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表. データマネージャー人材育成対象者の外部研修

2006年10月12～13日	２００６年ＡＰＥＣ医薬品等レギュラトリー・サイエンス・ネットワークシンポジウム
2006年11月1日	ＪＣＯＧデータセンター視察
2006年11月3日	普及啓発事業「小児医薬品エビデンス評価セミナー」(松田班)
2006年11月10日	ＪＣＯＧプロトコル検討会見学
2006年11月6日～	東大・生物統計学教室の統計勉強会に参加（週１程度）
2006年11月17日	第３回臨床研究審査を考える会
2006年11月29日	名古屋医療センター・臨床研究センター（ＪＰＳＬＧデータセンター）視察参加
2006年11月30日～12月1日	第３３回日本小児臨床薬理学会
2006年12月16日	第28回臨床研究・生物統計研究会
2007年1月12日	日本計量生物学会特別講演会
2007年1月29～30日	10th Annual Workshop in Japan for CLINICAL DATA MANAGEMENT
2007年2月15日	平成18年度小児疾患臨床研究成果発表会（研究者向け）
2007年2月16日	「医薬品・医療機器等レギュラトリーサイエンス総合研究事業」班会議
2007年2月28日～3月2日	臨床データマネジメントセミナー（CDMセミナー）

厚生労働科学研究費補助金（臨床研究基盤整備推進研究事業）
分担研究報告書

小児科領域における臨床試験支援体制整備

分担研究者　清水裕子　国立成育医療センター病院　看護部　副看護師長
治験管理室　治験リサーチナース

研究要旨
小児科領域における適切な臨床試験支援体制を検討した。国内外の臨床試験支援体制について情報収集し、それを基に、Ⅰ相試験・薬物動態試験の実施体制整備・治験以外の臨床試験実施支援について検討を開始した。3件の薬物動態試験について、その準備に関わり、具体的な実施方法の調整を行った。これら試験は現在、症例登録待ちの状態であり、これら試験の実施状況をふまえて、問題点や改善案を検討する予定である。現在日本では小児のⅠ相試験実施体制は不十分であり、小児特有の問題点を把握・解決しつつ、整備を進めていきたい。国立成育医療センターでの治験以外の臨床試験実施支援についても検討を開始し、院内各部門や事務局との調整を行い、円滑な試験実施のために症例ファイルなども作成した。この内容は他施設にも応用可能と考えられる。さらに、今年度行われた臨床試験の監査結果もふまえ、今後の支援方法について検討する予定である。実施体制整備のためには、病院全体の臨床試験の必要性の理解が不可欠である。ナショナルセンターとして小児科領域の臨床試験全体の基盤を整備すべく取り組みが必要であると考える。

A．研究目的

本研究では、小児科領域における適切な臨床試験支援体制を検討する。そのために必要な、小児の専門性を持った人材を育成する。

B．研究方法

初年度は、国外の臨床試験支援体制について情報収集し、実施可能かつ適切な臨床試験実施支援のあり方について検討した。また、薬物動態試験については、国内の実施状況を情報収集し、今後の支援体制について検討を始めた。

人材育成対象者については、採用が遅れたことにより平成19年4月より教育を開始する予定である。

（倫理面への配慮）

今回は主に体制整備が目的の研究であり、特に倫理的配慮の必要はなかった。

C．研究結果

1）国内外の臨床試験支援体制について情報収集

米国の臨床試験実施体制について情報を得るため、Children's National Medical Center と Children's Mercy Hospitals and Clinics を訪問した。

米国では、臨床試験は治験とほぼ区別なく同様の支援がなされていた。特に試験実施中だけでなく、試験計画段階から研究者はリサーチナースに実施可能性などを相談していた。また病院全体で研究をする体制があり、GCRC（General Clinical Research Center）のみでなく、病棟にも多くのリサーチナースが存在していた。（資料1）

2）臨床試験支援に必要な人材の育成

人材育成対象者については、平成18年4月の診療報酬改定に伴う看護師不足からか、募集をしても応募がなく、採用が遅れた。現在までに採用者は決定したが、教育の開始は平成19年4月以降となった。

3）Ⅰ相試験・薬物動態（PK）試験の実施体制整備

日本製薬工業協会の開発担当者と、小児

の薬物動態試験の実施体制について話し合いの場を持ち、問題点の把握、今後の方針について検討した。現在日本では、小児の薬物動態試験は実施困難と考えられている。施設側は設備や人員など体制整備を進める必要があり、依頼者側はアダプティブデザインやポピュレーション PK などデザインを工夫する必要があると考えられた。(資料2)

今年度できる作業として、計3件の PK 試験の準備段階で、その具体的実施方法や院内各部門との連携について検討した。具体的には、検体採取キット受け取りから採取、検体処理、検体受け渡し、データ送信までの流れを、臨床試験事務局と当院の臨床検査部等と調整した。現在臨床試験の臨床検査については病院内でも運用が定まっておらず、今回を機会に院内での運用を確立していく予定である。

4）治験以外の臨床試験実施支援

臨床試験実施に対する支援方法について、検討を開始した。

現在準備中の臨床試験（厚生労働科学研究費補助金小児疾患臨床研究事業「小児腎移植におけるミコフェノール酸モフェチルの有効性・安全性の確認、用法・用量の検討・確立に関する研究」）について、臨床現場でスムーズに実施できるよう、またプロトコールに沿って確実に実施できるよう、院内や事務局との調整、症例毎のファイルの作成を行った。(資料3)

今年度、すでに終了した臨床試験1件にについて試験的に監査が行われたが、プロトコール変更に伴う同意説明文書の変更への対応ができていない、必要事項を倫理審査委員会に申請していないなどが指摘された。

D．考察

1）国内外の臨床試験支援体制について情報収集

今回の視察にて、米国の臨床試験支援体制の充実と、病院全体の臨床試験に対する理解の高さを知ることができた。

日本では、小児分野で臨床試験を推進するべきであることについて、臨床現場で理解が乏しく、それにより支援体制の整備がされていないと感じる。臨床現場の理解が深まるような働きかけも今後行っていく必要がある。

2）臨床試験支援に必要な人材の育成

人材育成対象者の雇用が遅れたことにより、教育プログラムに遅れが生じているが、3名の CRC の採用が内定している。採用予定者のうち2名は CRC 経験者であることから、4月以降速やかに採用者個々の理解度を評価し、個人に合わせた教育を行っていく予定である。(資料4)

3）Ⅰ相試験・PK 試験の実施体制整備

小児の薬物動態試験の実施については、製薬企業側も体制整備を望んでおり、今後も検討を続けていく必要がある。国内でほとんど小児のⅠ相試験が行われていない現実をふまえると、同時進行で、我が国における小児治験推進策の策定も必要であろう。

薬物動態試験の院内の運用確立については、予定された3試験とも未だ被験者がエントリーしていないため、今回検討・計画した内容の評価はできていない。数例の被験者が薬物動態試験を実施した段階で、実施体制の問題点や改善案を検討する予定である。

4）治験以外の臨床試験実施支援

支援を開始した臨床試験については準備は終了しているが被験者のエントリー待ちであり、支援方法の評価はできていない。エントリーが開始され次第支援のあり方を評価し、見直していく予定である。

また臨床試験の監査結果により、現在行われている臨床試験の問題点が明確となった。今後は問題点を CRC の支援によって解決できるものと病院全体の体制として見直しが必要なものに分類し、解決に向けて検討していく予定である。(資料5)

E．結論

1）国内外の臨床試験支援体制について情報収集、2）臨床試験支援に必要な人材の育成、3）Ⅰ相試験実施体制整備、4）治験以外の臨床試験実施支援について検討した。

小児科領域では多くの臨床試験が行われているが、実施体制は不十分であり、またその必要性も理解されていないのが現状である。

当院が本研究で小児科領域の臨床試験実施体制を整備し、最終的にはそれを他施設に発信し、日本全体の実施体制を強化する

ことが、ナショナルセンターとしての役割であると考える。

F．研究発表

1.　学会発表

小児治験における CRC の取り組み. シンポジウム「CRC の専門性を考える：小児科領域－小児治験の現況と CRC への期待－」第６回ＣＲＣと臨床試験のあり方を考える会議 2006 in 大宮. 2006 年 10 月 7 日

CHILDREN'S NATIONAL MEDICAL CENTER

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

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY AND AUTHORIZATION TO USE PROTECTED HEALTH INFORMATION

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

"You" refers to "You" or "Your Child" throughout this document

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.

This form gives you information about the study. Your doctor will talk to you about the study and answer any questions you have. We encourage you to discuss this study with your family and anyone else you trust before making your decision. We will ask you to sign this form to show that you understand the study. If your child is seven years old or older, we may talk to your child about the study and ask your child to sign a form like this one but shorter. 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. 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.

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

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

Reviewed by IRB _____

A. PURPOSE OF STUDY

1. *Explain the purpose of the research study*
2. *Explain why the participant qualifies for the study. *Always refer to study patients as "**participants**" throughout this document.*

[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.

Your child is being asked to be in the study because your child has had hepatitis C for more than a year.]

B. PROCEDURE

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.*
5. *Distinguish the procedures that are standard clinical care from those which are purely for research.*

[Sample: We will divide the children in the study randomly into three groups (like flipping a coin, so your child has an equal chance of being in any group). We will give all three groups interferon. Interferon is the standard drug used for children with hepatitis C. 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 your child will receive less than that amount. If your child is in one of the two groups with the lower amounts of ribavirin and your child is not getting better after 12 weeks, we will put your child in the group to get the largest amount of ribavirin.

Your child will be taking two pills a day for one year. We will ask you to bring your child to the hospital every month for an exam and tests to see if the medicine is working and to see if there are any unexpected side effects.

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

- There are any unexpected side effects
- Your doctor thinks it is best for your child
- The medicine is not working after 24 weeks]

C. POTENTIAL RISKS/DISCOMFORT

1. *List all risks that are "more than minimal" (risks that have 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. If there are numerous risks, add the sample table on the following page to the summary of risks listed here.*

[Sample: There are some risks to the treatment your child 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.
- Your child 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 your child 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 your child and take blood tests. Your child's 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 your child or make your child 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. Use a table for Common (21-100/100), Occasional (5-20/100) and Rare (<5/100) risks sorted by Immediate (1-2 days of treatment), Prompt (within 2-3 weeks before next course), Delayed (any later time during treatment) and Late (after completion of treatment) onset wherever possible*

SAMPLE TABLE: (if not applicable, please delete table)

Ifosfamide

	Common Happens to 21-100 children out of every 100	**Occasional** Happens to 5-20 children out of every 100	**Rare** Happens to <5 children out of every 100
Immediate: Within 1-2 days of receiving drug	Nausea, vomiting, loss of appetite	Drowsiness, confusion, weakness, seizure, abnormal hormone function affecting levels of salt in the blood and urine, causing too much or too little urine	Poor brain function
Prompt: Within 2-3 weeks, prior to next course	Decrease in the number of red and white blood cells and platelets made in the bone marrow, abnormal changes in the heart function shown on the electrocardiogram (ECG), increased risk of bleeding; blood clots	Bleeding and irritation of the urinary bladder, damage to the heart with abnormal heart tissue	
Delayed: Any time later during therapy, excluding the above conditions	Hair loss	Abnormal kidney function, loss of certain important salts and minerals by the body	Numbness, tingling, clumsiness, sudden kidney failure, damage to the liver, damage/scarring to lung tissue, sleepiness, dizziness, confusion, hallucinations, and seizures, damage to the liver, decreased ability to have children
Late: Any time after completion of treatment			Cancer caused by treatment for a previous cancer or leukemia, damage/scarring to bladder tissue

D. VOLUNTARY PARTICIPATION

There will be no penalty or loss of benefits to which you are otherwise entitled if you decide to withdraw from the study.

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

E. POTENTIAL BENEFITS

1. *Explain the expected direct benefits to the participant, 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, your child may do better than with interferon alone.]

F. ALTERNATIVES TO PARTICIPATION

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 your child will get in this study would be better for your child, your doctor will tell you that and will not ask your child to be in this study. The only treatment now used for hepatitis C is interferon alone, and it only works in 15-20% of children.]

G. QUESTIONS – WHO TO CALL

We want you to ask questions about any part of this study or consent form either now or at any time in the future. If you have any questions about this study, call the Principal Investigator, [Insert PI Name], at [Insert Area Code and Number]. If you believe you have been injured as a result of being in this study, you should call the Principal Investigator, [Insert PI Name], at [Insert Area Code and Number]. If you have any questions or concerns about your rights in this research study at any time, please call Children's National Medical Center's Manager of Patient Relations, the Chief Academic Officer, or the Chair of the Institutional Review Board of the Children's National Medical Center. All parties may be reached at (202) 884-5000.

H. CONFIDENTIALITY

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. The federal government can review the study records and medical records to make sure we are following the law

IRB APPROVAL DATE:	*IRB EXPIRATION DATE:*

and protecting the children in the study. Your medical record is confidential, but just like any medical record; there are some exceptions under state and federal law.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA). This privacy law protects your individually identifiable health information (Protected Health Information or **PHI**). The privacy law requires you to sign an agreement so researchers can use or share your PHI for research purposes. This describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully and ask a member of the research team to explain anything you do not understand.

I authorize and his research staff to create, access, use, and disclose my PHI for the purposes described below.

Protected Health Information that may be used and shared includes:

- ☐ Information that identifies you such as name, address, telephone number, date of birth, Social Security number, and other details about you
- ☐ Information that relates to your health or medical condition from your medical records
- ☐ Information obtained from the study procedures outlined in this consent form, for example: things done to see if you can join the study such as physical exams, blood and urine tests, x-rays and other tests, and any other medical information we learn from you about your health history and family history
- ☐ Laboratory results obtained on specimens collected from you (blood, urine, tissue)
- ☐ Questionnaires or surveys you complete
- ☐ Interviews conducted with you by members of the research team
- ☐ Audio/ video recordings
- ☐ Other *[please specify]:

*Example: *list any additional information that may be obtained from participants that is listed above such as information about financial and social circumstances, or educational level.*

The Researchers may use and share my Protected Health Information with:

- The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge of doing work for the study;

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- Government agencies that have the right to see or review your PHI, including but not limited to the Office of Human Research Protections and the Food and Drug Administration;
- Children's National Medical Center Institutional Review Board;
- Audit Committee of the Children's National Medical Center Institutional Review Board;
- Quality Improvement Program Coordinator and other staff in the Office for the Protection of Human Subjects at Children's National Medical Center.

In addition to the above people and organizations, the Researchers may also use and share my Protected Health Information with:

☐ Doctors and staff at other places that are participating in the study. The name(s) of the other place(s) that are participating in this study are
☐ Laboratories and other people or organizations that look at your health information in connection with this study. The name(s) of the laboratory(ies) being used in this study is (are)
☐ The Sponsor of the study and people that the Sponsor may contract with for the study. The name of the Sponsor is
☐ The Contract Research Organization (an organization that helps the Sponsor run the study). The name of the Contract Research Organization is
☐ The Data Safety Monitoring Board (a group of people who examine the medical information during the study)
☐ The Medical Monitor for the Study (a person who reviews medical information during the study)
☐ The Patient Advocate or Research Ombudsman (person who watches out for your best interest)
☐ Any other outside entity who will receive health information
Please list:

Also, your primary physician will be contacted if during the course of the study the researcher learns of a medical condition that needs immediate attention.

Should your health information be disclosed to anyone outside of the study, your information may no longer be protected by HIPAA and this Authorization. However, the use of your health information will still be regulated by applicable federal and state laws.

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

Banking of Tissue Specimens:

We would like to store tissue specimens collected from you in this study in a tissue bank for future research as identified below. The tissue specimens consist of [specify]. The tissue bank is maintained by [insert name of institution. If tissue bank is maintained at CNMC, specify responsible Department].

Please indicate your approval of any or all of the following by initialing next to the statement:

My tissue may be stored in the above named bank for future analysis related to this study. ☐ Yes ☐ No _____ initials

My tissue may be stored in the above named tissue bank for future analysis related to [insert name of specific study]. ☐ Yes ☐ No _____ initials

My tissue may be stored in the above named tissue bank. Researchers may contact me to request my authorization for future studies that are not related to this study or the disease named above. ☐ Yes ☐ No _____ initials

My tissue may be stored without any of my identifying information for use in other studies of other diseases. ☐ Yes ☐ No _____ initials

I may change my mind at a later time and request that my tissue specimen be destroyed. If I change my mind and want to request that my tissue be destroyed, I must do so in writing to [insert name and contact information of PI].

Storage of PHI in a Database:

We would like to store personal health information collected from you in this study in a database for future research. The database is maintained by [insert name of institution. If database is maintained at CNMC, specify responsible Department].

IRB APPROVAL DATE:	*IRB EXPIRATION DATE:*

Please indicate your approval of any or all of the following by initialing next to the statement:

My personal health information may be stored in the above named database for future analysis related to this study. ☐ Yes ☐ No _____ initials

My personal health information may be stored in the above named database for future analysis related to [insert name of specific study]. ☐ Yes ☐ No _____initials

My personal health information may be stored in the above named database. Researchers may contact me to request my authorization for future studies that are not related to this study or the disease named above.
☐ Yes ☐ No _____ initials

My personal health information may be stored without any of my identifying information for use in other studies of other diseases. ☐ Yes ☐ No _____ initials

If you agree to participate in this research study, the research team, the research sponsor (when applicable) and the sponsor's representatives, may use Personally Unidentified Study Data. The Personally Unidentified Study Data does not include your name, address, telephone, or social security number. Instead, the researcher assigns a code to the Personally Unidentified Study Data. Personally Unidentified Study Data may include your date of birth, initials, and dates you received medical care. Personally Unidentified Study Data may also include the health information used, created, or collected in the research study. The research team or the research sponsor may share the Personally Unidentified Study Data with others to perform additional research, place it into research databases, share it with researchers in the U.S. or other countries, or use it to improve the design of future studies. They may also publish it in scientific journals, or share it with business partners of the sponsor and to file applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

You do not have to sign this Consent/Authorization. If you decide not to sign the Authorization, you will not be allowed to participate in the research study.

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

After signing the Consent/Authorization, you can change your mind and:

- Revoke this Authorization. If you revoke the Authorization, you will send a written letter to: to inform him/her of your decision.
- If you revoke this Authorization, researchers may only use and disclose the PHI that was collected for this research study before you revoked the Authorization.
- If you revoke this Authorization your PHI may still be used and disclosed if you should have an adverse event (unexpected side effect).
- If you change your mind and withdraw the Authorization, you will not be allowed to participate in the study.

You will be allowed to review the information collected for this research study until after the study is completed. If you are not allowed to review your information during participation in the study, when the study is over you will have the right to access the information.
This Authorization expires on

If you have not already received a Notice of Privacy Practices from Children's National Medical Center, you may request a copy and will be given one. If you have any questions or concerns about your privacy rights, you may contact the Children's Hospital Privacy Officer at 202-884-4550.

I. COMPENSATION

1. *The information in the following paragraph should be included, if the protocol presents "More Than Minimal Risk." It may be required in a "Minimal Risk" protocol if the risks are significant. The drug/device manufacturer's statement will not be accepted in lieu of the Compensation Paragraph.*

Children's National Medical Center cannot promise that the risks we have told you about or other unknown problems will not happen. If you think that something unexpected happened because you were in the study, please call the Chief Academic Officer of the Children's National Medical Center at (202) 884-5000. We will give your child any emergency treatment needed.

IRB APPROVAL DATE:	*IRB EXPIRATION DATE:*

J. ADDITIONAL ELEMENTS

When appropriate, discuss the following topics if not covered elsewhere.

- **Unforeseeable risks to participant or embryo**

It is not known if this study treatment can cause serious harm to unborn children or children who are breast-feeding. It may or may not be harmful to the health of a pregnant woman or a woman who recently delivered a baby. In addition, there may or may not be harmful side effects that are not yet known that could happen to the mother, unborn child, or beast-feeding child. For this reason, if you are pregnant you will not be allowed to participate in this study. If you are breast-feeding, please discuss this with your doctor. You may be allowed to participate in this study if you are willing to stop breast-feeding your baby.

You should not become pregnant or father a child while you are on the study treatment and for at least six months after completing your study treatment. To avoid becoming pregnant or fathering a child you should either abstain from sexual relations (not have sex) or use a reliable method of contraception. Except for surgically removing a woman's uterus, other contraceptive methods such as condoms, a diaphragm or cervical cap, birth control pills or patch, IUD, DepoProvera, or sperm killing products are not totally effective in preventing pregnancy. The only way to completely avoid risks to an unborn baby from the study treatment are: 1) do not become pregnant; 2) do not father a child; or 3) do not receive the study treatment. If you become pregnant while enrolled in this study, your participation will be ended and you should understand that there is an unknown risk to an unborn baby. If you are able to become pregnant, you will be given a pregnancy test before starting the study and possibly at other times during the study.

- **Additional costs to participants to take part**

Children's Hospital will give you the medicine used in this study for free. You will not be charged for anything else we do that is part of the study. You will still have to pay for any medical care that is not part of the study.

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

- **Consequences of withdrawing**
- **Significant new findings to be provided**
- **Termination from the study without consent**
- **Approximate number of total participants if it could be of concern to participant**

Research Subject Advocate:

The National Institutes of Health supports a Research Subject Advocate or RSA for the research study that you are being asked to join. The RSA, Dr. Tomas Silber, is here to answer your questions or concerns about taking part in this research. Dr. Silber does not work for the doctors who are doing this research and they do not pay him. He is here only to help and protect you during any research.

You may contact Dr. Silber at any time. This can be done before you decide to take part in the research, during the study, or even after you finish the study. You can call Dr. Silber at 202-884-3066 or reach him by e-mail at tsilber@cnmc.org.

CONSENT/AUTHORIZATION:

I am the participant or I am authorized to act on behalf of the participant. I have read this information and will receive a copy of this form after it is signed.

By signing this form, you agree that you have talked to your doctor about the study and understand it, and you want to be in the study. You agree that we have talked to you about the risks and benefits of the study, and about other choices. You may decide to stop being in this study at any time and no one will mind and nothing will change about your medical care other than not being in the study. Copies of this form will be:

(1) Kept in the study file by the Principal Investigator;
(2) Put in your medical record; and
(3) Given to you to keep.

Please call the Principal Investigator, [Insert PI Name], at [Insert Area Code and Number] if you have any questions.

IRB APPROVAL DATE:	*IRB EXPIRATION DATE:*

Printed Name of Participant: _____
Medical Record Number: _____
Printed Name of Parent(s)/Guardian(s): _____

Signature of Participant: _____ Date: _____
(Participant must be 18 years of age or older)

Signature of Parent(s)/Guardian(s): _____ Date: _____

*[Note: Signature of both parents required if more than minimal risk **and no direct benefit**, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child]*

Signature of 2nd Parent/Guardian: _____ Date: _____
(ONLY when applicable)

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

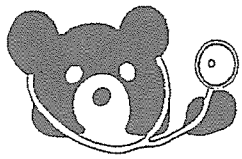
Translator's Signature (if, applicable): _____
Language: _____

AFFIDAVIT OF PERSON OBTAINING CONSENT: 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:***



CHILDREN'S NATIONAL MEDICAL CENTER

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

ASSENT (AGES 7 through 11) TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

TITLE OF STUDY: (As on Application)

PRINCIPAL INVESTIGATOR: (Name, Title, and Department)

[Sample for readability level illustration – see manual for additional instructions]

A & B. WHAT IS THE REASON FOR THE STUDY AND WHAT WILL HAPPEN IN THE STUDY?

[Sample: We will try a new medicine called ribavirin to see if it works better than the medicine you are taking now. You will still take the medicine you are taking now.]

C. WHAT POSSIBLE UNEXPECTED THINGS COULD HAPPEN?

[Sample: The new medicine might not work. It may make you feel worse. You could get a fever or an upset stomach. Your doctor and parents will look out for any problems and check to see how you are feeling. If you think something is wrong be sure to tell your parents right away.]

D. WHAT POSSIBLE GOOD THINGS COULD HAPPEN?

[Sample: The children who are part of the study will help us find out if the new medicine works. If the new medicine does work, it may help you feel better.]

ASSENT

I understand what the doctor has told me and I want to be in the study.

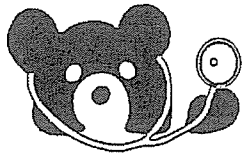
Printed Name of Participant: _____
Medical Record Number: _____

Signature of Participant: _____

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

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

Reviewed by IRB _____



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 Assent: _____

Title: _____ Signature: _____ Date: _____

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