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

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

**Title of the Project:**

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

**1. What will happen to me in this study?**

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

**2. Can anything bad happen to me?**

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

**3. Can anything good happen to me?**

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

**4. Do I have other choices?**

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

**5. Will anyone know I am in the study?**

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

**6. What happens if I get hurt?**

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

**7. Who can I talk to about the study?**

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

**8. What if I do not want participate in this study?**

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

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

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

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

**Date:**

**If you agree to your son/daughter to be in this study, please sign here:**

**Name of Assent’s guardian:**

**Signature of Assent’s guardian:**

***Agree***  **Child’s Name: Signature:**

***Don’t Agree*** **Child’s Name: Signature:**

**Guidelines:**

NOTE: All children 7 - 21 years of age should sign this assent form

Meeting Date with Patient

When you write your text follow the instructional text. Please use simple language and explain terms so the child can understand. When your text is written the instructional text should then be removed prior to submission to the committee. Red text in parenthesis ( ) should be filled in by information of your study.

1. What will happen to me in this study? (Description of the study)

 Explain the reason for the research.

 Describe what the child will be expected to do.

 Describe which part of the study is experimental.

 Describe all procedures using simple terms and explaining any medical terms.

2. Can any bad happen to me? (Risk of Discomforts of Participating)

 Explain any possible risk to the child, using simple terms.

 If something might be painful, state this in the assent.

 Explain that the child should inform his/her parents if they are sick or in pain as

 a result of being in the study.

3. Can anything good happen to me? (Benefit of participating)

 Only describe known benefits to the child.

 You may include any possible future benefits to other.

 If there are no known benefits, state so.

4. Do I have other choices? (Appropriate Alternatives)

 Describe any alternatives procedures that might be available to the child other

 than this study. If none, this section can be omitted

5. Will anyone know I am in the study? (confidentiality)

 Explain in simple terms that the child's participation in the study will be kept secret, but information about him/her will be given to the study sponsor. Note: This ` information may not be applicable in assent forms for very young children.

6. What happens if I get hurt? Compensation for participating/Medical Treatment Describe the child's parents/legal guardians have been given information on what to do if the child is injured during the study. Also explain any compensation (if any) or medical treatment that would be provided if the child is injured during the study.

7. Who can I talk to about the study? (Contact information)

 List people the child can contact if he/she has any questions or problems related to the study. For example: If you have any questions about the study or any problems to do with the study you can contact the Protocol Director (Name Protocol Director). You can call him/her at (Protocol Director's phone number). You can also call (Other name) at (Phone number). Keep the following sentence in exactly as written:

 If you have question about the study but you want to talk to someone else who is not a part of the study, you can call the Health Sciences Center, Kuwait University, Vice Dean for Research office (24636132 – 24636155 - 25319481)

8. What if I do not want to do this? (Voluntary Participation)

 Let the child know that they can stop being in the study at any time without getting in trouble and that their doctor will continue to treat them if treatment is necessary and available.

* The subject’s consent must be confirmed at the time of consent and the signature of both the subject and the person conducting the informed consent must be dated. If the subject is unable to read, oral presentation and explanation of the written informed consent form and information to be supplied to the subject must take place in the presence of an impartial witness. Consent must be confirmed at the time of the oral consent by the signature of the subject or by a locally recognized alternative (e.g. the subject’s thumb print or mark). All signatures must be dated. The witness and the person conducting the informed consent discussions must also sign and personally date the consent document.
* A copy of the signed consent document must be given to the subject. The original signed consent documents will be retained by the investigator.
* The investigator shall not undertake any aspect of the investigation until valid consent has been obtained.
* Subject names shall not be supplied to the sponsor. Only the subject number and subject initials will be recorded in the case report form. The subject will be informed that representatives of the sponsor, independent ethics committee, or regulatory authorities may inspect their medical records to verify the information collected, and that all personal information made available for inspection will be handled in the strictest of confidence and in accordance with local data protection laws.
* The investigator will maintain a personal subject identification list (subject numbers with corresponding subject names) to enable records to be identified.

Ethical Guidelines for Children (7 – 21 years old) in 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 child and his/her 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(child’s guardian).

 **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.** Parents or legal 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. Parents or legal guardians and patients (when applicable) must be allowed to ask questions and make a voluntary decision about their child 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.

**1.10** Kindly add your name and tel. no. in the end of the form as a contact

information for the participants.

**Note:**

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

**Thank You**