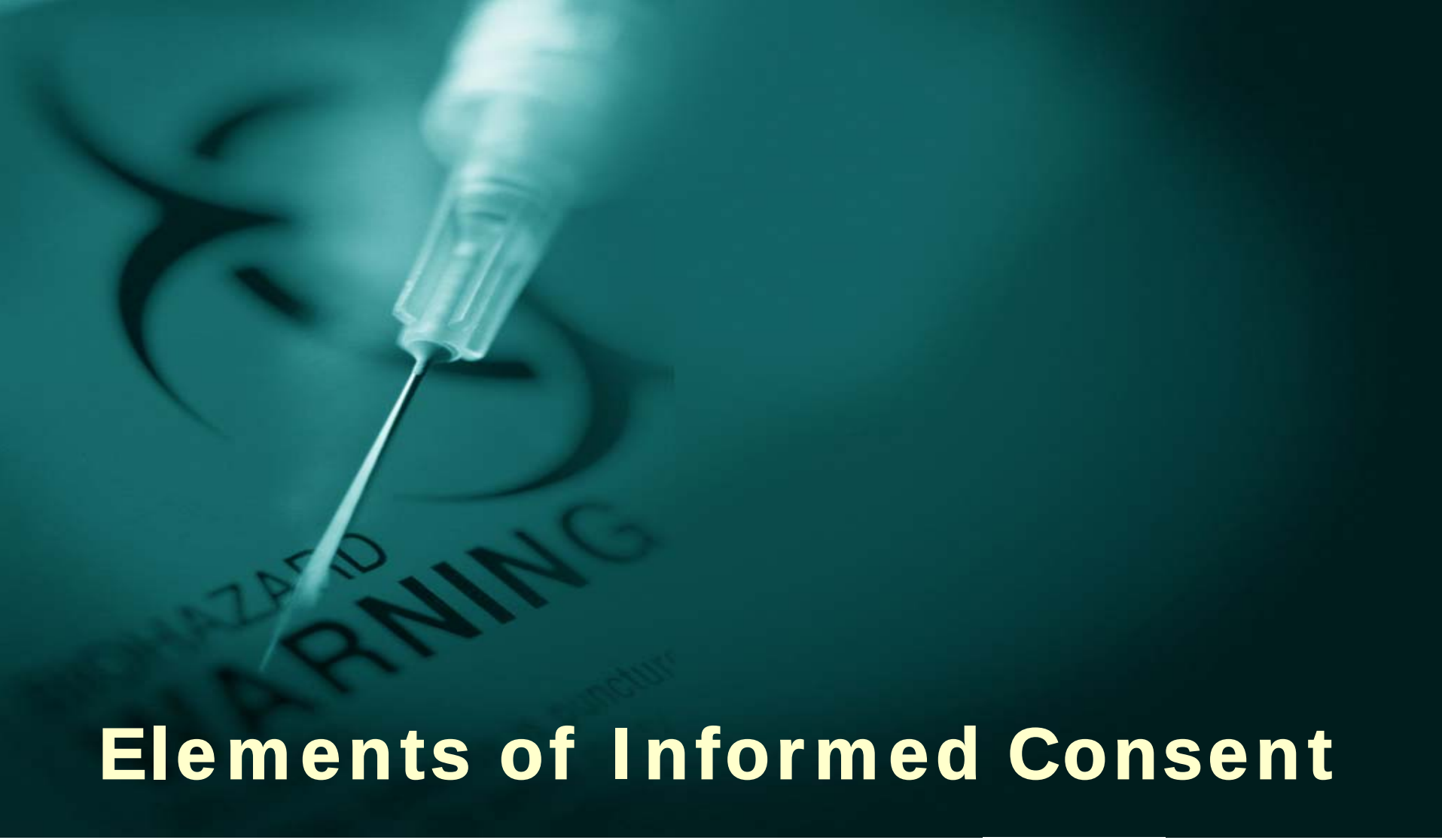

Elements of Informed Consent

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Informed Consent

- Informed consent is process of ensuring that subjects understand the research and voluntarily decide to participate. As part of this process, participants learn about study procedures, risks, benefits, and their rights.
- Individuals sign an informed consent document to authorize their agreement to participate in a study.

Informed Consent from all subjects

- Unless otherwise waived by the IRB, research investigators should obtain valid informed consent from all research subjects (or their legally authorized representatives) who participate in their research studies.

Basic Components of Valid Informed Consent

Disclosure of relevant information to prospective subjects about the research

Prospective subjects' **Compre-hension** of the information

their **voluntary agreement**, free of coercion and undue influence, to research participation

General Principles

- The information in the consent form should match the application.
- The written consent form should be approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

General Principles (Cont.)

- The form should be written in language that is understandable to the subjects.

  (Written at the reading level of 9th grade is advised in Taiwan)

- If the subject is being asked consent to various options (researchers accessing records, future use of tissue samples, being videotaped, audiotaped, etc) there should be one signature for overall consent for the study and separate signatures authorizing permission for each of the options.

Basic Elements of informed consent

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

Basic Elements of informed consent（Cont.）

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

The explanation of risks should be reasonable and should not minimize reported adverse effects.

Basic Elements of informed consent（Cont.）

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

The description of benefits to the subject should be clear and not overstated. If no direct benefit is anticipated, that should be stated.

The benefits to "others" may be an issue when benefits accruing to the investigator, the sponsor, or others are different than that normally expected to result from conducting research. Thus, if these benefits may be materially relevant to the subject's decision to participate, they should be disclosed in the informed consent document.

Basic Elements of informed consent（Cont.）

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

To enable a rational choice about participating in the research study, subjects should be aware of the full range of options available to them.

The person(s) obtaining the subjects' consent, however, should be able to discuss available alternatives and answer questions that the subject may raise about them.

Basic Elements of informed consent（Cont.）

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the competent authority of the Department of Health and the Ethics Committee may inspect the records.

Basic Elements of informed consent（Cont.）

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

Informed consent documents should describe any compensation or medical treatments that will be provided if injury occurs. The consent should also indicate whether subjects will be billed for the cost of such medical treatments.

Basic Elements of informed consent（Cont.）

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

The name of a specific office or person and the telephone number to contact should be provided for answers to questions about: 1) the research subjects' rights; 2) a research-related injury; and 3) the research study itself.

It should be considered to require that the person(s) named for questions about research subjects' rights not be part of the research team as this may tend to inhibit subjects from reporting concerns and discovering possible problems.

Basic Elements of informed consent（Cont.）

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Language limiting the subject's right to withdraw from the study should not be permitted in consent documents. If the subjects who withdraw will be asked to permit follow-up of their condition by the researchers, the process and option should be outlined in the consent document.

Additional elements of informed consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

Additional elements of informed consent (Cont.)

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

When applicable, subjects should be informed of circumstances under which their participation may be terminated by the investigator without the subject's consent.

Additional elements of informed consent (Cont.)

(3) Any additional costs to the subject that may result from participation in the research.

If the subjects may incur an additional expense because they are participating in the research, the costs should be explained.

Additional elements of informed consent (Cont.)

(4) The consequences of a subjects' decision to withdraw from the research and procedures for orderly termination of participation by the subject.

When withdrawal from a research study may have deleterious effects on the subject's health or welfare, the informed consent should explain any withdrawal procedures that are necessary for the subject's safety and specifically state why they are important to the subject's welfare.

Additional elements of informed consent (Cont.)

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

The IRB should determine that a system, or a reasonable plan, exists to make such notification to subjects.

Additional elements of informed consent (Cont.)

(6) The approximate number of subjects involved in the study.

If the numbers of subjects in a study is material to the subjects' decision to participate, the informed consent document should state the approximate number of subjects involved in the study.

(7) The amount of remuneration/compensation, if any, that will be provided to subjects.

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(8) When appropriate, a statement concerning an investigator's potential financial or other conflict of interest in the conduct of the study.

WAIVER OF INFORMED CONSENT

- An IRB may waive or alter some or all of the requirements for informed consent if:

1. The research presents no more than minimal risk to subjects
2. The waiver will not adversely affect the rights and welfare of subjects
3. The research could not practicably be carried out without the waiver

Gene Transfer or DNA research

- A separate Informed Consent document should be used for the gene transfer portion of a research project when gene transfer is used as an adjunct in the study of another technique, e.g., when a gene is used as a "marker" or to enhance the power of immunotherapy for cancer.

General Requirements

- Description/Purpose of the Study
- Alternatives
- Voluntary Participation
- Benefits
- Possible Risks, Discomforts, and Side Effects
- Costs

Specific Requirements

- **Reproductive Considerations**

To avoid the possibility that any of the reagents employed in the gene transfer research could cause harm to a fetus/child, subjects should be given information concerning possible risks and the need for contraception by males and females during the active phase of the study.

Specific Requirements (Cont.)

Long-Term Follow-Up

To permit evaluation of long-term safety and efficacy of gene transfer, the prospective subjects should be informed that they are expected to cooperate in long-term follow-up that extends beyond the active phase of the study.

The Informed Consent document should include a list of persons who can be contacted and the request that subjects continue to provide a current address and telephone number during the follow-up period.

The subjects should be informed about significant findings, the harms and benefits experienced by other individuals involved in the study, and any long-term effects that have been observed.

Specific Requirements (Cont.)

- **Request for Autopsy**

To obtain vital information about the safety and efficacy of gene transfer, subjects should be informed that at the time of death, no matter what the cause, permission for an autopsy will be requested of their families. Subjects should be asked to advise their families of the request and of its scientific and medical importance.

❖ Interest of the Media and Others in the Research

To alert subjects that others may have an interest in the innovative character of the protocol and in the status of the treated subjects, the subjects should be informed of the following: (i) that the institution and investigators will make efforts to provide protection from the media in an effort to protect the participants' privacy, and (ii) that representatives of applicable agencies (e.g., the Department of Health), representatives of collaborating institutions, vector suppliers, etc., will have access to the subjects' medical records.

Privacy

Indicate what measures will be taken to protect the privacy of subjects and their families as well as maintain the confidentiality of research data. These measures should help protect the confidentiality of information that could directly or indirectly identify study participants.


Thank You !