

9 BASIC ELEMENTS - INFORMED CONSENT FORM

1. **Research Statement**

- Involves research
- Purpose
- Duration
- Procedures
- What part is experimental
- Why you are being asked to join

2. **Risks and Discomforts**

- Reasonably foreseeable realistic risks/discomforts

3. **Benefits**

- Presumed positive outcome of trial is not a benefit

4. **Alternatives**

- Disclosure of subjects' alternatives to research participation, including possibly advantageous alternative procedures

5. **Confidentiality**

- Extent of confidentiality of identifiable records
- For FDA regulated research, a statement disclosing that the FDA may inspect records

6. **Compensation**

7. **Contact Person**

8. **Voluntary Participation and Right to Withdraw**

- Completely voluntary; and refusal or discontinuation to participate will not result in any penalty or loss of benefits to which is otherwise entitled.

9. **One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:**

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

ADDITIONAL ELEMENTS - INFORMED CONSENT FORM

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

- 1. Unknown Risks to Participants**
- 2. Termination of Participation**
- 3. Costs**
- 4. Consequences of Withdrawal**
- 5. New Findings Will Be Given to Subjects**
- 6. Number of Participants**

7. Biospecimens may be used for commercial profit
8. Disclosure of clinically relevant research results
9. Whether biospecimens will or may be used for whole genome sequencing

*All applicable to Clinical Trials, i.e. required by the FDA

- GINA: Genetic Information Nondiscrimination Act
- GWAS: Genome-Wide Association Studies
- Conflict of Interest (COI)

Sponsor and/or Funding Agency requirements

- Injury language
- Payment for procedures
- Access and Disclosure of information (HIPAA)