Handbook for

Ethical Rules and Regulations for Research Involving Human Subjects

Preface

Qatar University, represented by its Office of Research, has set, as part of its mission, to promote and strengthen research activity in the University to achieve excellence in research. Such research, as set in the QU Research Policies drafted by the Research Policies Committee, should serve a legitimate purpose and be consistent with the university's mission and the national requirements. Achieving such goals requires, in addition to research policies, ethical rules and regulations to ensure that researchers comply to generally accepted scientific principles and refrain from unacceptable practices, and that all proposed research is carried out safely and ethically in accordance with national and international standards.

This document, entitled “Handbook for Ethical Rules and Regulations for Research involving Human Subjects” aims at formulating regulations that apply to all researchers within Qatar University. This handbook starts with the generally accepted common scientific principles that researchers in all branches of, social and natural, sciences are expected to comply with, then detailing the guidelines for research involving human subjects. The document is based on the two documents: "Rules and Regulations for Research" of Hamad Medical Corporation (issued 2000), and "Research Policies, Procedures and Guidelines" of Shafallah Genetics Medical Center, (issued 2007), that, in turn, are based on the most famous international guidelines: the Nuremberg Code (1947), the Belmont Report(1979), Declaration of Helsinki (1964, amended 2000), the Canadian Tri-Council Policy Statement (1999), and the WHO recommendations presented in “ Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services”, (1998) and “Review of Ethical Issues in Medical Genetics and Genetic Services” (2003).

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1 Principles of Science

1.1 Objectivity

The *prima facie* principle for the practice of science is objectivity.
Objectivity is dealing with facts without interference of personal feelings, opinions or attitudes, to avoid all sorts of prejudices or biases. Scientists should refrain from fabricating data, changing data or results, and should be objective in all research steps, in collecting data, analysis and interpretation. As complete objectivity is impossible, scientists should be aware of, and strive to be committed to, the limitations their methods have for finding knowledge. Scientists should be also honest about their funding mechanisms and their commercial interests as these can influence the objectivity of science.

1.2 Cautiousness

Scientists should avoid erroneous results in research. They should strive to lessen the human, experimental and methodological errors to the minimum and avoid self-deception, bias and conflict of interests. This can be achieved by their continuous strive to be skeptic, critical and cautious.

1.3 Openness

Scientists should value, and be committed to, the principle of open research to maintain the advancement of knowledge, with some exceptions (e.g. military secrets). The principle of open research includes the scientists' exchanging data, results, methods, ideas and techniques. Scientists should also be open to criticism and peer review. Openness in science protects science from being dogmatic or uncritical, and helps create an atmosphere of truth and co-operation. Scientists have the ethical obligation to keep, as a sacred trust, the privileged communication of research findings given to them by colleagues prior to public distribution of this knowledge (e.g. for purpose of evaluation for publication or funding), otherwise it will encourage secrecy in science which, in turn, will impede the development of science, as well as, undermining the public trust in science.

1.4 Research Freedom and Social Responsibility

As a general rule, scientists are granted the freedom to pursue knowledge, to seek new ideas and examine the old ones. Placing too much restriction on new ideas may prevent advances in knowledge. However, the goal of science is to advance human health and welfare of all human beings. Therefore, scientists and the scientific community should bear and accept the responsibility for the consequences of their explorations by sticking only to those with social benefits and the minimum harm.

1.5 Promotion of Knowledge

Scientists are committed to a lifestyle of learning and teaching. They should make sure that they know how to practice good science as well as remaining current with developments in their field. Scientists should also transmit their knowledge, as well as teach future generations of scientists how to do good science. They should attract as many people as possible to the scientific profession to guarantee the development and promotion of science.

1.6 Compliance to the Law

All people, including scientists, have the ethical obligation of following laws. Science will suffer a great loss if scientists violate laws, as they may be arrested, grants withdrawn, scientific equipments seized and the public trust in science and scientists is undermined. In addition, there are specific laws that regulate scientific research that scientists have to comply to, like the laws that regulate the use of hazardous material, the use of animals and humans in research and methods of waste disposal as well as laws regulating printed materials and patents.

1.7 Equity

All scientists should be granted equal chances to do science, to pursue knowledge regardless of age, race, gender or nationality. All hypothesis, ideas or methods should be reviewed for originality, quality, efficiency or/ and benefit regardless of who they are produced by. Science produced by scientists from different social and cultural environments achieves the variety necessary for the advance of knowledge. All sorts of prejudice towards a certain race, age, gender or nationality will undermine the principle of fairness or equity that is necessary for the development of science.

1.8 Respect

The scientific community is based on the principles of co-operation and trust that may collapse if scientists don't mutually respect one another, and thus the social enterprise of science will dissociate, leading to an apparent delay in achieving the scientific goals. Therefore, scientists should mutually respect one another. Scientists' mutual respect includes abstention from harming one another, psychologically or physically, from the misuse of one another's experiments or results. Scientists should also treat associates and trainees with respect, encourage them and give credit for their contributions. In the fields of science where laboratory work is involved, scientists have responsibility for the health and welfare of their employees and trainees; therefore, they should seek to minimize any potential risk, informing their employees and trainees of these risks.

1.9 Respect for subjects

Though the goal of science is to advance human health and welfare of all human beings, scientists should uphold the highest ethical standards that respect all living beings, with

profound respect granted to human life and dignity. In case of using animal subjects in research, it is the duty of scientists to show a peer-reviewed scientific rationale for the purpose and proposed use, justification of the species and number needed, and assurance that there are no other less-invasive or non-animal alternatives to answer the experimental question, minimizing as much as possible the suffering and harm to animals used in research. In case of using human subjects, the highest ethical standards, for which, are codified in the Nuremberg Code (1946-49), the Belmont Report (1979), and the Declaration of Helsinki (1964, amended in 2000).

2. Guidelines for Research Involving Human Subjects

2.1 Requirements of the Research Involving Human Subject

2.1.1 General Requirements

1. All research that is to be conducted on human subjects must be submitted to the Office of Academic Research (OAR) for review of its scientific merit and to the Institutional Review board (IRB) for ethical acceptability.

2. The (IRB), one of the standing committees that support the (OAR), is charged to evaluate the religious, social and ethical aspects of all research proposals involving human subjects that are undertaken by members of, or within, Qatar University.

3. Human subject is defined as an individual about whom an investigator obtains (1) data through intervention or interaction with the individual or (2) identifiable private information (e.g. medical records).

4. In reviewing research protocols involving human subjects, the (IRB) is to consider the expertise and experience of the investigators as a major indicator of the minimal risks the subjects might be exposed to and the maximum benefits resulting from the study.

5. Principal investigators and co-investigators are responsible for having knowledge of all study procedures as well as the risks, benefits and adverse effects. (This information is provided to subjects as part of the informed process).

2.1.2 Rules and Regulations

The IRB must ensure that all of the following requirements are satisfied before it can approve the initiation of research on human subjects. These requirements comply with the Qatari Supreme Council of Health (SCH) requirements.

For detailed SCH requirements, see: "policies, Regulations and guidelines For Research Involving Human Subjects"

http://www.sch.gov.qa/sch/UserFiles/File/Research%20Department/PoliciesandRegulations.pdf

1. Risks to subjects are minimized:
    - *by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and*
    - *by using, whenever appropriate, procedures already being performed on the subjects for diagnostic or treatment purposes*

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may be reasonably expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The should not consider possible long – range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment, IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative and documented, in accordance with, and to the extent required by these rules and the SCH policies and Regulations (See the requirements for informed consent, and waiver of signed consent).

5. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

6. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

7. When some, or all, of the subjects are likely to be vulnerable to coercion or undue influence, such as children, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have to be included in the study to protect the rights and welfare of these subjects.

2.2 Research Review

2.2.1 Research that May be Reviewed by the IRB by an Expedited Review Process:

All research in human subjects other than those which IRB has the authority to review and approve by expedited review, or is exempt from IRB review, must be reviewed at a convened meeting of the full IRB. Categories of research that IRB has the authority to approve by expedited review are itemized below.

A) Categories of New and Continuing Research that May be Reviewed by the IRB through an Expedited Review Procedure:

1. **<u>Clinical studies of drugs and medical devices only when condition (a) or (b) is met.</u>**

    a. Research on drugs that are registered at the SCH of Qatar. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).
    b. Research on medical devices that are cleared /approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. **<u>Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture, according to the research proposal, is as follows:</u>**

    a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

    b. From other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency in which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. **<u>Prospective collection of biological specimens for research purpose by noninvasive means</u>**

    a. Hair and nail clippings in a non-disfiguring manner;

    b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

c. Permanent teeth if routine patient care indicates a need for extraction;

d. Excreta and external secretions (including sweat);

e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying dilute citric solution to the tongue;

f. Placenta removed at delivery;

g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

h. Supra and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

i. Mucosal and skin cells collected by buccal scrapping or swab, skin swab, or mouth washings;

j. Sputum collected after saline mist nebulization.

4. <u>Collection of data through non-invasive procedures (not involving general anesthesia or sedation)</u>

These are routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

Examples:

a) Physical sensors that are applied either to the surface of the body or at a distance and that do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy

b) Weighing or testing sensory acuity

c) Magnetic resonance imaging

d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electro retinography, ultra sound, diagnostic infrared imaging, Doppler blood flow, and echo cardiography;

e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

5. **Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non - research purposes (such as medical treatment or diagnosis)**

6. **Collection of data from voice, video, digital, or image recordings made for research purposes**

7. **Research on individual or group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies**.

8. **Continuing review of research previously approved by the convened IRB as follows:**

   a. where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research related interventions; and (3) the research remains active only for long term follow up of subjects; or

   b. where no subjects have been enrolled and no additional risks have been identified; or

   c. where the remaining research activities are limited to data analysis

B) Modifications in Research that May or May not be Reviewed by the IRB through an Expedited Review Procedure during an Approved Project Period:

The IRB Chairman is authorized to approve by expedited review of any change that falls into expedited categories 1 through 7, with the exception of interviews and surveys with children.
Modifications to the protocol or consent form that the **IRB** Chairman is **NOT** authorized to approve by expedited review include:

a. Addition of a new drug

b. Addition of a new device

c. Addition of an invasive procedure

d. Increase in medication dose or a decrease in dose that may increase the risk

e. Addition of vulnerable subjects as a study population

f. Prolongation of a patient's participation in the study other than for observational purposes

g. Change in the inclusion/exclusion criteria which may involve incorporation of populations at greater risk

h. Identification of new potentially significant risks

i. Collection of additional blood samples that exceed the limits set in expedited category

2.2.2 Research that May be Exempted from IRB Review:

Research protocols that may be eligible for exemption from **IRB** review must be submitted to the OAR for registration and approval by OAR and must contain a statement that justifies the request for exemption.

NOTE: **NONE OF THE EXEMPTIONS APPLIES TO RESEARCH ON PRISONERS, FETUSES, PREGNANT WOMEN OR HUMAN IN VITRO FERTILIZATION.**

NOTE: **EXEMPTION (b) CANNOT BE USED FOR RESEARCH ON MINORS IF IT INVOLVES SURVEYS OR INTERVIEW PROCEDURES OR OBSERVATION OF PUBLIC BEHAVIOR.**

Categories of research that may be exempted from IRB review

a. Research involving the collection or the study of existing data, documents, records, pathological specimens, if these sources are publicly available or if the information is recorded by the Investigator in such a manner that **SUBJECTS CANNOT BE IDENTIFIED, DIRECTLY OR THROUGH IDENTIFIERS LINKED TO THE SUBJECTS.**

b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior UNLESS:

   - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

- Any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

c. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

   - Research on regular and special education instructional strategies, or
   - Research on the effectiveness or of the comparison among instructional techniques, curricula, or classroom management methods.

d. Research and demonstration projects which are conducted by, or subject to, the approval of the SCH, and which are designed to study, evaluate or otherwise examine:

   - Public benefit or service programs;
   - Procedures for obtaining benefits or services under those programs;
   - Possible changes in or alternatives to those programs or procedures; or
   - Possible changes in methods or levels of payment for benefits or services under those programs.

2.2.3 Suspension / Termination of Research Projects by the IRB:

The following rules and regulations require that all research on human subjects be reviewed by the **IRB** annually. Consequently, administrative extensions **cannot** be granted beyond the approved project period (maximally one year). Enrollment of new subjects and/or, performance of research beyond the **IRB** approved project period are prohibited. Accordingly, any project that has not received the IRB final approval for continuation, prior to the project's expiration date, will automatically be suspended.

For the safety of subjects who are enrolled in research projects in which investigational therapy is being administered, the OAR do short-term continuation of the therapy beyond the RC approval date ONLY IF abrupt cessation of that therapy would be detrimental to the patient's health and upon the approval of Health Authorities. Although all Investigators are reminded of the upcoming expiration of **IRB** approval of their projects, it is the investor's ultimate responsibility to ensure that the **IRB** approval is continuous. If OAR approval has expired, and a research subject requires the investigational therapy, then, it is critically important that the Investigator rapidly reinstates the research project.

2.2.4 Reinstatement:

Reinstatement and approval of a research project require that the **IRB** review and approve the following at a convened meeting of the **IRB**:

a. A complete progress report;
b. A memo to the Director of OAR that incorporates the following information:

- An explanation of circumstances that led to the failure to submit the application at the appropriate time;
- A statement indicating whether patients were enrolled during the period that the project was not OAR approved
- A statement indicating the number of patients maintained on a therapeutic intervention after the expiration date of IRB approval and why abrupt cessation of that therapy would have been detrimental to each patient's health.

NOTE: Funding agencies and sponsors in general require that the IRB notify them of any suspension or termination of a research project. Consequently, it is clearly in the best interest of the research subjects and all investigators that progress reports receive IRB approval prior to their date of expiration of IRB approval.

2.3 INFORMED CONSENT

2.3.1 Ethical Principles of Informed Consent

Respect of the rights, dignity and safety

Respect of the rights, dignity and safety of the subjects must be the primary determinant of the researcher's actions.

As autonomous individuals, research subjects have **a right to be fully informed** about the nature of the research and extent of their participation. They must be free to agree, or to refuse, to participate in the research. Patients may feel obliged to agree because their physicians have asked them to participate. Co- workers in an Investigator's laboratory, office or clinic may agree in order to preserve the good will of the Investigator.

Prospective research subjects must be re-assured, verbally, that refusal to participate will in no way affect their care. In addition, the RC strongly feels that workers directly supervised an investigator should not be recruited to serve as control subjects. Co-Investigators and colleagues (in the specific sense of having a comparable position in the institution) are appropriate potential control subjects.

In addition, subjects must be free to withdraw their participation at any time.

Circumstances, which could put subjects at risk if they withdraw and procedures of withdrawal, must be described in the consent document.

Who can give consent?

Subjects who are fully informed about the protocol and have had all of their questions answered.

Who can solicit an informed consent? What is the process?

One who is completely familiar with all aspects of the study that relates to the subjects participation including the rationale for doing the study; eligibility requirements and exclusion criteria; the procedures to be used; costs, risks and benefits of participation; the time frame of participation; alternatives to participation; etc.

Informed consent must also be obtained at a time and in an environment which allows the potential subject to review, carefully and fully, the information provided (verbally and in writing), to have all questions answered fully and to consider the pros and cons of participation before making a decision.

2.3.2 Recruitment of Subjects

Protocols submitted to the IRB for review and approval must specify how subjects will be identified and recruited.

In case the subjects are patients, pPatients expect that **information on their medical condition will be kept confidential**, although an investigator may access this information in the conduct of a OAR approved research project. However, many patients would consider it a serious breach of confidentiality and of medical ethics that someone not involved in their care obtained this information and contacted them. For this reason,(permission to recruit a patient as a subject in a research study should be **obtained from the patient's physician** before the patient is contacted.

Where possible, the physician should first get permission from the potential subject, to allow the Investigator to contact him/her. If this is impractical, a letter, email or a message can be sent out by the physician informing the patient that the Investigator would like to contact him/her. The letter should include a reply card to be returned granting or refusing permission.)

Special circumstances:

If the nature of a study makes use of these procedures unrealistic, this must be fully justified to the **IRB** by the Investigator.

Such studies may require very narrow time windows for collection of data or involve large numbers of physicians and potential subjects.

In addition, it must be clear that the patients would very likely not be distressed by being contacted by someone not involved in their care. For such studies, individual or *blanket permission may be obtained from the physician(s) (preferably in writing) to contact a particular patient or all of the physician's eligible patients. The Investigator may, then, contact the patient(s) directly, without previous notification, indicating that their physician had given permission for the contact. If blanket permission is obtained and used, the Investigator must inform the physician each time that a patient is contacted.

Recruitment of Family Members:

If recruitment of family members is planned, for confidentiality reasons, the index patient should not be asked to provide the name of the family member(s) directly to the Investigator. Rather, the index patient should be asked to contact family members. If the family member is willing to speak with the Investigator, then the family member should be asked to contact the Investigator. Therefore, when research will include family members the protocol and consent form must indicate how family members will be contacted.

2.3.3 Advertisement for Research Subjects

All forms of advertising or dissemination of information for the purpose of recruitment of subjects into a research protocol, including newspaper advertisements, posters, and fliers, or newspaper articles which include recruitment information must be approved by the IRB prior to distribution or publication of the material.

In addition, letters to fellow physicians, both within and outside of the institution, must be approved. The following information must be contained in the advertisement:

- The purpose of the study
- The characteristics, which would qualify an individual for enrollment
- A straightforward description of any and all benefits to the subjects
- The IRB number of the protocol and the expiration date
- The name and number of whom to contact for further information

Nothing in the text should serve as an undue inducement to potential subjects to enter the study. Such inducements might include claims (explicit or implicit) about safety or efficacy of an investigational drug or device, equivalence or superiority to existing treatments, or closer monitoring of the patients condition.

The availability of compensation for time and effort related to participation can be included without mention of any specific amounts.

2.3.4 Guidelines for Consent Documents

NOTE:

These guidelines are in line with the SCH General requirements for informed consent (basic and additional) as indicated in SCH policy

The forms used in soliciting consent must provide, in writing, all of the information that the subject would reasonably want about the study and the extent of his / her involvement in it.

An Investigator shall seek such consent only under circumstances that provide the prospective subject, or the representative, sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence.

The informed consent, whether oral or written, may not include any exculpatory language through which the subject, or the representative, is made to waive, or appear to waive, any of the subject's legal rights or releases, or appears to release, the Investigator, the sponsor, the institution or the agents, from liability for negligence.

By completing these documents, as suggested below, all of the international requirements for informed consent should be fulfilled.

2.3.5 Who May Obtain Consent

Obtaining informed consent from a subject is the responsibility of the Principal Investigator. The Principal Investigator may delegate this task to a named co-investigator on the project who is familiar with all aspects of the information to be provided the subject.

For studies involving more than minimal risk, or procedures other than those performed for routine clinical care examination, consent should be obtained by the PI or the Investigator performing the procedure.

2.3.6 When and Where Consent should be solicited.

The setting in which consent is requested and obtained must be one in which the potential subject can consider the request as an autonomous individual, free from time constraints or a sense of obligation or dependency.

2.3.7 The Consent Process (*Consent form should be made in 3 copies*)

- The consent form must be signed by the potential research subject(s) and the person obtaining consent (Investigator or delegate).

One copy of the full completed and signed consent form must be given to the subject, and a second copy must be placed in the patient's chart (in case the subject is a patient).. The original completed and signed consent form must be retained for inclusion in the

Principal Investigator's research records.

2.4 MODIFICATION OF THE INFORMED CONSENT (WAIVER OF INFORMED CONSENT)

Under very specific circumstances, the **IRB** may totally waive the requirement for obtaining informed consents only when **ALL** of the following are applicable:

1- No more than minimal risk to the subject is involved
2- The research could not practically be carried out without the waiver
3- The research will not adversely affect the rights and welfare of the subject
4- The subjects will be provided with additional pertinent information after participation, whenever appropriate
5- Chart reviews & retrospective studies

2.5 PEDIATRIC SUBJECTS IN RESEARCH STUDIES

The enrollment of pediatric subjects requires that the research participant information sheet worded as "You/Your child". This is required because permission must be obtained from the parent and, in instances as specified below, the assent of the child must be obtained. In addition, documentation must be kept that assent was obtained freely and without coercion.

2.5.1 Minors and vulnerable subjects

Vulnerable subjects encompass children, pregnant women, fetuses, prisoners, educationally or economically disadvantaged persons and individuals with diminished mental capacity.

If vulnerable subjects are to be recruited and subsequently enrolled in to a research project they must, of course, be provided with all of the protections that are required for every other research project.

Furthermore, additional, even more rigorous, protections must be provided for them:

- The investigator must ensure that

  1) *the research might not equally well be carried out with normal non-vulnerable persons*
  2) *the purpose of the research is to obtain knowledge relevant to the particular health needs of these people and to the pregnant 's fetus(in case of pregnant women).*

As for children, there are additional protections for them.

2.5.2 Pediatric Assent Guidelines

All Pediatric research subjects should be fully informed about a research study, in language appropriate for their age, maturity and previous experiences, whether assent is to be requested or not.

This information can be provided verbally and should include all tests and procedures to be performed, frequency of interventions, duration of participation in the study, risks, discomforts and potential benefits.

The child should be encouraged to ask questions, all of which should be answered.

Depending on the nature of the study and on the maturity, psychological state and previous experiences of the child, assent should be obtained, and documented, from children ages 14 and older.

For children ages 13 – 14, assent should be obtained and documented unless the child's pediatrician considers him/her to be too immature to provide a true assent. Children age 7 – 11 should be fully informed about the research, using language appropriate to their age or maturity, and documented assent should be obtained from those deemed capable of making a meaningful decision.

Below age 7, information about study should be provided in a manner appropriate to child's age, but documented assent need not be obtained.

When enrolling minors into therapeutic research studies of potential therapies for their severely debilitating or life – threatening illness, the patients should be fully informed about the nature of the study and should be included in discussions of their participation, as is common pediatric practice. In such situations, however, documented assent need not be obtained since the wishes of parents or guardian would prevail. It would be inappropriate to ask for assent since a refusal by the child could be over – ruled by the parents or guardian.

2.5.3 Documentation of Assent

Assent given by the subject must be documented by a witness who is not a family member and not associated with the research study. The signed certification must be retained in the research study records.

If the documented assent is not obtained from minors, ages 12 and older, the reason for not obtaining assent must be noted in the research record for that subject.

QU- IRB Membership

According to SCH policies, QU IRB ensures the following:

(a) It is composed of at least 5 members with varying backgrounds to promote complete and adequate review of research activities. All members have received the relevant training that can enable them to have the professional competence necessary to review the proposals submitted.
(b) Members of QU IRB belong to various professions and of both sexes.
(c) At least one member has a scientific background and one member with a nonscientific background. A lay person may also be included
(d) It includes at least one member who is not affiliated with QU and who is not part of the immediate family of any QU IRB member affiliated to QU
(e) In no way will it contain a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
(f) It may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB

QU- IRB Records

QU- IRB maintains documentation of its activities as described in SCH policies (see above SCH website)