Professor in Optometry
Department of Ophthalmology
Sri Ramachandra University
Mobile no: 9884452651
Annexures

By signing this form, I agree to participate in this study. A copy of this form has been given to me.

Date: 

Name: 

Participant signature

Thumb impression

Witness name

Witness signature

Certification of Informed Consent

I certify that I have explained the nature and purpose of this study to the above named individual, and I have discussed the potential benefits of this study participation. The questions the individual had about this study have been answered, and we will always be available to address future questions.

Date: 

Name: 

Signature of person obtaining 

Signature of PI
CONSENT FOR RESEARCH (STUDY COPY)

I have read this Information Brochure carefully / this form has been read to me. I understand the consequences involved in participation in this research study that are explained to me. I have had an opportunity to ask questions and I am satisfied with the answers I have been given.

I, mother/father/guardian of ____________________ (please write the name) hereby voluntarily consent to participate my (son/daughter) _____________ in the study on “Visual functions in normal children- normative data analysis in hospital based population” as described in the Information Brochure. My child may undergo the series of visual tests and also would participate in the follow-up visit to ensure the benefit of the spectacle prescribed for daily activities. I wish to be contacted if findings are made that have implications for the child or my family.

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Ms JayaRajini Vasanth
Assistant Professor in Optometry
Department of Ophthalmology
Sri Ramachandra University
Mobile no: 9884452651
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Participant signature

Thumb impression

Witness name

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Date: Name:

Signature of person obtaining Signature of PI
Refractive and Accommodative status among the children with Cerebral Palsy in three special schools of Chennai and the impact of the optical intervention on the visual acuity and accommodative response
Annexures

Refractive and Accommodative status among the children with Cerebral Palsy in three special schools of Chennai and the impact of the optical intervention on the visual acuity and accommodative response

18

24-

48
Annexures

- A list of children with Cerebral Palsy
- Scope of the study
- Methodology
- Results

Refractive and Accommodative status among the children with Cerebral Palsy in three special schools of Chennai and the impact of the optical intervention on the visual acuity and accommodative response.
Refractive and Accommodative status among the children with Cerebral Palsy in three special schools of Chennai and the impact of the optical intervention on the visual acuity and accommodative response

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Annexures

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Refractive and Accommodative status among the children with Cerebral Palsy in three special schools of Chennai and the impact of the optical intervention on the visual acuity and accommodative response
## PROFORMA (Control group)

<table>
<thead>
<tr>
<th>S.NO:</th>
<th>NAME:</th>
<th>AGE:</th>
<th>SEX:</th>
</tr>
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<tbody>
<tr>
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</table>

**SENSORY TESTS:**

- Stereopsis:
- Worth four dot test:

**SCREENING TESTS:**

**BCVA (Distance):**

<table>
<thead>
<tr>
<th>OD:</th>
<th>OS:</th>
<th>with PH</th>
<th>OD:</th>
<th>OS:</th>
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</table>

**BCVA (Near):**

<table>
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<tr>
<th>OD:</th>
<th>OS:</th>
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</table>

**Colour vision:**

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<tr>
<th>OD:</th>
<th>OS:</th>
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**Hirschberg’s:**

**Visual field test:**

<table>
<thead>
<tr>
<th>OD:</th>
<th>OS:</th>
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</table>
Annexures

DIAGNOSTIC TESTS

Static Retinoscopy:
- OD:
- OS:

Dynamic Retinoscopy (MEM method):
- OD:
- OS:

Cycloplegic Retinoscopy:
- OD:
- OS:
Annexures

ETHICAL APPROVAL LETTER

INSTITUTIONAL ETHICS COMMITTEE

(Other than Clinical Evaluation of Drugs / Procedures/ Devices/ Diagnostics/Vaccine/ Herbal Remedies)

Chairman:
Dr. Venkatesan P

Member Secretary:
Dr. Padmavathi R

Members:
Dr. Ramesh Hari Hara Iyer
Dr. Darling Chellathai David
Dr. C.D. Narayanan
Dr. T.S. Lokeswari
Dr. S. Nirupa
Dr. Nalini Ganesan
Dr. Ravishankar
Ms. A.G. Shanthi
Mr. S. Rethinakumar – Legal Consultant
Ms. Sheeba Vinod

To
Ms. Jaya Rajini Vasanth
Senior Lecturer in Optometry
Department of Ophthalmology
SRMC & RI
SRU.

Dear Madam,

REF: IEC-NI/09/JUNE/10/18

SUB: Visual Issues among Children with Cerebral Palsy.

......

Thank you for submitting the clarifications raised by the Institutional Ethics Committee in its meeting held on 1.8.09. The Institutional Ethics Committee approves the project.

A Harvard Medical International Associated Institution
Annexures

You are advised to be familiar with ICMR guidelines on Biomedical Research in human beings and also to adhere to the Principles of good clinical practice. You are required to submit the final report on the completion of study to the Institutional Ethics Committee.

Yours Sincerely,

(DR.R.PADMAVATHI)
Member Secretary

Note: Please quote IEC Reference number in all future communications.
Annexures

SRI RAMACHANDRA UNIVERSITY
(Declared under Section 3 of the UGC Act, 1956)

INSTITUTIONAL ETHICS COMMITTEE
(Other than Clinical Evaluation of Drugs/Procedures/Devices/Diagnostics/Vaccine/Herbal Remedies)

Chairperson:
Dr. A. Nalini

Member Secretary:
Dr. Pankaj B. Shah

Members:
Dr. Padmavathi R.
Dr. Nirupa
Dr. C. D. Narayanan
Dr. T. S. Lokeswar
Dr. K. Punnagai
Dr. Leena Dennis Joseph
Dr. P. Seenivasan
Dr. S. Sujatha
Dr. Vaens Laxu
Mr. S. Rethina Kumar
Mrs. Sheeba Vinod
Mrs. Girija Kamarabu
Mrs. Sudha Ganapathy

10.04.2015

To
Ms. Jaya Rajini Vasanth
Senior Lecturer in Optometry
Department of Ophthalmology
SRMC & RI
SRU

Dear Madam,

REF: IEC-NI/09/JUNE/10/18
SUB: The visual functions assessment is being done as a routine in the Ophthalmology Out-patient services.

Thank you for submitting the clarifications raised by the Institutional Ethics Committee in its meeting held on 01.08.09. The Institutional Ethics Committee approves the project.

You are advised to be familiar with ICMR guidelines on Biomedical Research in human beings and also to adhere to the Principles of good clinical practice. You are required to submit the final report on the completion of study to the Institutional Ethics Committee.

Yours Sincerely,

(Dr. R. Pankaj B. Shah)
Member Secretary

Note: Please quote IEC Reference number in all future communications.