
بسم الله الرحمن الرحیم

Ethics in Laboratory

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To be discussed

Research ethics Milestone.

What is Laboratory?

What is Ethics?

What is Laboratory Ethics?

What is accreditation?

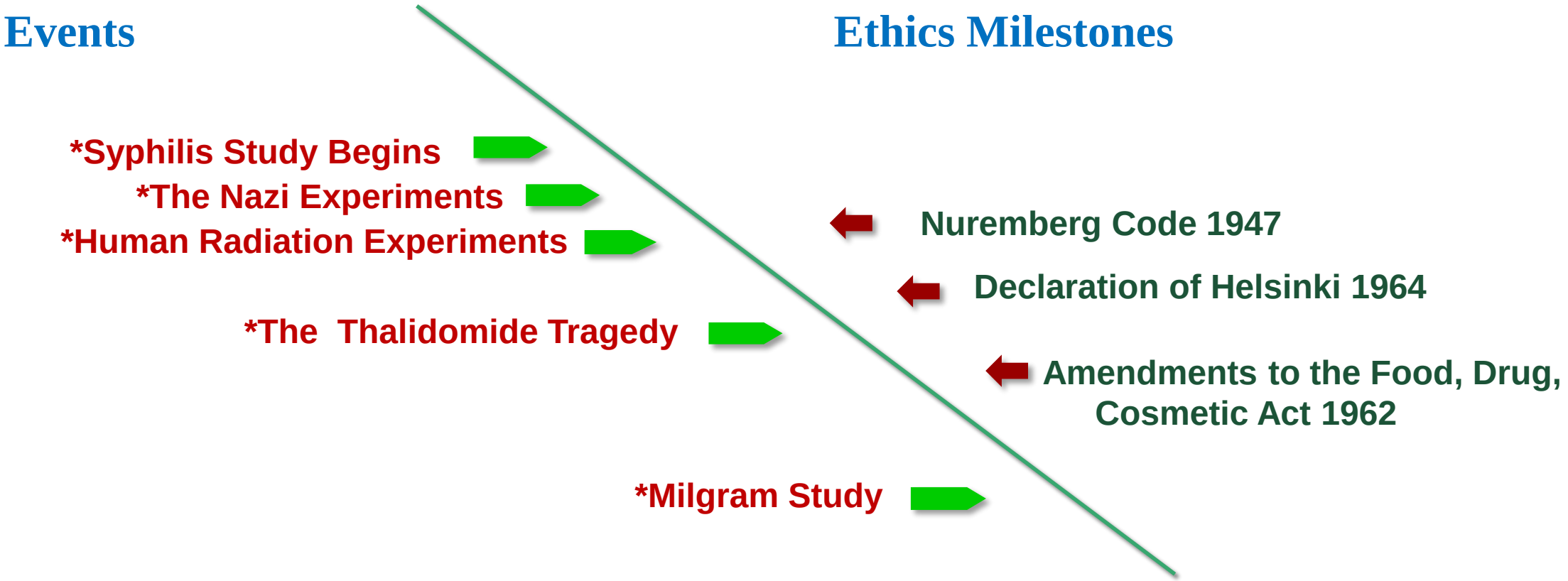
What is GLP?

Why should we do ethical research?

What is the relationship between accreditation and ethics and GLP?

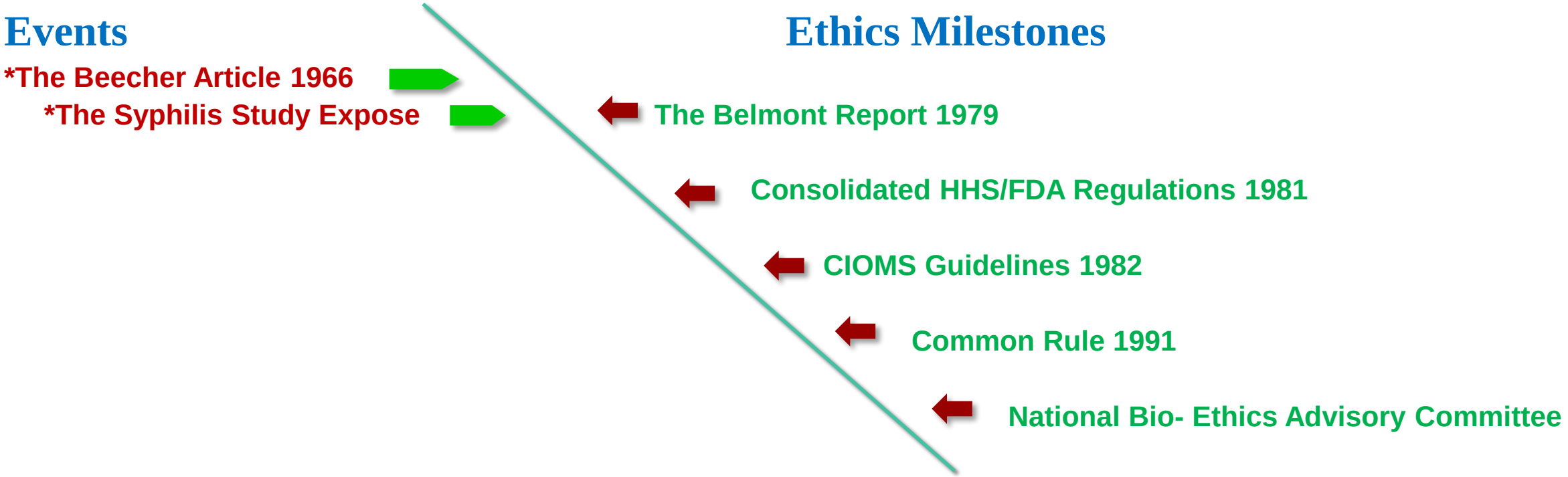
GLP in use!

Research Ethics Milestones



Adopted from Dr Siahi lecture on GLP

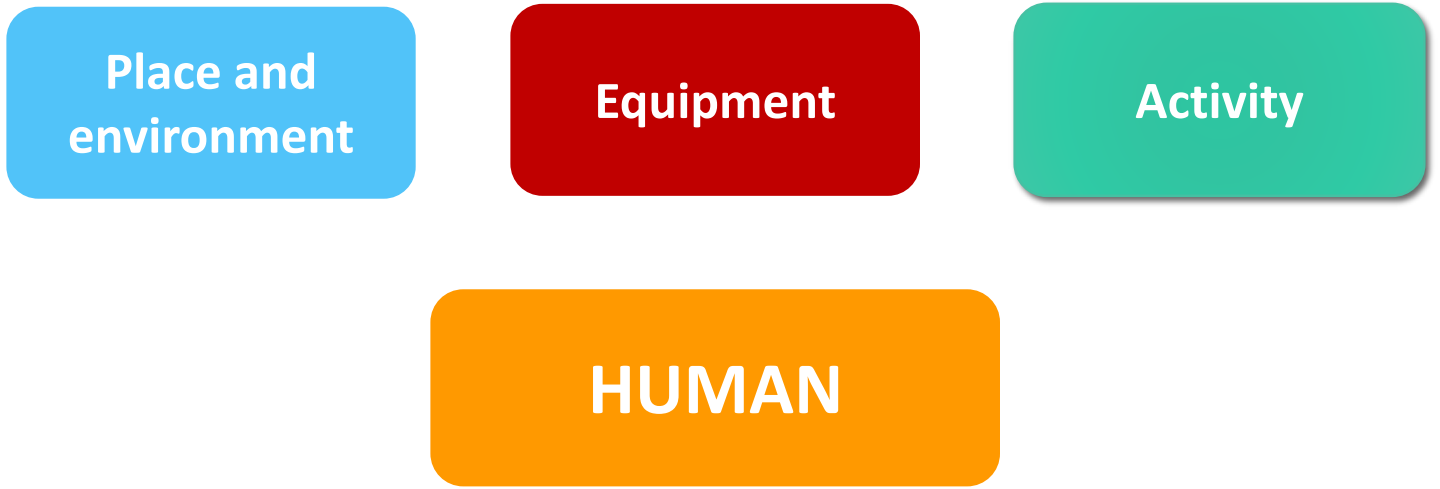
Research Ethics Milestones



Laboratory Definition

A building, part of a building, or other place equipped to conduct scientific experiments, tests, investigations, etc., or to manufactur e chemicals, medicines, or the like.

http://www.dictionary.com/browse/laboratory



Laboratory Definition: human

HUMAN

- **Qualifications**
- **Trainings and experience**
- **Competence**
- **Ethical Approach**

Types of Lab

- Medical labs
- Metrology labs
- Accredited Labs
- Governmental labs
  - Forensic labs
  - Reference labs
- Research labs
  - Academia
  - Non academia

What is “Ethics”

- The discipline dealing with, what is good and bad and with moral duty and obligation
- A set of moral principles
- A theory or system of moral values
- The principles of conduct governing an individual or a gro
- A guiding philosophy
- A consciousness of moral importance
- A set of moral issues or aspects (as rightness)

Webster’s online dictionary

Why Act Ethically?

Personal reputation

Organization business reputation

Enrich work life

What is Data Integrity?

Data integrity:

The overall completeness, accuracy and consistency of data

- Data of known and documented quality
- Representative, Comparable and Complete
- Defensible and Usable for its intended purpose, the first time.

What is accreditation

International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 :

General requirements for the competence of testing and calibration laboratories

Accreditation bodies

Regional

European Accreditation Cooperation (EA)

The Asia Pacific Laboratory Accreditation Cooperation (APLAC)

Southern Africa Accreditation Cooperation (SADCA)

Inter-American Accreditation Cooperation (IAAC)

International Laboratory Accreditation Cooperation (ILAC)

Methods of ABs

- The ANSI-ASQ National Accreditation Board and their recent acquisitions of L-A-B and ASCLD-LAB which are now both [http://www.anab.org/ ANAB]
- The American Association for Laboratory Accreditation (A2LA)
- Perry Johnson Laboratory Accreditation (PJLA)
- American Industrial Hygiene Association
- International Accreditation Service, Inc. (IAS)
- National Voluntary Laboratory Accreditation Program (NVLAP) - technically part of the US government and only accredits a few narrow disciplines

All accreditation programs have some focus on ethics

- They require detailed documentation in order to provide legally defensible laboratory data.
- Compliance with the requirements also enables the user or reviewer to track each step of the laboratory process in order to assure that data are reproducible.

1975 inspection lead to GLP

During these inspections the following events of non-compliance were found:

- Careless experimentation.
- Inaccurate analysis and reporting.
- Non-adherence to protocols.
- Data not subjected to periodic critical review.
- All available data not analyzed.
- Untrained, unqualified personnel.
- Improper laboratory procedures and animal care.
- Contract studies improperly monitored.

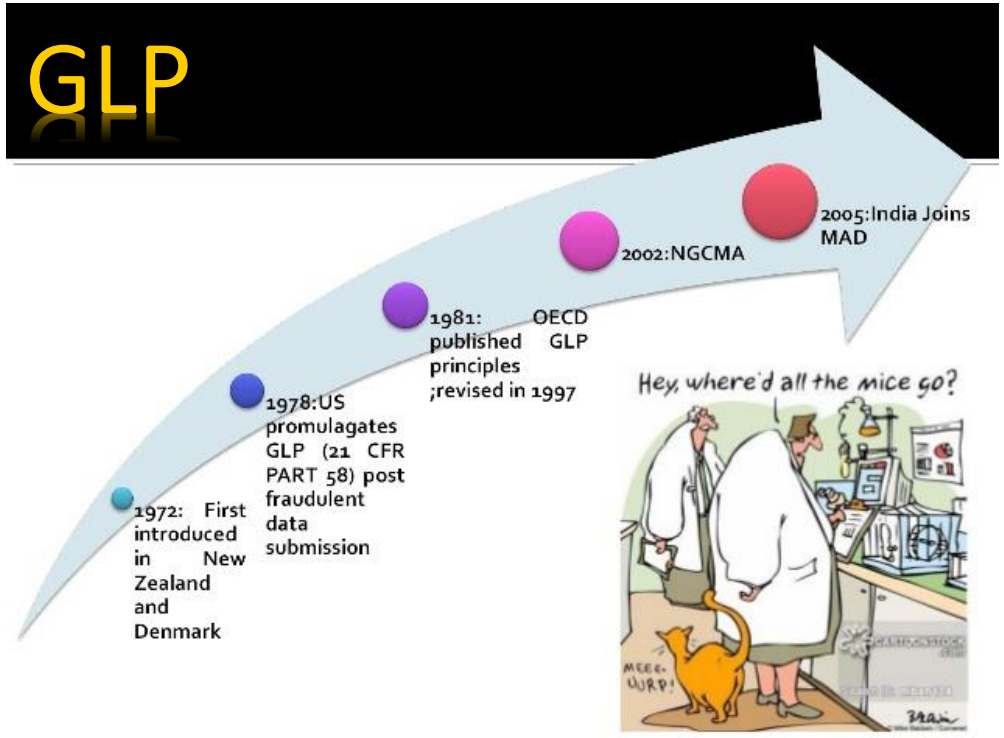
What is GLP

A quality system of management controls for research laboratories and organizations to try to ensure:

the uniformity,
consistency,
reliability,
reproducibility,
quality,

and integrity of chemical (including pharmaceuticals) non-clinical safety tests; from physio-chemical properties through acute to chronic toxicity tests.

What is GLP



Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived.

Basic elements of GLP

QA
Quality Assurance

Basic elements of GLP

Quality assurance program:

A defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these Principles of Good Laboratory Practice.

Basic elements of GLP

Personnel:

- Qualification of personnel (sponsor, manager (experiment and test facility), **study director**, quality assurance expert).

Facility:

- Qualification of facilities (e.g., bioanalytical/analytical testing facilities)
- Qualification and validation of apparatus (equipment, computers, or computerized systems).

Basic elements of GLP

Documents:

- Standard operating procedures .
- Performance of the study and reporting of study results .
- Storage and retention of records .
- Documentation and maintenance of records.

Materials:

- Qualification and validation of materials, and reagents, test and reference items
- Storage and retention of records and materials.
- Handling.

Types of Improper Laboratory Practices

Unintentional:

- Through ignorance or lack of communication.

Intentional:

- with minor impact on public health or environment
- jeopardizes public health.


FRAUD

What is “Fraud?”

- The Intentional misrepresentation of lab data to hide known or potential problems.
- The Intentional recording or reporting of incorrect information.
- An Intentional gross deviation from method specified analytical practices, combined with the intent to conceal the deviation.

Be the Solution, NOT the Problem

Fraudulent data puts public health at risk (including you and your family).

Others watch your fraudulent procedures and will imitate your techniques.

Regulatory agencies ALSO watch your fraudulent procedures will be happy to give you free room and board for about 5 years.

What should we do?

Mentoring and training

Laboratories must have a quality system that will enable any user to follow the traceable flow of the work performed.

Mentoring and training

The internal flow includes:

The staffing and training files of each person performing the analysis with evidence of proper experience and education capabilities.

Procedures written to instruct the analysts.

Receipt and traceability of all materials.

Documented calibration of instrumentation.

Control of data documentation and archives.

Mentoring and training

And

Staff that understand the importance of utilizing ethical decisions throughout the test process.

Quality assurance program

"A testing facility shall have a Quality Assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations.

For any given study, the Quality Assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of the study."

Overall QAU Responsibilities

There are 3 things the Quality Assurance Unit is responsible for verifying:

1) Is the Study being conducted in accordance with the protocol

2) Is the Study being conducted in accordance with relevant SOPs

3) Is the Study being conducted in accordance with the GLP regulations

QAU Responsibilities

- Maintain a copy of a master schedule sheet of all non-clinical studies conducted at the testing facility indexed by:
  - test article
  - test system
  - nature of the study
  - date study was initiated
  - current status of study
  - Sponsor
  - Study Director

Role of the QA unit

- QA reviews SOPs for compliance with GLPs
- QA does not approve SOPs (in a GLP environment)
- GLPs do not require that QA sign SOPs
  (It is an industry standard)
- QA is responsible for assuring Management that working procedures comply with the SOPs
- QA is responsible for reporting deviations to Study Directors and to Management

Study director

- Designate a Study Director before the study is initiated
- Replace the Study Director promptly, if necessary
- Assure that there is a Quality Assurance Unit
- Assure that the test and control article have been appropriately tested for identity, strength, purity, stability and uniformity, as applicable
- Authorize significant changes in SOPs
- Assures that any deviation from GLP regulations reported by the quality assurance unit are communicated to the Study Director and corrective actions are taken and documented

Study director

“ For each non-clinical laboratory study, a scientist or other professional of appropriate education, training and experience, or combination thereof, shall be identified as Study Director”.

Study director

- Only one person is designated as Study Director
- There cannot be a co-Study Director
- There can be an alternate Study Director
- There is no requirement for a Study Director in GMPs
- The GCPs require a Principal Investigator

Equipment requirements

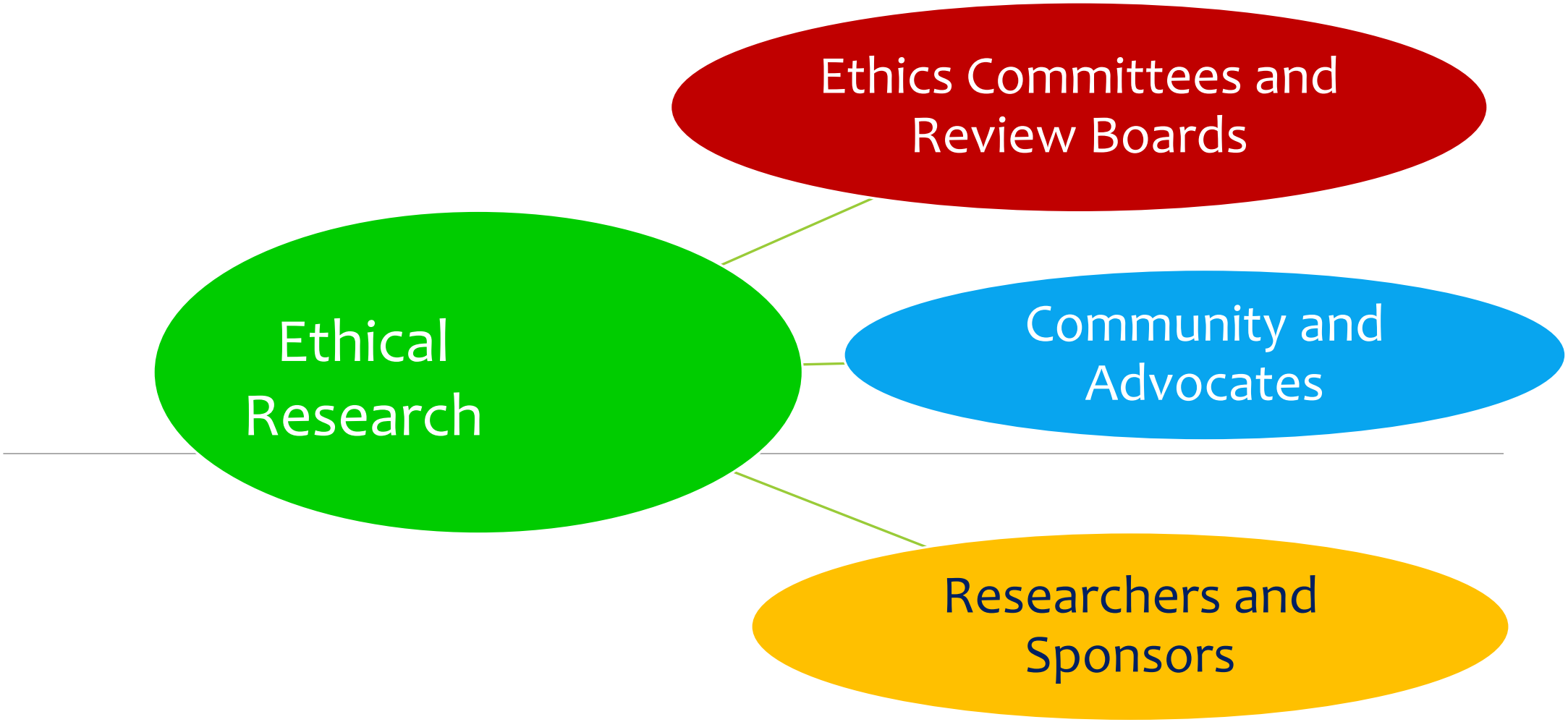
“ A testing facility shall have standard operating procedures in writing setting forth non-clinical laboratory study methods that Management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study.”

Laboratory area

“ Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed. Published literature may be used as a supplement to standard operating procedures.”

“ A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.”

Ugly data is better than Fraud data


Ethics Committees and Review Boards
Ethical Research
Community and Advocates
Researchers and Sponsors

Applied GLP

Cleanliness and Safety Broadcast Pride in a Lab's Work

Keep the Lab Area Clean!

Organize All Reagents and Equipment!

Use Proper Safety Equipment!

Keep Adequate Documentation!

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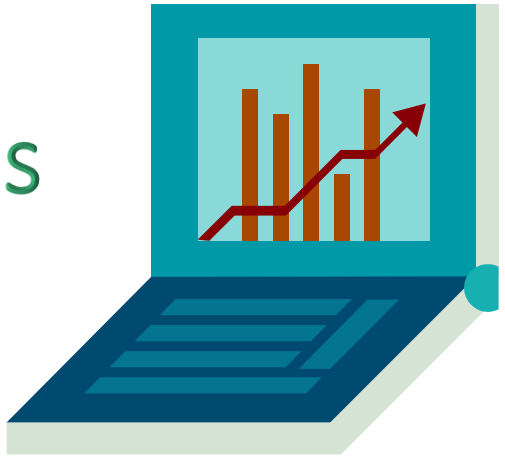
Examples of Improper Lab Practices

Not a “How To” but a ‘How Not To”

Improper Preparation Practices

Improper Spiking Procedure

Improper Calibration Procedures



Data Deletion

Improper Analytical Procedures

Ethics will work when

Laboratory personnel and researchers must feel that ethical standards of conduct are a priority in the laboratory.

Ethics will work when

Management must support this concept not only during training but also in daily communication to employees.

Thanks for your attention

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