**Faculty:** …………………………...… **Hospital:** ………………………

**Department:** ……………………… **Department:** …………………………

**Title of the Project:**

…………………………………………………………………………………………………..

**What is the purpose of the Study?**

…………………………………………………………………………………………………..

…………………………………………………………………………………………………..

**Why has your child been invited to participate?**

…………………………………………………………………………………………………..

**What procedures will be performed on your child?**

…………………………………………………………………………………………………..

…………………………………………………………………………………………………..

**What are the benefits of your child’s participation in this study?**

…………………………………………………………………………………………………..

**What are the risks of your child’s participation in this study?**

…………………………………………………………………………………………………..

**What will happen to the information provided by your child’s participation?**

…………………………………………………………………………………………………..

…………………………………………………………………………………………………..

**Who do you contact if you want further information?**

Investigator name: ……………………………………………… Tel.: ………………………………

**Invitation to participate *(PI shall update this part according to his/her project)*:**

Please note that you have the right to accept or to reject for your child to participate in this study. In case you accepted, you have the right to withdraw your child’s participation at any stage of the study, without affecting his/her medical treatment (if the child was patient).

**Date:**

***Agree***  **Name of** **Guardian** **of** **Patient/Participant: Signature:**

***Don’t Agree*** **Name of** **Guardian** **of** **Patient/Participant:**

**Signature:**

**Guidelines:**

* Inthe **Procedures** section, you shall describe the tests (type of test, samples, volume and frequency) that you and your co-investigators will use in this research. Please make sure that you are using simple language (layman language) so that the guardian can understand exactly what will happen to his/her child during this study. Do not use scientific details that may does not concern the guardian.
* Inthe **Controls** section, Control subjects (specify example: healthy brothers/sisters of the patients, others and what will they be subjected to if anything at all)
* After explaining the procedure and purpose of the study, you must emphasize that every guardian has the right to accept or refuse admission of his/her child to the study. Upon agreement, the investigators promise to keep the child’s personal information strictly confidential, not to share any information outside the spectrum of this study, and not to send any samples abroad for other purposes without approval of the **HSC Ethical Committee**. In case of refusal to participate, the child will continue to receive the standard treatment for his/her disease.
* Kindly add your name and tel. no. in the end of the form as a contact information for the participants.

Ethical Guidelines for Pediatrics Research

 Children are a vulnerable group in society, who need to be protected and nurtured. They have peculiar and special needs that must be recognized at all times. They pose special challenges when it comes to getting them involved as research subjects. To prevent abuse and lasting physical or psychological disabilities, research involving children must be based on principles recognized by international professional, legal and ethical bodies. They must also take into consideration cultural and religious sensibilities.

 The following guidelines and principles must be followed:

* 1. Research involving children is important for the benefit of all children and should be supported, encouraged and conducted in an ethical manner.

 **1.2.** Research should only be done on children if comparable research in adults could not.

 **1.3.** Children must be protected from harm during research investigations.

 **1.4.** Researchers must use the least stressful procedures possible, ensure that potential stress is outweighed by the benefits and correct unforeseen negative consequences of the research.

**1.5.** The child’s participation must be based on informed and voluntary consent and assent from the guardian. When applicable "When a subject deemed legally incompetent, such a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to consent of the legally authorized representative. Guardians and patients (when applicable) must be allowed to ask questions and make a voluntary decision about their child participation. Children also should be informed about the study (4 – 6 years old), in age-appropriate language and given the chance to agree or disagree to participate.

 **1.6.** The consent form where the project is described in a simple own language (layman’s language) and include purpose of the project, duration of study, samples to be obtained such as blood or tissue samples and procedures such as radiologic or endoscopic or others.

**1.7.** Guardians must be informed of all aspects of the research that could affect their willingness to let their child participate, including study procedures, risks and benefits, protection of the child’s privacy, and child’s freedom to discontinue participation.

 **1.8.** Researchers should share findings responsibly with parents and scientific community in a way that protects participant’s identities and minimizes misinterpretation.

 **1.9.** A research procedure which is not intended directly to benefit the child subject is not necessarily either unethical or illegal.

**Note:**

**Please do not print these pages of guidelines when you submit your papers for the committee secretary.**

**Thank You**