CHILDREN'S NATIONAL MEDICAL CENTER

Department of _____
111 Michigan Avenue, NW
Washington, DC 20010
(202) 884-5000

ASSENT (AGES 12 to 18) TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

TITLE OF STUDY:	As on Application
PRINCIPAL INVESTIGATOR:	Name, Title, and Department

INTRODUCTION: We would like to invite you to be part of a research study at Children's National Medical Center. Before you decide if you would like to participate, we want you to know why we are doing the study. We also want you to know about any risks (anything unexpected that might happen) and what you will be expected to do in the study. You can only be in the study if your parent(s) agree(s).

This form gives you information about the study. Your doctor or a research staff member will talk to you about the study and answer any questions you have. We encourage you to discuss this study with your family before making your decision. We will ask you to sign this form to show that you understand the study. We will give you a copy of this form to keep. It is important that you know:

- You do not have to join the study;
- You may change your mind and stop being in the study any time you want and no one will mind. In some cases however, stopping the study medication early may cause harm to you. Your doctor will discuss this with you;
- If we make any important change to the study we will tell you about it and make sure you still want to be in the study.

A. WHAT IS THE REASON FOR THE STUDY?

1. *Explain the purpose of the research study. If it is a FDA IND study, you must include as a purpose the evaluation of the safety and effectiveness of the drug.*

IRB APPROVAL DATE: ***IRB EXPIRATION DATE:***

2. *Explain why the participant qualifies for the study* ****Please note: always refer to study patients as "participants"***

[Sample: We want to see if a drug called ribavirin helps in the treatment of children with hepatitis C. We now use a drug called interferon to treat hepatitis C. Interferon is approved by the Food and Drug Administration to use in children. Ribavirin is an experimental drug for children because it has not been tested on children. In tests on adults, using interferon and ribavirin together works better than using interferon alone. We want to see if using interferon and ribavirin together works better for children too. We also want to find out what amount of ribavirin works best with interferon.]

B. WHAT WILL HAPPEN IN THE STUDY?

1. *Briefly explain the study design and treatment methods. Discuss clinical detail only as relevant to consent (i.e., to the risks, benefits, or burdens of the study).*
2. *Identify what is experimental about the study.*
3. *Specify the number of required inpatient or outpatient visits, other time commitments, number of venipunctures, amount of blood to be drawn (in household measures), tests, exams, interviews, other burdens, etc.*
4. *Explain how the treatment groups will be assigned. Explain randomization in lay terms. If the study is placebo controlled, participants must be informed that there is a possibility that they will receive 'no treatment,' and the consequences of no treatment or withholding previous treatment regimen should be discussed.*

[Sample: We will divide the children in the study randomly into three groups (like flipping a coin so you have an equal chance of being in any group). We will give all three groups interferon. We will give one of the groups a small amount of ribavirin. We will give one of the groups a larger amount of ribavirin. We will give the last group the largest amount of ribavirin.

You should know that in adults, the largest amount of ribavirin worked the best and was safe, and that there is a two out of three chance that you will receive less than that amount. If you are in one of the two groups with the lower amounts of ribavirin and you don't get better after 12 weeks, we will put you in the group to get the largest amount of ribavirin.

IRB APPROVAL DATE: ***IRB EXPIRATION DATE:***

You will be taking two pills every day for one year. You will come to the hospital every month for an exam and tests to see if the medicine is working and to see if there are any bad side effects.

We will ask you to drop out of the study if:

- You have any unexpected side effects
- Your doctor thinks it is best for you
- The medicine is not working after 24 weeks]

C. WHAT POSSIBLE UNEXPECTED THINGS COULD HAPPEN? (Text Box)

1. *List all risks that are more than minimal (no greater probability or magnitude than those ordinarily encountered in daily life or during routine medical tests). Include physical, psychological, social, economic, legal or other risks, where present.*

[Sample: There are some risks to the treatment you will be given in this study:

- Interferon shots can cause pain, redness or swelling, and there may be some oozing from the spot where the needle went in.
- You may have an allergic reaction to either interferon or ribavirin.
- Sometimes, children who are given both drugs get headaches, fever, chills and upset stomachs, like having the "flu." This usually gets better after a few shots.
- There are sometimes more serious side effects. Interferon can make you depressed (feel sad) and ribavirin can cause anemia (low iron). The two drugs together can cause coughing, itching, problems in breathing, dizziness or thyroid problems.
- Rare mild side effects include diarrhea, stomach pain, dry skin and eye infection.
- Rare serious side effects include weight loss, suicidal thoughts and attempts, and lung and liver problems that could lead to death.
- We will look for side effects when we examine you and take blood tests. Your doctor may have to lower the amount or stop giving the drugs if the side effects are serious.
- We do not know if the two drugs will help you or make you worse. There may be risks we don't know about. We will tell you if we find out about new risks that may affect your willingness to continue in the study.]

2. *Describe the severity and probability of all material risks, and the implications, in understandable terms.*

IRB APPROVAL DATE: *IRB EXPIRATION DATE:*

D. WHAT POSSIBLE GOOD THINGS COULD HAPPEN? (Text Box)

1. *Explain the expected benefits, if any, and their likelihood. If none, say so.*
2. *You may mention general benefits for science, or for other persons, if any.*

[Sample: The children who are part of the study will help us find out if using the two drugs together is a better treatment for hepatitis C than using only one drug. If it is, you may do better than with interferon alone.]

E WHAT OTHER CHOICES DO YOU HAVE IF YOU DO NOT WANT TO BE IN THE STUDY

1. *Explain the treatment alternatives in sufficient detail for meaningful comparison with participation in the study to assist in enabling an informed decision.*

[Sample: If your doctor thinks that any treatment other than what you will get in this study would be better for you, your doctor will tell you that and will not ask you to be in this study. The only treatment now used for hepatitis C is interferon, and it only works in 15-20% of children.]

F. HOW WILL WE KEEP YOUR RECORDS PRIVATE?

We will keep the records of this study confidential. Only the people working on the study will know your name. They will keep this information in case we have to find you later to let you know of any new information that may affect your health.

ASSENT

By signing this form, you agree that you have talked to your doctor about the study and understand it, and want to be in the study. You also agree that you have been told about the risks (unexpected things) and benefits (good things) of the study, and about other choices. You may stop being in the study at any time and no one will mind and nothing will change about your medical care other than not being in the study. Please call the

IRB APPROVAL DATE: ***IRB EXPIRATION DATE:***

IRB Protocol No.: { }
Date: {Insert Current Date}
Page 4 of 5
Reviewed by IRB _____

Principal Investigator, [Insert PI Name], at 202-884-[Insert Number] if you have any questions.

Printed Name of Participant: _____
Medical Record Number: _____

Signature of Participant: _____

Witness (to signature): _____ Date: _____
(may be investigator)

Translator's Signature (if, applicable): _____ Date: _____
Language: _____

AFFIDAVIT OF PERSON OBTAINING ASSENT: I certify that I have explained to the above individual(s) the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Individual Obtaining Consent: _____

Title: _____ Signature: _____ Date: _____

IRB APPROVAL DATE: ***IRB EXPIRATION DATE:***

IRB Protocol No.: { }
Date: {Insert Current Date}

Reviewed by IRB _____

CHILDREN'S HOSPITAL
Department of _____
111 Michigan Avenue, NW
Washington, DC 20010
(202) 884-5000

WAIVER OF ASSENT
TO PARTICIPATE IN A CLINICAL RESEARCH PROJECT

TITLE OF STUDY: As on Application

PRINCIPAL INVESTIGATOR: Name, Title, and Department

PI Statement:

Assent is waived because of the mental age ☐, psychological state of the child ☐, or because there is potential for medical benefit to the child by participating in this research protocol ☐.

Acknowledgement of Waiver:

Printed Name of Participant: _____
(Child is between 7 & 18 years of age)

Medical Record Number: _____

Printed Name of Parent/Guardian: _____

Signature of Parent/Guardian: _____

Printed Name of Individual Obtaining Waiver: _____

Title: _____ Date: _____ Signature: _____

I have witnessed the explanations made by the investigator and heard the responses to questions. I have no conflicting interest in the activity proposed.

Printed Name of Witness: _____

Signature of Witness: _____

IRB USE:

IRB Protocol No.: { }
Date: {Insert Current Date}
Page 1 of 1

Revised Form December 2001

SOP No. _____
Standard Operating Procedures: Informed Consent/Assent
Effective Date: _____

I. PURPOSE

To outline activities and procedures for obtaining and documenting informed consent/assent and/or parental/legal guardian permission for participation in clinical research studies in accordance with ethical principles and regulatory standards.

II. SCOPE

This policy applies to all clinical research involving human subjects conducted within the PPRU for which waiver of informed consent is not applicable. Each Site will have a local Standard Operating Procedure providing further guidance regarding site-specified requirements.

III. POLICY

The study-specified Principal Investigator is ultimately responsible for ensuring adequate informed consent/assent/permission for each subject's participation in a clinical research study. The ethical principles of respect for persons, beneficence and justice supporting this requirement are described in the Declaration of Helsinki, revised in October, 2000, and the Belmont Report. Regulatory standards and responsibilities of the Principal Investigator and Institutional Review Board are outlined in 21 CFR Parts 50.20-27 and 45 CFR 46.116

III. DEFINITIONS AND ABBREVIATIONS

PPRU	Pediatric Pharmacology Research Unit
IRB	Institutional Review Board
PI	Principal Investigator
Site	The individual PPRU site
Sponsor	The sponsor of the study. Sample sponsors are Industry, NIH, other governmental agencies or Principal Investigator of investigator initiated protocols.

IV. MATERIALS AND EQUIPMENT: N/A

V. DESCRIPTION

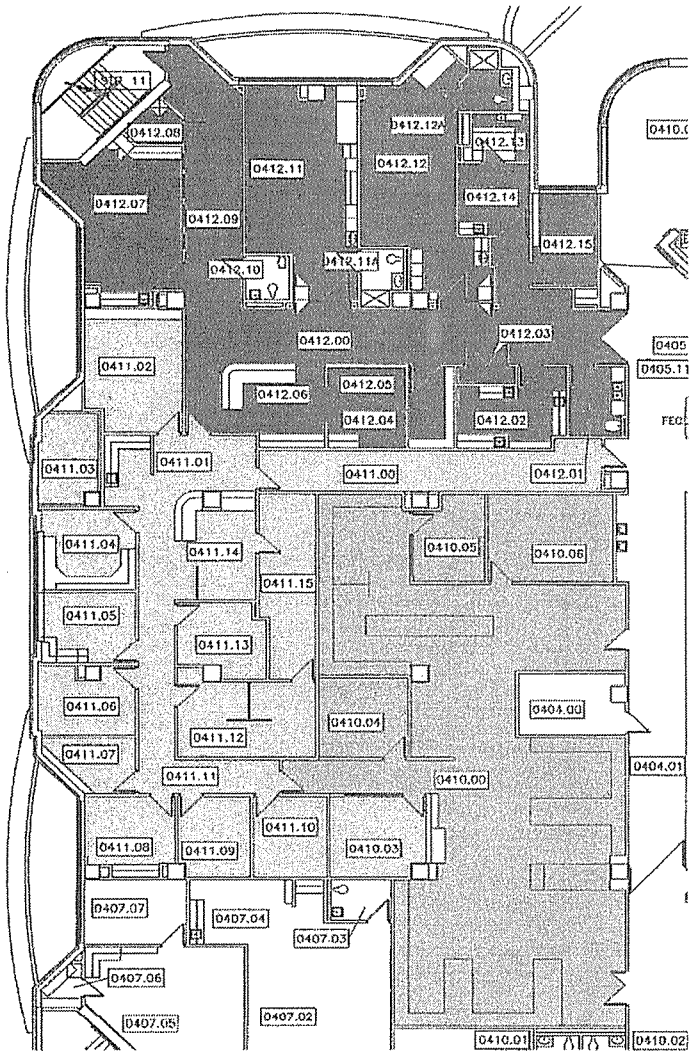
A. Responsibilities and Procedures

1. The principal investigator (PI) is responsible for assuring study subject informed consent is conducted in accordance with ethical principles and regulatory standards. The PI may delegate the duty of obtaining informed consent to appropriate clinical site research personnel according to local SOPs. The principal investigator is responsible for assuring that any such designated member of the team is knowledgeable about the specific research study and process of informed consent.
2. The PI is responsible for assuring that the content of the consent form is in compliance with Institutional Review Board (IRB) and other regulatory requirements as applicable. The PI may delegate the development and processing of the consent form to appropriate clinical research personnel.

3. The PI is responsible for assuring that the written consent form and any other written information to be provided to subjects is revised whenever important new information becomes available that may be relevant to the subject's consent. Any such revisions should receive approval from the sponsor (if applicable), local IRB, and appropriate regulatory agencies prior to use. The PI is also responsible for ensuring that all subjects enrolled and still participating in the study sign a revised consent form when information becomes available that would impact the patient's safety or willingness to continue in the study. The PI may delegate this duty to appropriate clinical site research personnel.
4. Informed consent must be obtained for each research subject prior to providing any research-specific activity.
5. Upon identification of a potential study subject, the PI or designee will be responsible for identifying who is legally authorized to give consent in accordance with each Site's local policies. If the subject or the subject's legally authorized representative is unable to speak or read English, translation will be provided in accordance with the Site's local policies.
6. The principal investigator or designee will fully inform the subject or the subject's legally authorized representative (either or both referred to collectively below as "subject") of all pertinent aspects of the trial including the written information as approved by the IRB. The process includes:
   a. Giving the subject adequate information concerning the clinical investigation in language understandable to the subject and in language as non-technical as possible, at the reading level specified by the Site's IRB.
   b. Providing ample time and opportunity for the subject to inquire about the details of the clinical trial and to decide whether or not to participate in the trial as well as to consider other available options, if any.
   c. Responding to subject's questions—all questions about the trial should be answered to the satisfaction of the subject.
   d. Obtaining the subject's voluntary consent.
7. Informed consent will be documented by using the current written consent form as approved by the IRB. Signatures must be provided as required on the IRB-approved consent form.
8. If the protocol will enroll subjects within the age range for which assent is required by the IRB, affirmative agreement by the subject will be documented as required by the IRB in addition to the documentation of agreement by the subject's legally authorized representative.
9. Documentation of the consent process should be recorded in the subject's research file or medical record in accordance with policies at the local site.
10. The original signed consent will be filed in the research chart or medical record, as locally applicable, and the investigator or designee will provide a copy of the consent form to the person signing the form.

VI. REFERENCES:

Declaration of Helsinki, October 2000
Belmont Report
21 CFR 50.20-50.27 Elements of informed consent
21 CFR 56.109 IRB review of research
21 CFR 56.111 Criteria for IRB approval of research
21 CFR 312.60 General responsibilities of investigators
21 CFR 312.62 Investigator record keeping and record retention
45 CFR 46.116 General requirements for informed consent
International Conference on Harmonization; Good Clinical Practice: Consolidated Guidelines.



PEDIATRIC PHARMACOLOGY RESEARCH UNIT

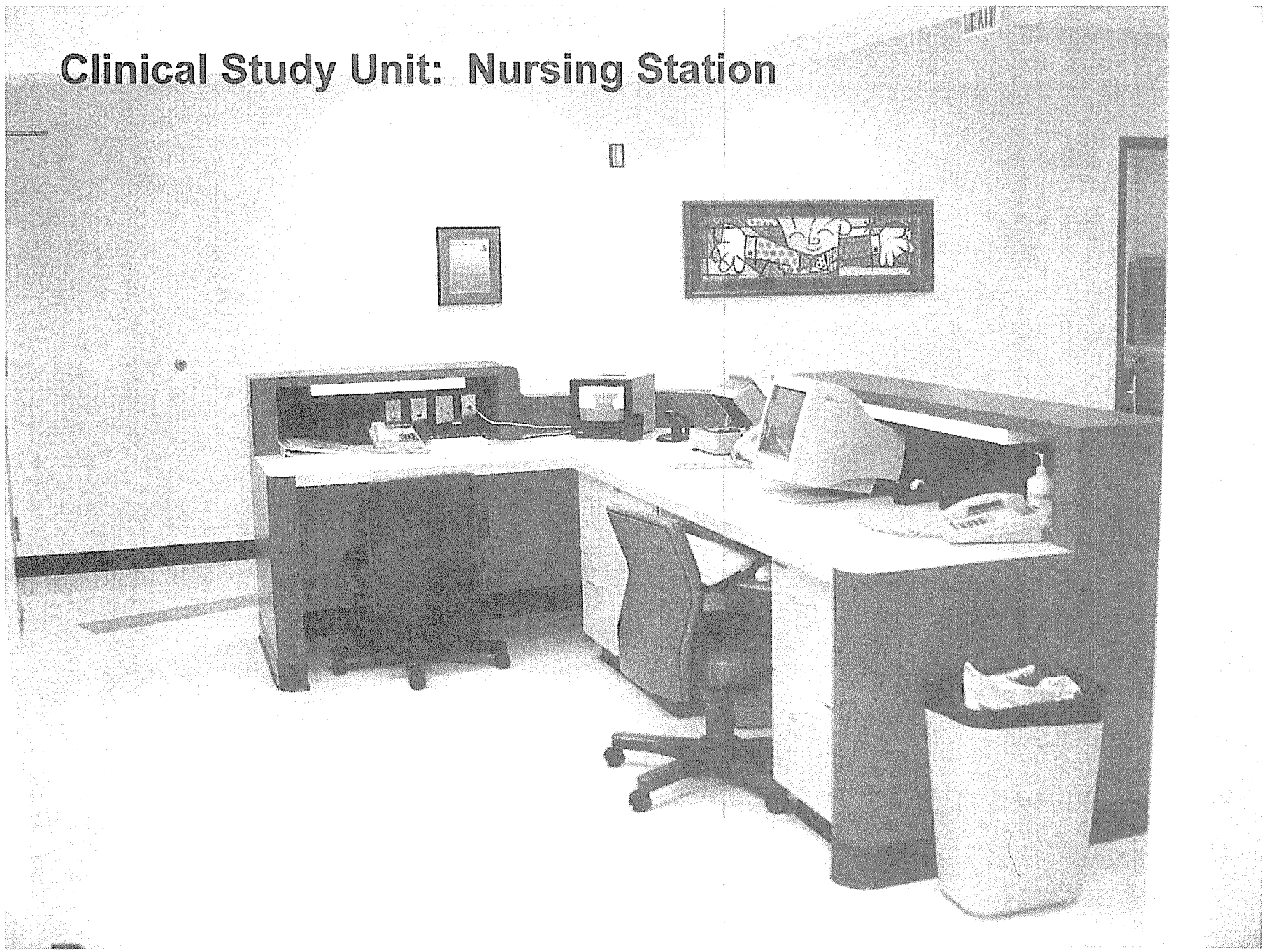
Division of Pediatric Pharmacology & Medical Toxicology

Children's Mercy Hospitals and Clinics, Kansas City, Missouri

Pediatric Clinical Research Unit	3,200 ft²
Core Office Complex	3,000 ft²
PPRU Core Laboratory	3,800 ft²

Clinical Study Unit: Corridor

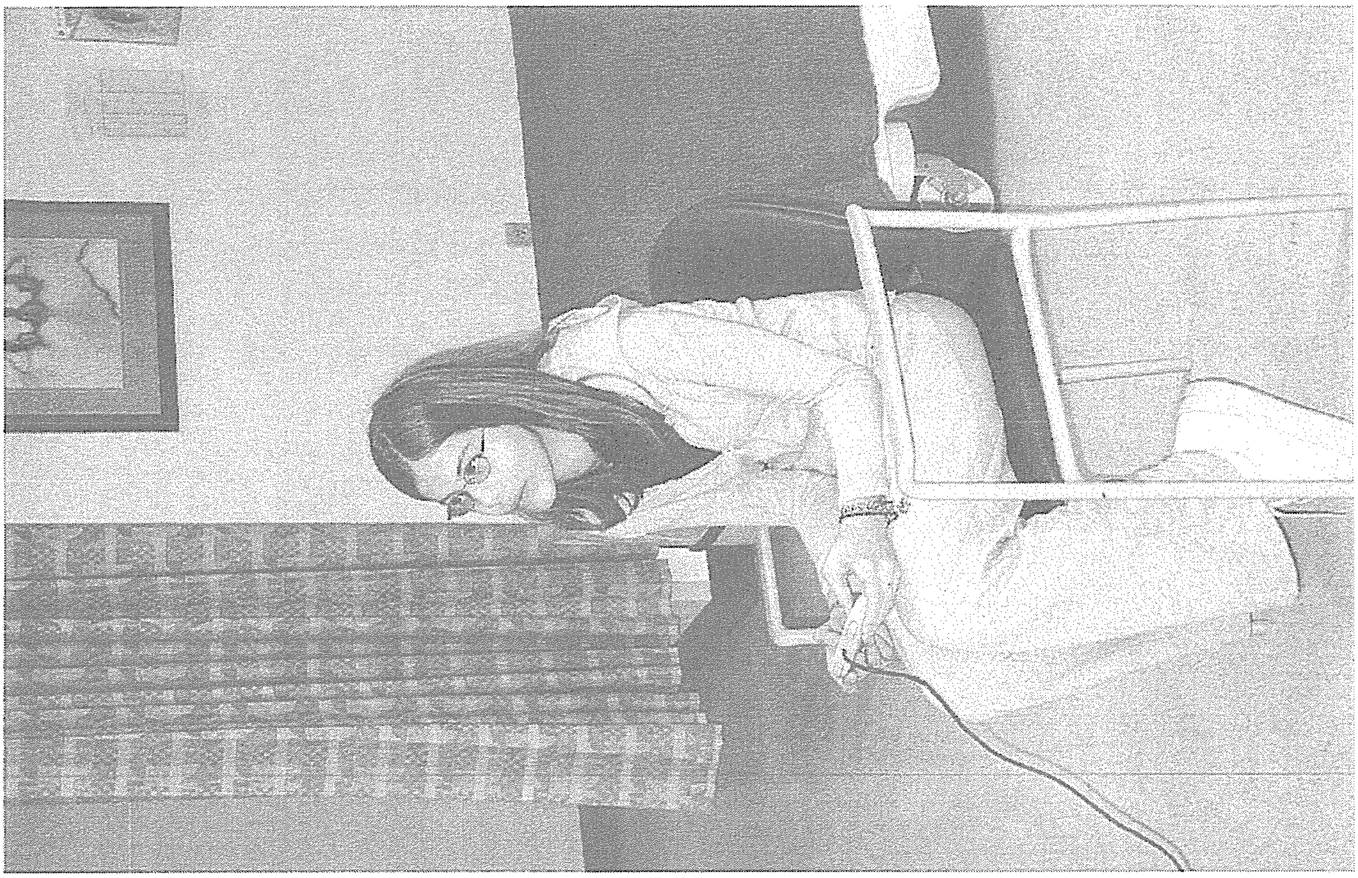
Clinical Study Unit: Nursing Station

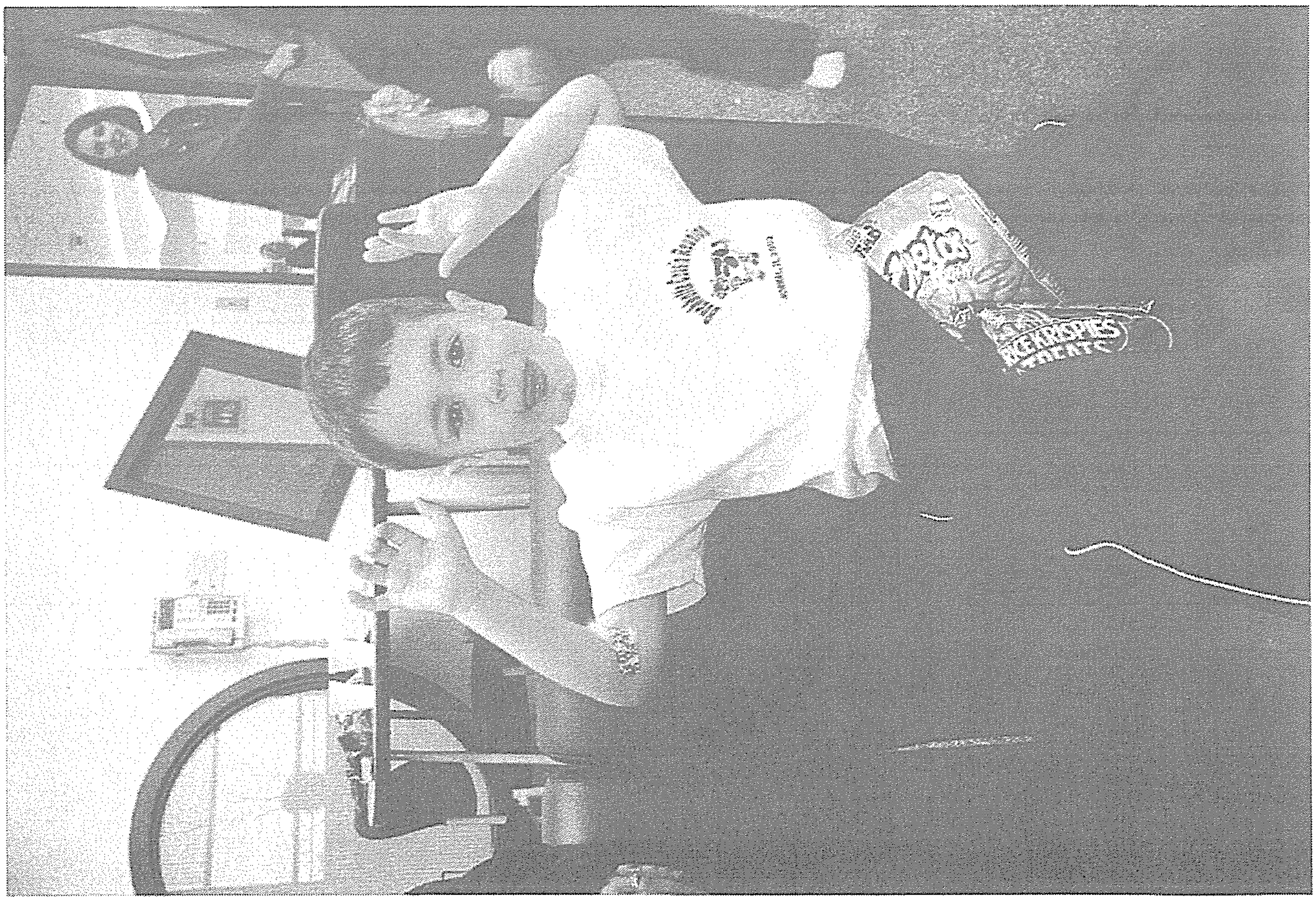


Clinical Study Unit: CRA Room
CHARTING
0412.05

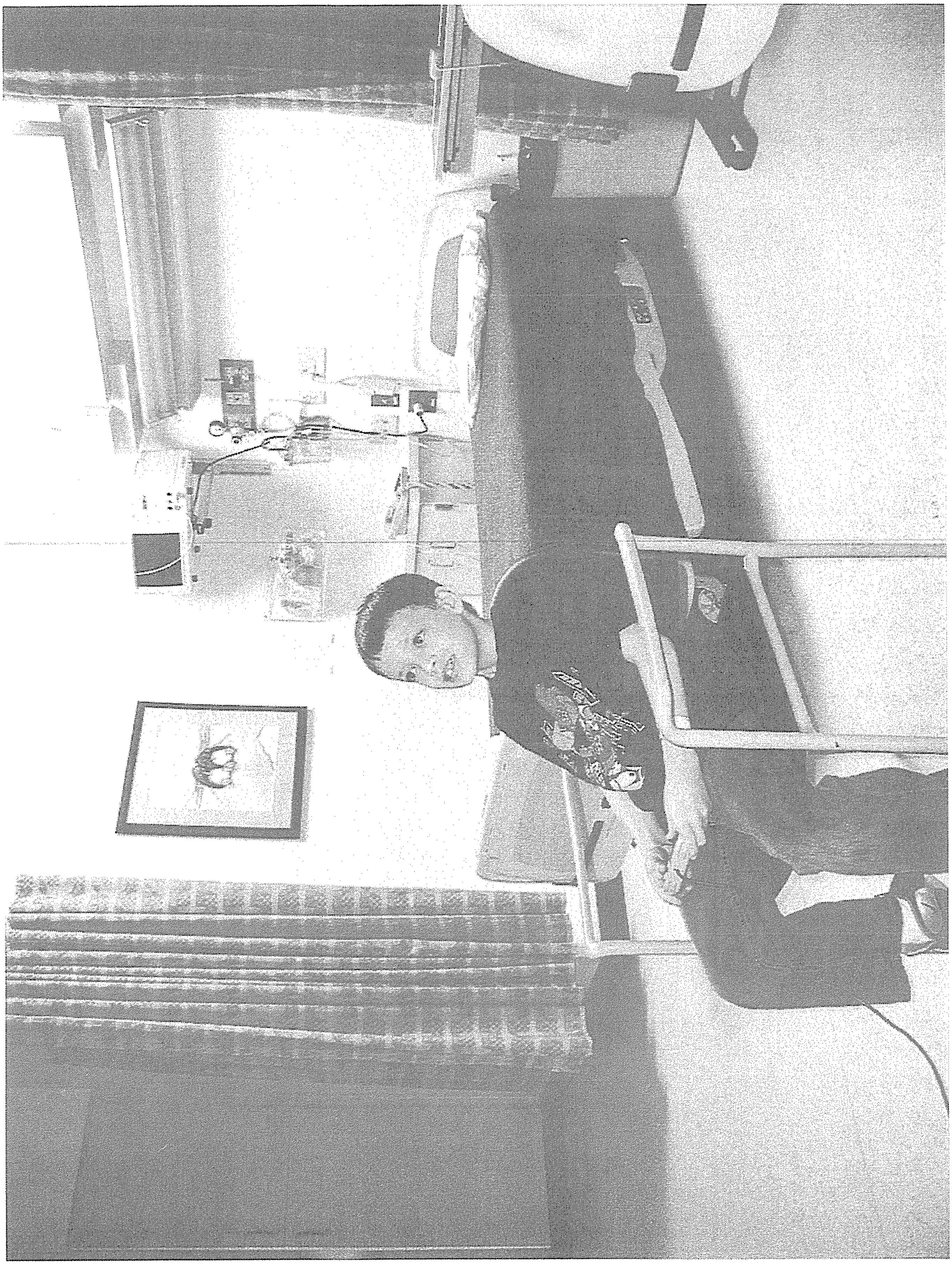
Clinical Study Unit: Playroom

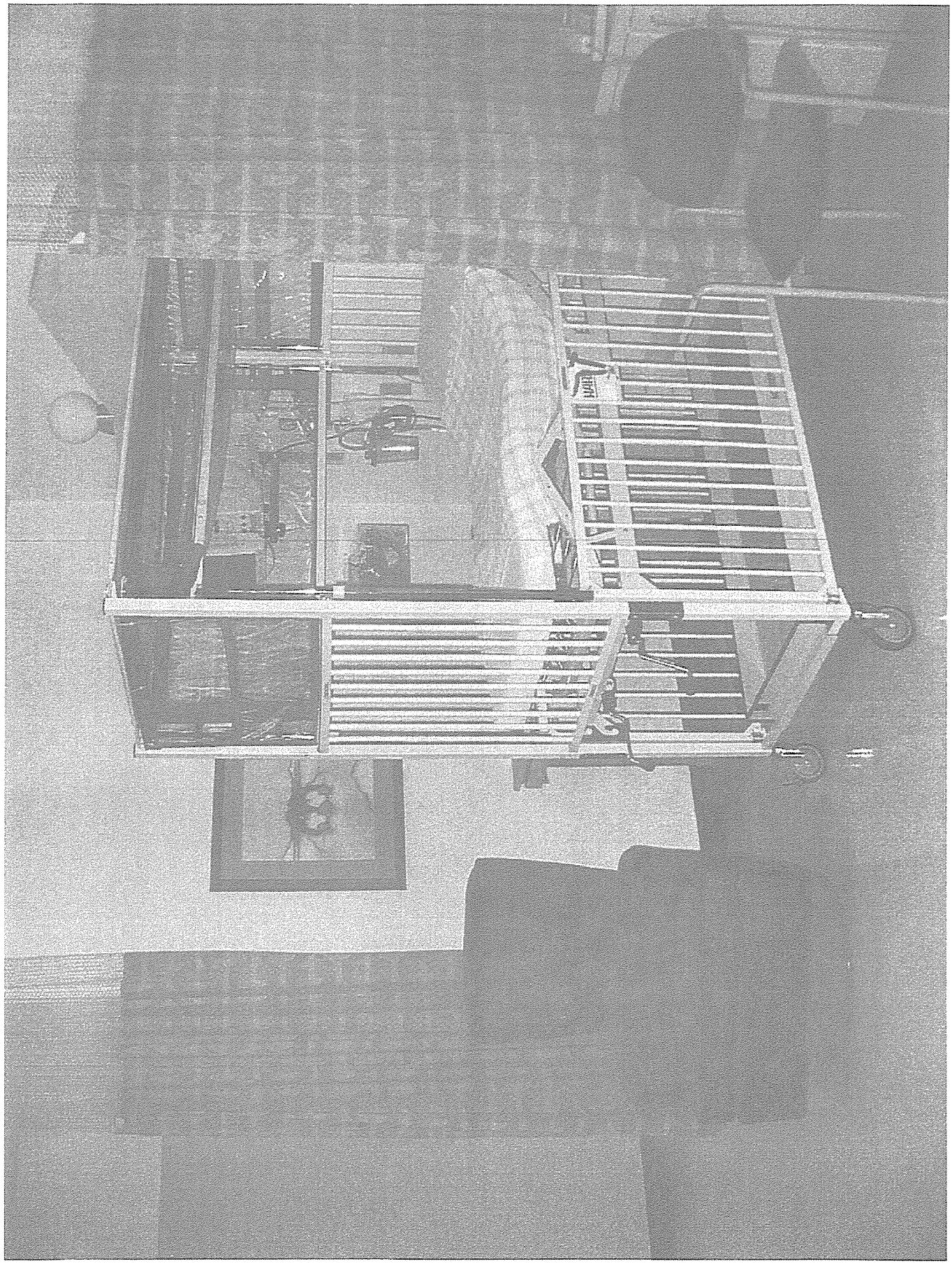
Clinical Study Unit: Playroom





Clinical Study Unit: Inpatient Room





Nutrition and Drug Room