



The International
Pleuropulmonary Blastoma Registry

Children's Hospitals and Clinics of Minnesota
2545 Chicago Ave. S., Suite 412
Minneapolis, MN 55404 USA
Fax: 612.813.7108 Phone: 612.813.7115

To Parents and Caregivers:

The following are consent forms for the International PPB Registry. Two forms are required in most situations (3 forms for patients ages 7 and 17 years):

1. General "Research Consent":

This is a plain English description of the PPB Registry and its purposes, to be signed by a parent or guardian of the PPB child. This form includes a Release of Information form.

2. "HIPAA" form:

This is a federal Privacy Act requirement. Similar to forms now used at all hospitals and doctors offices. Legal language. It is necessary so that patients understand that certain private information will be shared with the PPB Registry, but that such information is protected in most circumstances.

3. "Assent" Form:

Required only for older children and adolescent PPB patients (ages 7 – 17 years). This form is required in order to obtain the "assent" (agreement) of children who are old enough to understand that research will be done about their PPB, but who are too young to give formal consent.

- **PLEASE DOWNLOAD AND PRINT THESE ORMS**
- **READ CAREFULLY**
- **SIGN FORMS**
- **FAX or MAIL TO THE PPB REGISTRY**
- **RETAIN A COPY FOR YOURSELF**

THANK YOU FOR PARTICIPATING IN THE REGISTRY'S RESEARCH

Name of Participant (please print)

Children's Hospitals and Clinics of Minnesota
2525 Chicago Avenue South, Minneapolis, MN 55404 USA
347 North Smith Avenue, St. Paul, MN 55102 USA

RESEARCH CONSENT FORM

The International Pleuropulmonary Blastoma Registry

This is a research registry (a database about patients). Research registries include only patients who choose to take part. Please take your time to make your decision. Discuss it with your friends and family.

You are being asked to take part in The International Pleuropulmonary Blastoma Registry. You are being asked because your child has been diagnosed with pleuropulmonary blastoma (PPB), a rare tumor of the lung and the pleura (which is the tissue lining the chest cavity).

You are considering whether or not to authorize your child's hospital to send information on your child to The International PPB Registry, a central database about your child's illness, its treatment, and the clinical course over time. Because PPB is rare, this kind of information is often not available in the medical literature.

This research is conducted by The International Pleuropulmonary Blastoma Registry, which is based at Children's Hospital and Clinics of Minnesota, St Paul and Minneapolis, Minnesota USA and Barnes-Jewish and Children's Hospitals of Washington University, St Louis, Missouri USA. The International PPB Registry is supported by charitable contributions.

WHY DOES THIS REGISTRY EXIST?

Cancer researchers study different types of cancer to learn more about what causes cancer, how to prevent it, how to stop it from spreading to other parts of the body, and how to cure it. The purpose of this Registry is to collect clinical information about patients who have PPB and about their families. The Registry then analyzes this information (that is, does research). The results of this analysis are made available to doctors to help in the care of PPB patients and for research about the causes and treatment of PPB.

HOW MANY PEOPLE WILL TAKE PART IN THE REGISTRY?

All patients diagnosed with PPB are eligible to be a part of this registry. It is estimated that 25 - 50 new patients are diagnosed with PPB each year around the world and are eligible to be part of the Registry.

WHAT IS INVOLVED IN THE REGISTRY?

If you give your permission for your child's case of PPB to be included in the Registry, information about the patient's diagnosis, age, date of birth, sex, x-rays and x-ray reports, surgical and pathology reports and findings, detailed family medical history, and treatment records are sent to the Registry at Children's Hospitals and Clinics of Minnesota in Minneapolis, Minnesota. In addition, pathology specimens of your child's tumor from the hospital where the diagnosis was made will also be sent to the Registry and will be reviewed and retained by the Registry pathology consultants at the Pathology Department of Barnes-Jewish and St. Louis Children's Hospital at Washington University Medical Center in St. Louis, Missouri USA. In some cases as part of the diagnostic process, frozen tumor tissue is sent to the Registry for special testing. If the Registry wishes to retain this frozen tissue for future research into genetic (DNA) changes associated with PPB, the family will be asked to sign a separate consent giving permission for retaining the frozen tissue. The patient's name and other identifying information is removed from these records, and each patient is assigned a random Registry number to protect their privacy.

WHO WILL BE RESPONSIBLE FOR PATIENT CARE DECISIONS?

Your local physicians retain all responsibility for patient care decisions.

HOW LONG WILL MY CHILD'S INFORMATION BE IN THE REGISTRY?

A patient's clinical information will be stored indefinitely.

WHAT ARE THE RISKS OF THE REGISTRY?

Many steps are taken to keep all personal information confidential, as described below. Nevertheless, there is some risk that confidentiality will not be maintained.

ARE THERE BENEFITS TO TAKING PART IN THE REGISTRY?

There is no immediate or direct benefit from being included in this registry. Indirectly, having the patient's medical data in the Registry will help physicians and researchers learn more about PPB and its treatment. The information may be helpful in the treatment of PPB in the future.

WHAT OTHER OPTIONS ARE THERE?

The other option is to not participate in this Registry.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep all personal information confidential, but we cannot guarantee absolute confidentiality. Records of patients are private and will be kept in locked cabinets in the offices of The International PPB Registry staff. Patient names will be replaced in the files and the database with randomly-assigned Registry case numbers. Information collected by the Registry may be published in scientific journals but will not identify any patients.

WHAT ARE THE COSTS?

There is no cost to patients if they participate. You will receive no payment for taking part in this Registry.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this Registry is voluntary. You may choose not to take part, and you may withdraw from the Registry at any time. The health care your child will receive at your local hospital will be the same whether or not you choose to take part in the Registry or choose to withdraw at a later time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the Registry, contact Dr. Yoav Messinger at Children's Hospitals and Clinics of Minnesota, St Paul, Minnesota USA (651 220 6732 or yoav.messinger@childrensmn.org) or Dr. Jack Priest at The International PPB Registry in Minneapolis, Minnesota USA (612 813 7115 or jprst@prodigy.net).

If you have any questions about your rights as a research participant, discuss them with your physician and obtain their advice. Your physician may direct you to a local Research or Ethics Board administrator at your hospital who can also help you. You may also call Elizabeth Kipp-Campbell, Ph.D., Children's Hospitals and Clinics of Minnesota Institutional Review Board Administrator at (651) 220-5818 in St. Paul, Minnesota USA.

If you have any questions or concerns that you feel you would like to discuss with someone who is not on the research team, you may seek advice from someone within the Social Service/Social Work Department or Nursing Services Department of your hospital.

WHERE CAN I GET MORE INFORMATION?

The Registry suggests that you look at the Internet website for the International PPB Registry (www.ppbregistry.org) for information about PPB and about the Registry activities.

You will get a copy of this form. You will be given a copy of the protocol (full study plan) upon request.

SIGNATURES

I agree to have my child's PPB case be part of The International PPB Registry.

I agree to have the physicians, nurses, data mangers/data clerks or Medical Records Department at my child's hospital and clinic send the following to the International PPB Registry; this information is also summarized on the Authorization to Release Information, which is on the following page :

- Hospital discharge summaries
- Pathologist's reports on surgical specimens, bone marrow, spinal fluid
- Surgical/operative reports
- Radiology reports (x-ray, CT scan, MRI scan, bone scan etc) and/or copies of x-ray films, scans, electronic files
- Treatment records (chemotherapy, radiation therapy, including chemo roadmaps)
- Consultations
- Pediatric Oncology CLINIC records
- Pathology specimens for confirmation of diagnosis and enrollment in PPB Registry
- Family medical history including family medical history diagram

Please send the requested information to:

The Pleuropulmonary Blastoma Registry
Children's Hospitals and Clinics of Minnesota
2545 Chicago Avenue South
Suite 412
Minneapolis, MN 55404 USA
E-mail inquiries: gretchen.williams@childrensmn.org

Telephone: 612 813 7115
Fax: 612 813 7108

Participant/Patient _____ Date _____

Participant/patient did not sign. Reason (for example, young age) _____

Parent/Guardian Signature _____ Date _____

Parent/Guardian Signature _____ Date _____

IRB# 98107

Initial IRB Approval: 11/17/04

Most recent IRB approval: 11/10/10

Please also answer this question:

Do you agree to be contacted in the future about additional, special studies proposed by the International PPB Registry? These additional studies include, but are not limited to, a study that seeks to identify gene changes that may lead to the development of the PPB cancer syndrome and to understand how other tumors, such as cystic nephroma, are associated with these same genes changes within a family (IRB#0504-038).

YOU DO NOT NEED TO AGREE TO THIS.

_____ I agree to be contacted in the future

_____ I do not agree to be contacted
in the future

IF YOU AGREE:

Name: _____

Address: _____

City, State, Postal/Zip Code: _____

Telephone Number: _____

Email address: _____

AUTHORIZATION FOR RELEASE OF INFORMATION

This information is released for clinical research conducted by:

The International Pleuropulmonary Blastoma (PPB) Registry

The PPB Registry cooperates with the Rare Tumor Sub-Committee of the Children's Oncology Group (COG) but is not an official part of or sponsored by COG.

Patient Name: _____ Date of Birth: _____
Please print (mo / day / year)

I authorize the following to release clinical and laboratory information on my child named above:

Doctor's Name: _____

Hospital Name: _____

The following information is requested:

- Hospital discharge summaries
- Pathologist's reports on surgical specimens, bone marrow, CSF
- Surgical/operative reports
- Radiology reports (x-ray, CT scan, MRI scan, bone scan etc) and/or copies of x-ray films, scans, electronic files
- Treatment records (chemotherapy, radiation therapy, including chemo roadmaps)
- Consultations
- Pediatric Oncology CLINIC records
- Pathology specimens for confirmation of diagnosis and enrollment in PPB Registry
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I understand that the information in my (my child's) health record may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV). It may also include information about behavioral or mental health services, child abuse and treatment for alcohol and drug abuse.

This Authorization does not have an expiration date, but I understand that I have a right to revoke this authorization at any time. I understand that if I stop this authorization, I must do so in writing to the PPB Registry. I understand that stopping this authorization will not apply to information that has already been released or disclosed.

I understand that authorizing the release of this health information is voluntary. I can refuse to sign this authorization. I understand that I may inspect or copy the information to be used or disclosed. I understand that any disclosure of information carries with it the potential for redisclosure and the information may not be protected by federal privacy rules.

Printed Name of Parent or Guardian

Date Signed

Signature of Parent or Guardian

Relationship to Patient

Address City State Zip Code

Parent or Guardian Home Phone

Parent or Guardian Work Phone

Name of Participant (please print)

Children’s Hospitals and Clinics of Minnesota – St Paul & Minneapolis, Minnesota

Assent Form for Child or Adolescent

The International Pleuropulmonary Blastoma (PPB) Registry

You are being asked to be in a research study because you have an illness called PPB. PPB is a lung tumor (a kind of cancer) which can be very serious, but which can be cured in many children. PPB is very rare; so your doctors want to share your case with others who are collecting information on PPB. The PPB Registry collects information from all over the world on children with PPB. Already a lot has been learned about PPB because of the information which has been collected. But all the doctors and researchers hope that if more is learned, the treatments of PPB will be more successful.

If you are part of this research study, information about you is sent to the main research office. Information about your illness and how you respond to treatment will be sent. We do not use your name on any forms. Instead, we use a number so that you can be private.

We hope that you will allow us to share information about your illness with the PPB Registry. But if you do not want to be in this research project, you are free to say "no" and not to sign this permission form. No one will be mad at you if you say "no". You will still receive the best possible treatment for your PPB if you are not part of this project.

Name of Participant (please print)

Signature: Assent by child/adolescent

Date

Please also answer this question:

Do you agree to be contacted in the future about additional, special studies proposed by the International PPB Registry? These additional studies include, but are not limited to, a study that seeks to identify gene changes that may lead to the development of the PPB cancer syndrome and to understand how other tumors, such as cystic nephroma, are associated with these same genes changes within a family (IRB#0504-038). **YOU DO NOT NEED TO AGREE TO THIS.**

_____ I agree to be contacted in the future _____ I do not agree to be contacted in the future

IF YOU AGREE:

Name: _____

Address: _____

City, State, Postal/Zip Code: _____

Telephone Number: _____

Email address: _____

To the professional:

This form is to be used for a child with PPB who is between age 7 and 17 years. It is to be discussed with the parent(s) or guardian(s) before being discussed with the child. They may be the ones who discuss this form and The PPB Registry with the child, but the conversation should be observed by the medical staff.

If the child does not sign this form but you and the family (or guardians) believe the child has in fact *actively assented* to be included the Registry, document the discussion here. Please state the specific behaviors of the child's assent (*child shook head yes or child said "OK" after hearing about the research Registry*):

Researcher or medical staff witnessing assent

Date

IRB# 98107

Initial IRB Approval: 11/17/04

Most recent IRB approval: 11/10/10

- Researchers working with The International PPB Registry at the Children's Hospitals and Clinics of Minnesota, St Paul and Minneapolis, Minnesota and Barnes-Jewish and St. Louis Children's Hospitals, St. Louis, Missouri
- Federal and state agencies that have authority over the research, over Children's, or over patients (for example the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Office of Human Research Protections, the Department of Social Services or other governmental offices as required by law).
- Hospital accrediting agencies or other accrediting agencies.
- Clinical staff not involved in the study who may become involved in you/your child's care, if it is potentially relevant to treatment
- The Children's Hospitals and Clinics of Minnesota Institutional Review Board
- Children's Hospitals and Clinics of Minnesota officials or representatives

What is the potential for re-disclosure of your/your child's PHI?

All reasonable efforts will be used to protect the confidentiality of your/your child's PHI. It will be shared with others involved in this research to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share it with others if the law requires them to do so, and they may share it with others who may or may not be required to follow the federal privacy rule. Although The International PPB Registry is required to inform you of the above possibilities, the Registry does not foresee a situation where it will disclose your/your child's PHI to others who are not covered by the federal privacy rule.

For how long will you/your child's PHI be used or shared with others?

There is no scheduled date at which this information will be destroyed or no longer used. This is because information that is collected for research purposes continues to be analyzed for many more years and it is not possible to determine when this will be complete. Because of this, this authorization does not have an expiration date.

What are your/your child's rights after signing this authorization?

You/your child have the right to withdraw at any time from participating in this research. You have the right to revoke in writing your permission (1) for your physicians and hospital to share you/your child's PHI with the Registry and (2) for The International PPB Registry to use the PHI acquired in connection with the research, except to the extent that the Registry has already relied on your permission to conduct the research and related activities, such as oversight. If permission is withdrawn and you are no longer participating in the Registry study, no further PHI will be acquired. If you want to withdraw your permission, contact the investigator and you will be asked to complete a written form.

You have the right to choose not to sign this form. If you decide not to sign, you will not participate in the research. Choosing not to sign will not affect the current or future care you/your child receives at your hospital and will not cause any penalty or loss of benefits to which you are otherwise entitled.

If you/your child choose to share PHI with anyone not directly related to this research, the United States federal law designed to protect your privacy may no longer protect this information.

What are you/your child's rights to access your/your child's PHI?

Subject to certain legal limitations, you/your child have the right to access the PHI on you/your child that is created during this research that relates to your treatment or payment provided and is not exempted under certain laws and regulations. You may access this information only after the study analyses are complete. To request this information, you will need to contact The International PPB Registry Privacy Officer at 612-813-6911 in Minneapolis, Minnesota USA.

By signing this form, you authorize your physicians, nurses, data managers/data clerks and Medical Records Department to disclose your/your child's PHI to The International PPB Registry for the purposes described above. You also permit your/your child's doctors and other health care providers to disclose you/your child's health information for the purposes described above.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you should contact your physician or the Ethics or Review Board at your hospital. You may call the Registry Privacy Officer at 612-813-6911 in Minneapolis, Minnesota USA.

CERTIFICATIONS AND SIGNATURE SECTION

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

SIGNATURE of Research Subject (Child) or
Research Subject's Authorized Representative (parent)

Date

PRINTED NAME of Research Subject (child) or
Research Subject's Authorized Representative (parent)

Representative's relationship to Research Subject

Please explain Authorized Representative's relationship to the Subject and include a description of the Representative's authority to act on behalf of the subject:

