Code of Ethics in Clinical Pathology Laboratory Services

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Laboratory Services

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1. Objective

The objective of this manual is to consider ethical issues encountered during the daily work of laboratory medicine specialists. It aims to complement guidelines and documents that are available in the laboratories and to offer a framework for addressing ethical issues encountered in the practice of laboratory medicine.

2. Introduction

The evolution of medical and bio-ethics, over the years, is well documented and includes the Nuremberg Code from 1947 (1), the Declaration of Geneva from 1948 (2), the Declaration of Helsinki from 1964 (3), and the Belmont report from 1978 (4). These documents focus on medical research, and are also applicable to the practice of clinical medicine.

The manual identifies three core principles.

a) **Respect for persons**: Acknowledgement of autonomy and protection of those with diminished autonomy.
b) **Beneficence:** The duty to act in the best interests of patients or research subjects. The goal of maximizing benefits and minimizing harm.
c) **Justice:** The duty or obligation to treat patients equally and to distribute, what is rightly due in terms of benefits, risks and cost.

These principles can be applied to both research and clinical settings. In this procedure these three principles will be cited to clarify the ethical issues in laboratory medicine.
Our Laboratories are obliged to adhere to high ethical standards according to ISO 15189:2012 for "Medical laboratories − Requirements for quality and competence" (5). Section 4.1.1.3 of the document summarizes the ethical conduct expected in laboratories.

The document states that laboratories should have in place means to ensure that:

a) "*there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity;*
b) *management and personnel are free from any undue commercial, financial, or other pressure and influences that may adversely affect the quality of work;*
c) *where potential conflicts in competing interests exist, they shall be openly and appropriately declared;*
d) *there are appropriate procedures to ensure that staff treat human samples, tissues or*

remains according to relevant legal requirements;

e) *confidentiality of information is maintained*."

Ten principles of ethical conduct according to the American Association for Clinical Chemistry (AACC) are as follows:

1. "*Uphold standards of professionalism, be honest in all professional endeavors, and maintain a high level of personal integrity.*
2. *Avoid scientific and professional misconduct including, but not limited to fraud, fabrication, plagiarism, concealment, inappropriate omission of information, and making false or deceptive statements.*
3. *Report any health care professional who engages in fraud or deception or whose deficiency in character or competence jeopardizes patient care or other personnel.*
4. *Maintain a high level of quality in the product(s) of my professional endeavors, including validity and reliability of test results, interpretive opinions, publications, and scientific research.*
5. *Respect the privacy and confidentiality of protected health information encountered during the course of my professional activities in accordance with legal and ethical obligations.*
6. *Continuously strive to augment my professional qualifications, knowledge, and skills, and present them accurately.*
7. *Promote the safety and welfare of patients, employees, co-workers, colleagues, the public, and the environment.*
8. *Avoid, or promptly disclose and work to resolve, actual or potential conflicts of interest.*
9. *Encourage open and honest discussion among physicians, other healthcare providers and/or facility managers regarding disclosure to patients of information about medical errors, if such information is material to any patient's well-being.*
10. *Comply with relevant laws and seek to change them when they are contrary to the best interests of the patient*." (6)

This manual will focus on the ethical issues encountered during the daily routine work of laboratory medicine specialists and will consider the pre-analytical, analytical and post-

analytical phases.

3. Ethical Issues in the Pre-analytical Phase

The maintenance of ethical standards in the pre-analytical phase is the collaborative responsibility of the laboratory, the health care provider, researcher, phlebotomist, nurse, or whoever collects the specimen. Their roles include:

- Proper identification of the patient or subject.
- Collection of the appropriate sample using the appropriate technique.
- Appropriate identification and labeling of the sample so that the right tests are performed.
- Appropriate handling of the specimen until testing is performed.

In particular, the application of the three principles is as follows:

a) Respect for persons:

- **Informed Consent** should be obtained prior to sample collection, (the patient knows what testing is being performed and why) and may be either expressed or implied. Consent is expressed if the subject is asked for written or verbal agreement. Consent may be implied when a patient provides a requisition and willingly sits in a collection chair and allows a sample to be taken.
- Informed consent may pose an ethical problem if the patient is incompetent to make a decision due to age, mental status, or critical illness. Children under 18 years are not competent to make decisions for themselves; usually their parents are legally responsible.
- The patient's right to refuse to be tested should be respected. However, there are certain situations in which patient autonomy is not absolute. For instance, as when the patient is unconscious, mentally ill, or under the influence of drugs.
- Confidential information about patient demographics, the visit of a patient to a testing facility, which tests were ordered, and the reasons for those tests, should be given only to appropriate personnel.
- Confidentiality must be maintained at every step of the process including specimen transportation and data entry.

b) **Beneficence:** All tests should benefit the patient based on the best medical evidence. In addition:

- Sample collection should not cause harm, for example infection or pain from the collection process and adverse events associated with bone marrow aspiration and biopsy testing.
- Trained personnel should be in place to prevent or manage any adverse events in the collection procedure.
- The collection procedure should be carried out using universal precautions to protect the patient and the healthcare worker, and should be performed with the least amount of patient discomfort possible by properly trained personnel.
- Additional specimens shall not be collected for research procedures without informed consent from the patient and approval from the appropriate ethics board.
- Specimens should be labeled with at least 2 unique identifiers, and all aliquot tubes should be similarly identified.
- Samples should be transported in a manner to preserve the integrity of the sample.

c) Justice:

- The laboratory will provide access to a wide variety of laboratory tests for free and at reasonable cost for the insured patients and cash payers.
- The laboratory will evaluate the need to introduce new tests and the opportunities to discontinue older tests when better tests are available.
- There should be no preference given to individuals to facilitate or expedite the collection process at the expense of other patients.

4. Ethical Issues in the Analytical Phase

Confidentiality, quality and competence are vital for all laboratories and settings. The difficulty of achieving each of these goals may vary among laboratories and among parts of the laboratory. Confidentiality during the analytical phase may be almost a by-product of automation in a laboratory that uses automated bar code readers, automated analysis, and auto-verification and where the patient names for most samples are usually unseen by those in the laboratory. It is important that any site conducting patient testing strive to maintain ethical standards.

a) Respect for persons:

- Patient have the right to decline to have their specimens analyzed even after the specimens have been collected and processed.
- Confidentially should be respected and maintained.

b) Beneficence: The aim of the laboratory in the analytical phase is to provide the best possible analytical result. This is achieved through good laboratory practice and maintenance of professional standards.

- The maxim “a wrong result is worse than no result” is a guiding principle in this regard.
- Good laboratory practice includes refusal to analyze or report a result when there is evidence of poor sample integrity, incorrect or poor labeling or other deficiencies that may compromise the test result.
- Acceptability of samples that are classified as "difficult to obtain” (such as cerebrospinal fluid) may be considered a special case.
- Only qualified, properly trained and regularly assessed personnel should perform laboratory analysis

c) Justice:

- All patient samples are to be treated equally, discrimination in the analysis of patient samples based on gender, age or racial origin is an injustice.
- Specimens designated as STAT or priority must be analyzed promptly to meet the medical need as well as possible.
- The laboratory should develop appropriate operating procedures for this type of testing, and state which tests are included and the expected turnaround times. It is expected that all specimens are analyzed accurately and in a timely manner.

5. Ethical Issues in the Post Analytical Phase

The post analytical phase includes reporting and interpretation of results, residual specimen storage, and data access. The laboratory will have a policy for specimen storage that is analyte dependent. Archiving of results in either electronic or hard copy format is an important aspect of good laboratory practice. Archived documents may include: (1) request forms, (2) raw analytical and quality control data, (3) results and (4) reports. Policies on retention and destruction of medical records and specimen retention and discard should be put in place. Identification of authorized personnel allowed to access medical records such as doctors, patients, and laboratory staff should be documented in the policy manual. In addition, the patient should be allowed to give consent for access by others (such as family members) as required.

Applying the three principles:

a. **Respect for persons:**

- Confidentiality of results: the patient and the referring clinician are the sole legitimate recipients of laboratory data. Exceptions are made if the patient is a juvenile or is incapable of receiving or understanding laboratory results.
- In case of children, the patient's family is regarded as legitimate recipients of a patient's laboratory results.
- Reliable transmission methods will be used, and security in relaying the results through NCI Hospital information systems, and hand deliveries by messengers.
- Individuals have the right to decide when and if their records or specimens shall be used outside the normal medical care to which they have consented.

b. **Beneficence:** Misinterpretation of results can lead to patient harm; to minimize this harm, only qualified personnel should interpret reports.

- The reporting of results should be performed in a manner such that the patient's clinician receives the right result within an appropriate time with information that allows for the correct interpretation of the results.
- The results should include an appropriate name for the test performed, an appropriate reference interval, which may be age and gender specific, the unit of measurement and, when possible, a designation that the test is within or above the reference interval.
- Turnaround time (TAT) should be as short as possible, and achieving this TAT should not compromise validity of the results.
- Timely access to results is important, and withholding of results because of non-payment might lead to harming the patient especially in emergency situations.
- The data included on a report, including patient demographics and the above-mentioned test information, should be formatted on each report so that the clinician can make clinical decisions based on information that is clearly provided.
- Delays in reporting, for whatever reason, should be avoided.
- Incorrect results can lead to mismanagement. Ordering clinicians should be notified of errors as soon as they are identified, and test results should be corrected as soon as possible. The change should be marked on the report, and the incorrect result or results should remain accessible and be clearly identified as erroneous.

c. **Justice:**

- The reporting of results should be consistent for all patients.
- Rapid reporting may be required for some results, such as for "critical" and "significant-risk" results, but the rules for rapid reporting must apply regardless of the source of the sample and the patient's ability to pay.
- Withholding of laboratory results because the patient has not paid should be avoided.

6. References

1. Nuremburg Code http://www.cirp.org/library/ethics/nuremberg/, Accessed 9 January 2016.

2. Declaration of Geneva; **http://www.wma.net/en/30publications/10policies/g1/WMA_DECLARATION-OF-GENEVA_A4_EN.pdf,** Accessed 9 January 2016.

3. Declaration of Helsinki http://www.wma.net/en/30publications/10policies/b3/17c.pdf Accessed 9 January 2016.

4. Belmont Report http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html, Accessed 9 January 2016.

5. ISO 15189:2012 Medical Laboratories – Requirements for quality and competence. https://www.iso.org/obp/ui/#iso:std:iso:15189:ed-3:v2:en Accessed 9 January 2016.

6. AACC Ethics guidelines. American Association of Clinical Chemistry, Accessed 9 January 2016. https://www.aacc.org/about-aacc/governance/ethic-guidelines.

7. American Society for Clinical Laboratory Science; Code of Ethics www.ascls.org/about-us/code-of-ethics Accessed 9 January 2016.

8. College of American Pathologists Principles of Ethical and Professional Conduct http://www.cap.org/web/oracle/webcenter/portalapp/pages/search-results.jspx?searchTerms=cap%20principles%20ethical%20professional&_afrLoop=1212918502052812#%40%3FsearchTerms%3Dcap%2Bprinciples%2Bethical%2Bprofessional%26_afrLoop%3D1212918502052812%26_adf.ctrl-state%3Dcqx515pog_4 Accessed 4 January 2016.

9. Pathology Australia Code of Ethics and Practice Guidelines- http://www.pathologyaustralia.com.au/wp-content/uploads/2010/07/02_Pathology-Australia-Code-of-Ethics-and-Practice-Guidelines-November-2012.pdf, Accessed 9 January 2016.

10. Canadian Society for Medical Laboratory Science (SCMLS) – http://www.csmls.org/About-Us/Who-We-Serve/Code-of-Conduct.aspx Accessed 9 January

2016.

11. College of Pathologists Pakistan. Ethics for Pathologists, http://www.healthwayslabs.net/docs/ethics.pdf., Accessed 9 January 2016.

12. Bruns, DE, Burtis CA, Gronowski AM, McQueen MJ, Newman A, Jonsson JJ. Variability of ethics education in laboratory medicine training programs: results of an international survey. Clin Chim Acta 2015;442:115-118.