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- Clinical studies of drugs and medical devices only under specific conditions
- Collection of blood samples
- Biological specimens obtained by non-invasive means
- Collection of data through non-invasive procedures
- Materials collected solely for non-research purposes
- Collection of data from voice, video, etc.
- Research employing surveys, etc.
- Continuing review under specific conditions

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- U.S. Food and Drug Administration (FDA)—regarding clinical investigations with human subjects involving products
- Animal studies also included
- Clinical trials for drug investigations must comply with FDA regulations

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- Includes any subset of health information, including demographic information, that identifies the individual (or there is a reasonable basis to believe that the information can be used to identify the individual).
 - 1. Name
 - 2. All elements of dates except Year.
 - 3. SSN
 - 4. Driver's License Number
 - 5. Geographic subdivisions smaller than a State.
 - 6. URL's and IP's
 - 7. Vehicle Identifiers including VIN and License #
 - 8. Phone numbers

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Essential Information for Informed Consent

- 1. Introduction of research activities
- 2. Statement of research purpose
- 3. Selection of research subjects
- 4. Explanation of procedures
- 5. Description of risks and discomforts
- 6. Description of benefits
- 7. Disclosure of alternatives
- 8. Assurance of anonymity and confidentiality



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European Union General Data Protection Regulation

- The General Data Protection Regulation (GDPR) imposes new rules on organizations that offer goods and services to people in the European Union (EU), or that collect and analyze data tied to EU residents, no matter where they are located.
- Enforced on May 25, 2018

GDPR Data Definitions Regardless of Nationality or EU Residence

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Personal Data (from GDPR)

...means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.'

Examples:

- Name
- Identification number (e.g., Social Security number)
- Location data
- (e.g., home address)Online identifier
- (e.g., e-mail address, screen names, IP address, device IDs)Genetic data
- (e.g., biological samples from an individual)
- Biometric data (e.g., fingerprints, facial recognition)

"The GDPR also requires compliance from non-EU organizations that offer goods or services to EU residents or monitor the behavior of EU residents."

Source: Brief: You Need An Action Plan For The GDPR; Forrester Research; October 2016

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