LAY LAB LANGUAGE FOR INFORMED CONSENTS

Karen G. Davenport RN, BSN, CCRC
Senior Clinical Research Coordinator
Clinical Trials Office

Lori Ratliff MSN, ANP, CCRC
Administrator / Nephrology
Clinical Research Center

Gloria A Carter LPN, CCRP
Advanced Clinical Research Coordinator
Urology Department

Harriette Wheatley RN, BSN, CCRC
Clinical Research Coordinator
Clinical Trials Office

Wendie Price, RN, CRC
Clinical Research Coordinator
Department of Medicine, Division of Endocrinology

University of Virginia School of Medicine

Abstract: *We formed a committee of 5 coordinators to develop standardized wording to use for the lab tests and as definitions for a few other identified words that were difficult to explain. The committee met with each member providing some wording that they had used successfully in the past. We developed a map of what we wanted to define, refined those definitions we already had, then divided the various tests for further work. Each person sent their final definitions to Karen Davenport, who put them in order and forwarded them to the IRB for review. After some minimal requested changes, the glossary was approved and added to the IRB's website for use by everyone.*

Over the years, and particularly following research site closures by federal regulatory agencies, the IRB at the University of Virginia School of Medicine (Human Investigation Committee) has developed and refined their templates for protocol and informed consent submissions.

The format for these templates has become more and more specific and has required more and more specifically worded information for the research subjects. The most recent requirement has been for the protocol-required laboratory tests to be specifically identified and explained in layman's terms. It can be a difficult and frustrating task to explain in a consent form what these lab tests mean. Almost all of our research subjects have no medical background, and many may have little formal education.

Our research coordinators meet on a quarterly basis to hear speakers, discuss current trends in research and offer support and advice to one another. At a recent meeting, representatives from our IRB spoke about the newest changes to the protocol and consent templates. At that time we asked if they had preferred standardized wording to explain the lab

tests. They did not, but they were willing to review any simplified language we could present and, once approved, add it to their website to be available to everyone.

We formed a committee of 5 coordinators to develop standardized wording to use for the lab tests and as definitions for a few other identified words that were difficult to explain. The committee met with each member providing some wording that they had used successfully in the past. We developed a map of what we wanted to define, refined those definitions we already had, then divided the various tests for further work. Each person sent their final definitions to Karen Davenport, who put them in order and forwarded them to the IRB for review. After some minimal requested changes, the glossary was approved and added to the IRB's website for use by everyone.

It was our feeling that standardized wording saves time and effort when submitting a protocol and consent and offers consistency to our research subjects. The following is the Glossary of Suggested Lab Wording that was approved by our IRB.

GLOSSARY OF SUGGESTED LAB WORDING

GENERAL DEFINITIONS:

- **Gene** – The basic unit of heredity. A gene contains the instructions or code for making a protein. Proteins are the building blocks of life.

- **Gland** – A part of the body that makes a hormone or fluid.
    - adrenal glands – there are two adrenal glands. They control blood pressure, the level of salt and potassium in the body, and affect the speed of the body's chemical functioning and sweating.
    - hypothalamus – produces hormones that affect the production of other hormones.
    - ovaries – female glands that produce eggs.
    - pancreas – gland that produces insulin that regulates sugar in the body
    - parathyroid gland – regulates calcium and phosphorus in the body
    - pituitary gland – controls most other glands.
    - salivary glands – produce saliva in the mouth
    - testes – male glands that produce sperm.
    - thyroid gland – controls the speed of the body's chemical functions and helps regulate growth and physical maturity.

- **Hormone** – A substance made in the body that is sent directly out into the bloodstream to increase or decrease the function of certain organs, glands, or other hormones.

- **Metabolism –** The chemical changes in cells that provide energy to the body.

Definition of Certain Hormones:

Aldosterone: produced by the adrenal glands. Helps to regulate salt and water balance by holding on to salt and water and removing potassium.

Antidiuretic hormone (vasopressin): produced by the pituitary gland. Causes the kidneys to hold on to water and helps to control blood pressure.

Corticosteroid: produced by the adrenal glands. It helps fight inflammation, regulate blood sugar levels, maintain blood pressure, muscle strength, and helps control salt and water balances.

Erythropoietin: produced by the kidneys. Stimulates red blood cell production.

Estrogen: produced by the ovaries. Controls the development of female sex characteristics and the reproductive system.

Glucagon: produced by the pancreas. Raises the blood sugar level.

Growth hormone: produced by the pituitary gland. Controls growth and development and promotes protein production.

Insulin: produced by the pancreas. Lowers the blood sugar level, affects the metabolism of blood sugar, protein, and fat throughout the body.

Luteinizing hormone (LH) and Follicle stimulating hormone (FSH): produced by the pituitary gland. These hormones work together to control reproductive functions including the production of sperm and semen, the maturing of the females' eggs, and the menstrual cycle. They control male and female characteristics such as body hair, muscle formation, skin texture, and thickness, and voice.

Parathyroid hormone: produced by the parathyroid glands. Controls bone formation and the removing of calcium and phosphorus from the blood.

Progesterone: produced by the ovaries. Prepares the lining of the uterus (womb) for the fertilized egg and prepares the breasts for milk production.

Prolactin: produced by the pituitary gland. Starts and maintains milk production in the female.

Renin and angiotensin: produced by the kidneys. These hormones work together to control blood pressure.

Thyroid hormone: produced in the thyroid gland. Regulates growth, physical maturing, and the speed of metabolism.

Thyroid stimulating hormone (TSH): produced in the pituitary gland. Stimulates the production and secretion of hormones by the thyroid gland.

Testosterone: produced by the testes. Controls the development of male sex characteristics and the reproductive system.

DEFINITIONS OF LABORATORY TESTS:

CBC – complete blood count that measures certain red and white blood cells.

Chemistry – Safety blood tests to determine the balance of the salts and proteins in your blood.

- **albumin** – a protein in your blood
- **alkaline phosphatase (alk phos)** – a protein in your blood that can be measured to help determine liver disease.

DEFINITIONS OF LABORATORY TESTS (Chemistry continueed):

- **BUN** – a measure of how well your kidney is working to remove waste
- **creatinine** – a measure of how well your kidney is functioning
- **electrolytes** – a measure of normally-occurring salts and gases in your blood
- **glucose** – measure of sugar in your blood
- **total bilirubin** – a measure of how well your liver is working

Diabetes – ***abnormally high level of sugar in your blood***

- **C-Peptide** –indirect measure of how much insulin your body produces
- **Hemoglobin A1c (also called glycosylated hemoglobin)** – blood test that shows your average blood sugar level over the past 2 to 3 months
- **IGF-1** (Insulin-like Growth Factor) – a blood test of the level of growth hormone production. Growth hormone (GH) stimulates growth and regulates metabolism.

Hematology – tests certain blood cells including:

- **Hct (Hematocrit)** –a measure of red blood cells
- **Hgb (Hemoglobin)–** a measure of the amount of oxygen-carrying protein
- **Plt (Platelets)** –a measure of cells that help clot your blood
- **PT, PPT (Prothrobmin Time, Partial Prothrombin Time)** – measures of time for specific blood products to clot
- **WBCs (White Blood Cells)** – a measure of the number of these cells indicates the presence of infection or the ability to fight infection

Kidney Function Tests – blood tests that show how well your kidneys are working to remove waste. Kidney function blood tests include **BUN (Blood Urea Nitrogen)** and **Cr (Creatinine).**

Lipids – HDL (good) and LDL (bad) cholesterol and triglycerides. Types of fats in your blood.

Liver Function Tests – blood tests that measure how well your liver is producing and processing many of the things needed by your body (such as vitamins, fats, iron, protein, and sugar).

Pharmacokinetics – a blood test that measures how much of a drug is in your system.

Pituitary Hormone Tests – blood tests that measure how well your pituitary gland is working.

Thyroid Function Tests – blood tests to measure how well your thyroid is working

- **Includes thyroxine, TSH, T3, and T4**

General Urinalysis - urine screening test for abnormalities like infection or kidney problems

- **Creatinine Clearance** – kidney function test determined by 12 or 24 hour urine collection
- **Microalbumin or microalbuminuria –** urine test for protein, which may indicate an early stage of kidney disease
- **Total Urine Protein** – kidney function test determined by a 12 or 24 hour urine collection