

**RESEARCH INFORMATION AND CONSENT FORM**

COG PROTOCOL:

**Title :**

**Participant’s Name:**

**Persons responsible :**

* Montreal Children’s Hospital : Dr. Sharon Abish

 or Dr. \_\_\_\_\_\_\_\_\_\_\_, researcher responsible for this project

* CHU Sainte-Justine : Dr Yvan Samson,

 or Dr. \_\_\_\_\_\_\_\_\_\_\_, researcher responsible for this project

* CHU de Québec : Dr. Bruno Michon

**Funding Source:** COG, Leucan **(Adapt to context)**

It is a principle of medical ethics to obtain a written informed consent before starting any experimental procedure or treatment or participation in a research study.

If you are a parent or legal guardian of a child who could take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say “you” in this consent form, we mean you or your child.

**WHY ARE YOU BEING INVITED TO TAKE PART IN THIS STUDY?**

You are being asked to take part in this study because…

This study is called a clinical trial. A clinical trial is a research study that attempts to find or improve treatment of a disease in human patients. This study is organized by the Children’s Oncology Group (COG). COG is an international research group that conducts clinical trials for children with cancer. More than 200 hospitals in North America (16 in Canada), Australia, New Zealand and Europe are members of COG. COG is funded by the federal government in the United States through the National Cancer Institute (NCI).

It is common to enroll children and adolescents with cancer in a clinical trial that seeks to improve cancer treatment over time. Clinical trials include only people who choose to take part. You can choose to participate in this clinical trial, or not. If you choose not to participate, you will be offered the standard treatment.

Please take your time to make your decision. You may want to discuss it with your doctor, family and friends. We encourage parents to include their child in the discussion and decision to the level that the child is able to understand and take part.

**WHAT IS THE CURRENT STANDARD OF TREATMENT FOR THIS DISEASE?**

Specific to each consent.

**WHY IS THIS STUDY BEING DONE?**

Specific to each consent.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

About \_\_\_ patients from different hospitals, here, and around the world will take part in this study.

**WHAT WILL HAPPEN ON THIS STUDY THAT IS CARE VERSUS RESEARCH?**

Specific to each consent.

If there is an FDG PET-scan:

FDG PET Scan

A FDG PET Scan is a type of imaging study (scan) that uses a special dye flurodesoxyglucose (FDG) that is considered investigational in Canada. We are doing them as a part of this study. Some subjects on this study will have an FDG PET scan to help find out if FDG PET scans are good at finding tumours or showing tumour changes during therapy. A special dye (FDG) is given in a vein and travels to the places where there is high activity in your cells, which can mean tumour cells. Next, you have to lie very still on the PET scanner while the pictures are being taken You do not have to have an FDG PET scan to be on this study [*this will vary according to protocol requirements*]. The risks and inconveniences of FDG PET scans include:

* Fasting for several hours before the scan.
* FDG is given in a vein, which usually requires a needle stick.
* The FDG dye has a small amount of radiation. It is less than the amount you would get from a chest CT scan.
* Some people feel closed-in during the PET scan, but the scan itself does not hurt.

HOW LONG IS THE STUDY?

Participants in this clinical trial will receive (if pertinent add “experimental”) treatment as part of this research project for a period of \_\_\_\_ months. Participants will also undergo examinations and medical tests as described here as part of their follow up.

We would like to continue collecting information about your health every year for about \_\_\_years after the end of your active participation in the research project. Keeping in contact with you for some time after you finish your treatment may help us to learn about the long-term effects of the experimental treatment being studied.

Your doctor or the doctor in charge of this research project can also decide to take you off this study, namely:

* If she or he believes it would be in your best interests;
* If your disease gets worse;
* If you have side effects that she or he believes are too dangerous;
* If new information shows that another treatment, more appropriate for you, becomes available.

WHAT ARE THE RISKS OF THE STUDY AND HOW ARE THE RISKS DIFFERENT FROM STANDARD TREATMENT?

Specific to each consent.

**Risks related to standard treatment**

Everyone who receives a treatment for cancer is at risk of side effects. As well as getting rid of cancer cells, chemotherapy can also damage healthy tissue and cause side effects. These side effects usually go away once the chemotherapy is stopped, but in rare cases, side effects can persist for a long time or even never go away. Some of the side effects are unpleasant but not dangerous, others can put your life at risk.

The risks of each of the medications administered as part of standard treatment are listed in Attachment #2.

Common side effects include nausea, vomiting, hair loss and fatigue. We can give medication to prevent or minimize nausea and vomiting. Hair loss is usually temporary but can, in rare cases be permanent. Some chemotherapies can affect your ability to have children in the future. In rare cases, some people can develop a second cancer related to the chemotherapy. If this happens, it is usually years after chemotherapy has been stopped.

Side effects can be increased when chemotherapy medications are combined.

The most common serious side effect of cancer treatment is a drop in blood cell counts that causes anemia and increases the risk of infection and bleeding.

**Risks specific to this research project**

Giving the combination of \_\_\_\_\_\_\_\_ with the standard chemotherapy as part of this research project is experimental. We do not know how participants with \_\_\_\_\_\_\_\_\_ will react to this new approach to chemotherapy. We do not know if administering \_\_\_\_\_\_ with standard chemotherapy will be better at stopping your cancer from coming back for as long as possible.

Using \_\_\_\_\_\_ in association with the standard chemotherapy may cause more complications than the standard chemotherapy alone.

It is possible that the experimental treatment we are studying could be less effective than the current standard of treatment.

**If pertinent :**

The risks of an FDG-PET scan include the discomfort of fasting, exposure to the small amount of radiation, pain from the needle stick, and discomfort/feeling closed in while lying still for the scan.

**Notices Specific to project**

Participation in this research project may also have other risks that we do not know or have not predicted.

**Reproduction risks**

Women should not become pregnant and men should not father a baby while on this study because the drug(s) in this study could be bad for an unborn baby. If you or your partner can get pregnant, it is important for you to use birth control or not have sex while on this study. Some birth control methods are not recommended for participants in this study. Check with your study doctor which birth control method is suggested for participants on this study and for how long you should use it. Women and men must use the birth control method throughout their participation but also for \_\_\_\_ months after they stop participating. Women should not breastfeed a baby while on this study. Also check with your doctor about how long you should not breastfeed after you stop the study treatment(s).

**Exceptional Case – possible shortage of study medication**

Even though it probably won’t happen, the manufacturer could stop providing [*Insert name of drug(s)*] for this research project for some reason. If this were to happen:

* It may be possible to obtain the medication directly from the manufacturer or from your pharmacy.
* If the medication is no longer available at all, no one will be able to get more and the study would close. A different care plan would then be offered to you.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

We hope that you will get some personal medical benefit from participation in this clinical trial, but we cannot be certain. A potential advantage we hope for is to stop your cancer from coming back for a long period of time or to stabilize the disease.

We also hope that what we learn from doing this study will help us find better ways to treat patients with this disease in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of participating in this research project, you could choose one of the following options:

* Receive the standard treatment.
* Participate in another research project if available.

**If relevant, add :**

* Receive comfort care, sometimes called palliative care. This kind of care aims to reduce pain, fatigue, appetite problems and other kinds of symptoms caused by cancer. Palliative care does not actively treat the cancer, instead it aims to help you feel as well as possible and to maintain a life as active and comfortable as possible.

Please talk to your doctor about these options.

**WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**

The study medication(s) administered as part of this research protocol will be provided to you. You will not have to pay for them, nor any of the tests or procedures that are part of the study.

Neither the hospital, nor the sponsor of this protocol, the US National Institutes of Health or the COG, has a program for monetary compensation in case of harm resulting from your participation. If you suffer side effects as a result of your participation in this research project, you will receive all necessary care that is covered by Quebec’s provincial health insurance plan (RAMQ) and by your medication insurance plan. You would be responsible for any costs that are not covered.

**ARE THERE OTHER FINANCIAL ASPECTS?**

If you choose to enroll your child on this study, your hospital will receive some money from the COG to cover part of the costs related to conducting the research.

You will not be paid, nor reimbursed for any costs incurred, for taking part in this study.

**If applicable:**

This study includes collecting specimens for research purposes; You will receive no profit from any new products developed from research done using your specimens.

**WHAT ABOUT PRIVACY?**

The members of the research team will access your medical record to collect the information needed for this research project.

All information obtained during the study will be kept confidential as required or permitted by law.

Your identity will be protected by replacing your name with a research number. Only the research team at your own hospital will have access to the code linking your name to this number.

For your safety, a copy of this signed consent form and some information about the research, ex. name of any experimental medications given, will be filed in your medical record.

In order to ensure your protection and quality control of the research project, the following organizations could consult your research and medical records:

* + The Children’s Oncology Group and its collaborators;
	+ Representatives from the National Cancer Institute (NCI), and their Pediatric Central Institutional Review Board;
	+ Canadian, American or International governmental regulatory bodies such as Health Canada, the Food and Drug Administration (FDA) in the US and European Medicines Agency;
	+ The research ethics committees of the Quebec hospitals where the research is happening or a person mandated by one of them;
	+ The drug company that makes (study drug) or its representatives.

They all adhere to confidentiality policies.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

The principal investigator at your hospital will be responsible for securely storing the research data for 25 years.

Only coded data (and/or biological samples if applicable) will be sent to or stored by COG in the United States.

**IS YOUR PARTICIPATION VOLUNTARY?**

Yes. Taking part in this study is voluntary. You may choose not to be in this study. You can decide to stop being in the study at any time. If you decide to stop participating in the study, please speak with a member of the research team who will help make sure you stop safely.

If you decide not to participate, or stop participating later on, this will not affect the quality of care you receive.

We will tell you about any new information that may affect your health, well-being, or your willingness to stay in this study.A committee outside of COG closely monitors study reports and notifies the hospitals if changes must be made to the study.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

If you have any questions about this research project or if you suffer any problems you believe are related to your participation in this research, you can call the researcher responsible for the project in your hospital:

Montreal Children’s Hospital, MUHC: Dr. Sharon Abish, at (514) 412-4445

* CHU Sainte-Justine : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* CHU de Québec : \_\_\_\_\_\_\_\_\_\_\_\_\_.

In case of emergency, please contact the Hematology-Oncology department of your hospital or go directly to the closest emergency room**.**

If you would like information about your rights related to your participation in the research, you may contact your hospital’s Ombudsman (Patient Representative):

* Montreal Children’s Hospital, MUHC : 514-412-4400, poste 22223
* CHU Sainte-Justine : 514-345-4749.
* CHU de Québec au 418-654-2211

**WHERE CAN I GET MORE INFORMATION?**

* + The**COG Family Handbook for Children with Cancer**has information about specific cancers, tests, treatment side effects and their management, adjusting to cancer, and resources. Your doctor can get you this Handbook, or you can download it at [www.thechildrensoncologygroup.org/familyhandbook](http://www.thechildrensoncologygroup.org/familyhandbook).
* The **Canadian Cancer Society** toll free at **1–888–939-3333** or http://www.cancer.ca
* A description of this clinical trial will be available at <http://www.ClinicalTrials.gov> as required by US law. This website will not include information that can identify you. At most, the web site will include a summary of the results. You can search this website at anytime.
* A description of this clinical trial will also be available at: <http://canadiancancertrials.ca/>
* During your follow up visits, you may request a summary of the results of this research project; the results will only be available after the entire project has been completed. A summary of the results will also be posted on the Children’s Oncology Group website at (<http://childrensoncologygroup.org/>) in English only. To obtain the results you can either (1) visit the website to check if the results are available, or (2) register on the COG website to receive an e-mail when the results become available. The pediatric oncology team of your hospital can also offer more information on how to get results. Please note that the summary of results may only become available several years from now, after ALL the participants have fully completed their participation, and not simply once you have completed yours.

You will receive a signed copy of this consent form. You may also request a copy of this research protocol (complete study plan).

**RESEARCH ETHICS COMMITTEE**

The research ethics committee of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ approved this project and will monitor the project.

CONSENT AND ASSENT FORM

**Title**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**COG # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I have been explained this study and what will happen if I participate. I read the research information and consent form of \_\_\_ pages including the addendums and was given a copy to keep. I asked my questions and was answered to my satisfaction. After thinking about it, I agree to participate (18 years +) or that my child participate in this research project.

I authorize the research team to consult my medical records or the medical records of my child to collect the information relevant to this project.

In no way does consenting to participate in this research study waive your legal rights nor release the sponsor or the institution from their legal or professional responsibilities if you are harmed in any way.

Child’s name Assent of child able to understand Date

(Print) the nature of the research project

 (signature) or verbal assent obtained by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of parent(s) or legal guardian Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of participant (18+) Signature  Date

I have explained to the participant and/or his parent/tutor all the relevant aspects of this study. I answered any questions they asked. I explained that participation in a research project is free and voluntary and that they are free to stop participating at any time they choose.

Name of Physician (signature) Date

(Print)

**Addendum to consent form**

**Participant who has now become an adult (18)**

**Title of COG research project \_\_\_\_\_\_\_\_\_\_\_\_\_**

Today, I reviewed the information and consent form that my parents signed on my behalf when I enrolled in this research project and a copy of that signed consent was given to me.

I agree to continue my participation in this research project.

I understand that my participation is free and voluntary and that I can stop participating in this research project at any time I choose.

I authorize the research team to consult my medical records to collect the information relevant to this project.

In no way does consenting to participate in this research study waive your legal rights nor release the sponsor or the institution from their legal or professional responsibilities if you are harmed in any way.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of participant  Signature  Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physician Signature Date

Annexe 1

**INFORMATION ABOUT THE BIOLOGICAL ASPECT OF THE RESEARCH AND CONSENT FORM**

COG PROTOCOL:

**Title :**

It is common practice to use biological specimens (ex. Blood, bone marrow, etc) to better understand the underlying causes of cancer. The biological aspect of this research project will only be conducted on samples from people who agreed to participate. You may choose not to participate in this part of the research, and still participate in the rest of the project.

**WHY ARE WE DOING THIS BIOLOGICAL ASPECT ?**

**Specific to each consent**

**WHAT WILL HAPPEN IN THIS BIOLOGICAL ASPECT?**

**Specific to each consent**

**aspect – additional analyses of specimens**

We are trying to understand biological factors that can cause \_\_\_\_\_\_\_\_\_\_\_\_\_\_in children with \_\_\_\_\_\_\_\_\_\_\_\_\_\_. We would like to do some extra tests/analyses on your child’s sample of \_\_\_\_\_\_\_\_\_\_\_ for research purposes.

The samples used to do these tests will be sent to a research laboratory in the United States.

**Specfic to each consent** :

What kind of sample and how it will be collected

Volume of sample

Number of samples to be taken

Will these samples be taken at the same time as other samples taken as part of clinical care?

**Biobank Aspect**

The main goal of this study is to collect samples of biological material, namely \_\_\_\_\_\_\_\_\_\_\_ and information about patients who have a diagnosis of \_\_\_\_\_\_\_\_\_\_\_. These samples and the related information will be saved in a “biobank” so that they can be studied and used in future research projects aiming to better understand the biological mechanisms that cause \_\_\_\_\_\_\_\_\_ and its treatment. The samples and the information could be used by researchers anywhere in the world. Access to the samples will be granted by an American committee.

**HOW LONG IS THE BIOLOGICAL OR BIOBANKING PARTS OF THE STUDY?**

We will continue to collect information about your health for the next \_\_\_\_\_\_ years.

Your samples will be sent to the United States and destroyed once the testing has been completed.

OR

Your sample will be sent to the United States and used only for this particular project until there isn’t any sample left.

OR

Any left over samples will be conserved in a biobank located in the United States for an indefinite period of time. Your samples can be used for as long as there is any sample left.

OR

Your sample will be sent to the biobank, located in the United States. It will be conserved there for an indefinite period of time. Your samples can be used for as long as there is any sample left.

**WHAT ARE THE RISKS SPECIFIC TO THE BIOLOGICAL ASPECT?**

**Adapt according to context**

Examples :

The samples for research will be taken at the same time as samples being taken for patient care. No extra procedures will be done solely for the purpose of getting these research samples. Possible inconveniences could include a longer time needed to acquire the extra sample, more pain or a higher risk of infection. The amount of sample taken is safe.

Taking blood can be unpleasant and can cause bruising, discomfort and rarely, an infection. The amount of blood taken is safe.

**\*\*NOTE to researchers : Bone marrow aspirates or lumbar punctures for strict biological research purposes : refused by Quebec REB’s unless there is a strong ethical justification for doing so.**

**WHAT ARE THE ADVANTAGES OF PARTICIPATING IN THE BIOLOGICAL ASPECT?**

There is no direct personal benefit to you by participating in the biological aspect of the research.

We hope that what we learn from doing these biological studies will be useful in the treatment of other patients who are diagnosed with this disease in the future.

**WILL I BE INFORMED OF THE RESULTS?**

You will not be informed of any results from these biological analyses.

OR

It is highly unlikely that these tests would give us any information that has any impact on your actual or future health. If this should happen, the researchers will contact your doctor by tracing your sample through COG processes to explain the results to him. Only your doctor will be informed and the information will not be put in your medical file. These results would remain confidential. Your doctor could recommend a consultation with a genetic counselor or to repeat the test in a certified laboratory. It is also possible that your doctor will not recommend any further investigation.

**WHAT ARE THE FINANCIAL ASPECTS?**

This research project will collect biological samples to use for research. New commercial products could be developed from these samples and eventually generate profits. However, you will not have a right to share in any profits.

**WHAT ABOUT PRIVACY?**

Your identity will be protected by replacing your name with a research code. Only the research team at your hospital will have access to the link between that code and your name. Only coded information and samples will be sent to or stored by COG.

**IS YOUR PARTICIPATION VOLUNTARY?**

The biological aspect of this research is optional and will only be carried out if you agree. If you do not agree to participate in the optional biological aspect, you can still participate in the rest of the study.

To stop participating in the biological aspect, you must tell the research doctor or a member of the research team. If you withdraw from the biological aspect, any remaining samples will be retraced and destroyed.

Any data analysis that has already been completed will be kept.

**COMITÉ D’ÉTHIQUE DE LA RECHERCHE**

The research ethics committee of \_\_\_\_\_(hospital)\_\_\_\_\_\_\_\_\_\_ approved this project and will monitor the project.

N.B.: The COG becomes the owner of any tissue or samples and the information related to them once you consent to their storage and use for future research (this project). Accordingly, the Quebec research ethics committee and the researcher at your hospital will have no authority over the use made of your samples in the future.

**ASSENT AND CONSENT**

Titre du projet de recherche

**COG # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I have been explained what will happen on the biological aspect of this study. I read the information I was given about the biological aspect of the project. I asked my questions and was answered to my satisfaction. After thinking about it, I agree to participate (18 years +) or that my child participate in the biological aspect of this research project.

**Examples of choices :**

I accept \_\_\_\_\_ (initial) or I do not accept \_\_\_\_\_ (initial) that my sample of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ be stored in a biobank for future research that aims to better understand, prevent or treat cancer.

I accept \_\_\_\_\_ (initial) or I do not accept \_\_\_\_\_ (initial) that my sample of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ be stored in a biobank for future research that aims to better understand, prevent or treat other health problems (ex. Diabetes, Alzheimer’s, heart disease).

I accept \_\_\_\_\_ (initial) or I do not accept \_\_\_\_\_ (initial) that samples of my blood be taken for the purpose of studying pharmacokinetics.

I authorize the research team to consult my medical record or my child’s medical record to collect the information relevant to this project.

Child’s name Assent of child able to understand Date

(Print) the nature of the research project

 (signature) or verbal assent obtained by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of parent(s) or legal guardian Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of participant (18+) Signature  Date

I have explained to the participant and/or his parent/tutor all the relevant aspects of the biological study. I answered any questions they asked. I explained that participation in a research project is free and voluntary and that they are free to stop participating at any time they choose.

Name of Physician (signature) Date

(Print)

**Addendum to consent form**

**Participant who has now become an adult (18)**

**Title of COG research project # \_\_\_\_\_\_\_\_\_\_\_\_\_**

Today, I reviewed the information and consent form that my parents signed on my behalf when I enrolled in the biological aspect of this research project and a copy of that signed consent was given to me.

I agree to continue my participation in the biological aspect of this research project.

I understand that my participation is free and voluntary and that I can stop participating in the biological aspect of this research project at any time I choose. If I withdraw from the biological aspect of the study, my remaining samples will be retraced and destroyed.

I authorize the research team to consult my medical records to collect the information relevant to this project.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Name of participant  Signature  Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Physician Signature Date

**Attachment nº2**

**Table of risks related to standard treatment**

**Attachment #3**

**Certificate of Confidentiality**

The Children's Oncology Group has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research subjects. The Certificate protects against the involuntary release of information about subjects collected during the course of our covered studies. The researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the subject or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the subject or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act.

The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.