BIOGENIX

POLICY PROCEDURE FOR PATIENT CONSENT

	NAME	DESIGNATION	SIGNATURE	DATE
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1. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

2. REVIEW HISTORY

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3. POLICY STATEMENT

3.1. Asking for informed consent is done as per this policy

4. PURPOSE

4.1. To set out the principles for patient Consent that is important before making any clinical investigation.

4.2. To advise on the best practice for obtaining Consent for procedures.

4.3. To provide a framework for good practice that covers the various situations that Biogenix staff may face in their day to day work in regard to consent.

4.4. To identify practices that support patient rights to participate in informed decision making, the process by which accurate and adequate information is disclosed for relevant medical procedures.

4.5. To recommend measures that BIOGENIX takes to provide patients and those authorized to make decisions on their behalf/Substitute Consent Givers with information.

The procedure is as per clause 5.4.4.1. of ISO 15189: 2012 Medical laboratories –requirement for quality and competence.

5. SCOPE

8.1. Consent applies to all the procedure outlined in here

8.2. Target Audience: All BIOGENIX Laboratory staff

6. DEFINITIONS

CATEGORY	DEFINITION
Consent:	A declaration of willingness to undergo a procedure, treatment, intervention or investigation which is evidenced in the patient record.

Informed Consent:	Informed Consent is established when a patient (or Substitute Consent Giver) following consultation with the physician and/or health care professional declares his/her willingness to authorize and undergo a procedure, intervention or treatment. Informed Consent takes place when the patient is informed about the inherent risks, its benefits and alternative methods of the intervention or treatment, the consequences of non-treatment, any expected result or outcome of treatment and the name of the physician(s) and/or health care professionals who will be performing the procedure, intervention or treatment. Informed Consent usually evidence by written documentation from the patient and/or the Substitute Consent Giver and/or physician and/or health care professional.
Implied Consent:	Implied Consent is established during consultation with the physician and/or health care professional on their health status and when the patient and/or a Substitute Consent Givers conduct indicates a willingness to submit to general medical treatment which has minimal risk such as screening tests, prevention programmes, monitoring of vital signs, general administration of ongoing treatment, diagnosis an emergency department or clinic, assessments and examination, laboratory tests, radiology and other appropriate non-invasive procedures that are considered to be routine in the provision of patient care.
Substitute Consent Giver :	A person who is authorized to Consent for another person based on UAE Law. A person who may act as the Substitute Consent Giver in the event that the patient is unable to do so. This person is ideally a close relative and should have familiarity with the patients presumed wishes regarding their medical

	care. In accordance with the Law the Substitute Consent Giver can be: • A relative up to the fourth degree in the following order of priority: father, mother, husband, wife, son, daughter, grandfather, grandmother, son's children, daughter's children, paternal uncle, paternal aunt, maternal uncle, maternal aunt, paternal' s uncle children and maternal aunt's children A court appointed guardian in UAE or elsewhere • A parent for a minor (less than 18 years of age) • The father even if he is less than 18 years of age • In the absence of the father the mother can give Consent even if she is less than 18 years of age • If the Substitute Consent Giver is deemed incompetent an alternate Consent Giver should be sought.
Incompetent Patient :	A patient may be judged incompetent by a physician or allied health care professional if, for any reason, it is felt that they are unable to understand the information provided in the process of obtaining Consent. Reasons for declaring incompetence may include, but are not limited to the following conditions: inadequate age, mental disability, impairment of judgment by drugs (alcohol or medications), acute disturbances of consciousness, impaired reasoning or memory loss caused by disease/injury validated by clinical assessment.
Adult :	A person or patient who has reached the age of 18 years.

Minor :	Any person or patient who is less than 18 years of age.
Referring Physician :	Physician who is responsible for the overall care of a patient.
Health care Professional :	Is a HAAD licensed health care professional authorized within their scope of practice to provide preventive, curative, promotional or rehabilitative health care services in an evidenced and systematic way to individuals, families or communities.
Invasive Diagnostic Procedure	A medical procedure that invades (enters) the body, usually by cutting or puncturing the skin, mucous membranes or connective tissue and/or by inserting instruments into the body orifices. The performance of an invasive diagnostic procedure may be comparable to an operative or invasive procedure in that it may: • Involve a hospital defined invasive procedure; • Result in a reaction due to the administration of a drug or fluid; and • Places the patient at risk of harm
Patient Medical Record:	A collection of documents (may include electronic) which provide an account of each episode in which a patient visited or sought treatment and received care or a referral for care from a health care facility. It contains information such as; the assessment of the patient's Consent form, health status, the health history, laboratory and radiologic reports of tests performed, notes by physicians and/or health professionals regarding the daily condition of the patient, as well as order sheets, medication sheets, admission records, discharge summaries, and other pertinent data. The record is confidential as per UAE Law and is held by the health care facility.

7. ACRONYMS

N.A.

8. RESPONSIBILITIES

8.1. All BIOGENIX Laboratory Staff.

8.2. Treating doctor is responsible for obtaining consent before ordering lab investigation like drug of abuse, HIV, cytogenetics study, IVF procedure, HLA Typing and some Molecular Genetics testing.

9. PROCEDURE

9.1. Consent and Need For Consent

Consent is a declaration of a person's willingness to undergo a procedure, investigation or other intervention. Consent is needed as an ethical instrument demonstrating the right of the patient to control his/her health care and the BIOGENIX laboratory's ethical duty to involve the patient in his/her care. Consent evidences voluntary choice by the competent patient whose referring physician had disclosed all information necessary for the decision-making. Consent is required for the sharing/receiving Confidential Health Information (CHI) with/from an Authorized Health Insurance Company/Health care Provider. Reasons for this include to:

. Share/receive Confidential Health Information (CHI) with/from an authorized Health Insurance Company/Health care Provider

. Grant the Authorized Health Insurance Company the right to audit the electronic medical records/related information, such as billing

9.2. Consent giver:

9.2.1. Patient:

Consent can be signed directly by the patient if the patient is18 years of age or older, unless there is evidence to verify incompetence by the referring physician / consultant regarding the decision to be made.

9.2.2. Substitute Consent Giver

Situations requiring a Substitute Consent Giver:

9.2.2.1. When the patient is less than18 years of age

9.2.2.2. Deemed incompetent

9.2.2.3.

9.3. Information on the Procedure

9.3.1. When a patient comes to laboratory with a request form and willingly submits to the usual collecting procedure, for example, venipuncture. It means he wants to do tests with us.

9.3.2. At the time of registration reception staff handover, a general consent form to the patient or guardian of the patient to read and to give consent.

9.4. Patients are requested to fill the Informed Consent for Cytogenetic study, Patient should know that Cytogenetic testing may:

9.4.1. Diagnose whether or not the patient has (or my child or fetus has) a particular condition or he is at risk for developing this condition.

9.4.2. Identify a chromosomal condition that the patient did not know (or her child or fetus) was at risk for.

9.4.3. Indicate whether the patient (or her child or fetus) is a carrier for this condition.

9.4.4. Be indeterminate or negative due to the patient (or her child's or fetus') clinical status (post-transfusion, etc) at the time the sample was drawn.

9.4.5. Be indeterminate due to technical limitations.

9.4.6. Cytogenetic testing may provide information aiding the patient (or patient child's or fetus') diagnosis. It will not detect the specific gene mutations responsible for a specific disorder.

9.4.7. Clinical information and family history may be necessary for optimal test interpretation.

9.4.8. Several sources of error are possible including, but not limited to: sample mishandling, sample misidentification, and sample contamination.

9.4.9. Growth failure is expected in tissue and biopsies sample.

9.5. Even when the health care provider does not ask for the written consent, patient should still be told what tests or treatments are being done, and why.

For Example:

9.5.1. Men should know the reason for and pros and cons of a PSA blood test that screens for prostate cancer before they have the test.

9.5.2. Women should know the reason for and pros and cons of a Pap test or other test.

9.5.3. Anyone who is being tested for an infection that occurs after sexual contact should be told about the test and why they are being tested.

9.6. Duration and Validity of Consent

The reception staff is generally responsible for ensuring that the Consent remains valid from the time of Consent is given to the intervention or investigation or release of results unless it is withdrawn by the patient and/or Substitute Consent giver.

A competent adult has the right to refuse any referral, even though such refusal may endanger life or health. Where referral is refused, the laboratory director has an obligation to make reasonable attempts to inform the patient of the risks involved in refusal. The laboratory director documents in the consent form the fact that the information is given. Ideally, when patient refuse, the refusal of referral, is signed by the patient.

Consent is valid only when the following elements are present.

9.6.1. Competency (decision making ability);

9.6.2. Disclosure of information Specificity;

9.6.3. Opportunity for questions and answers;

9.6.4. Accuracy;

9.6.5. Respect for patient decision

10. CROSS REFERENCE

10.1. HAAD guidelines for patient consent.

10.2. ISO 15189:2012 Medical laboratories requirements for quality and competence.

11. RELEVANT DOCUMENTS & RECORDS

11.1. BG/REC/GEN/004 Consent form