

MEDICAL UNIVERSITY OF SOUTH CAROLINA HUMAN RESEARCH PROTECTIONS PROGRAM (HRPP)

Informed Consent, HIPAA, and Waivers



GENERAL REQUIREMENTS FOR INFORMED CONSENT

(45 CFR 46.116)

No investigator may involve a human being as a subject in research...unless the investigator has obtained the legally effective informed consent of the **subject** or the **subject's legally authorized representative**.





GENERAL REQUIREMENTS FOR INFORMED CONSENT

45 CFR 46.116

Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

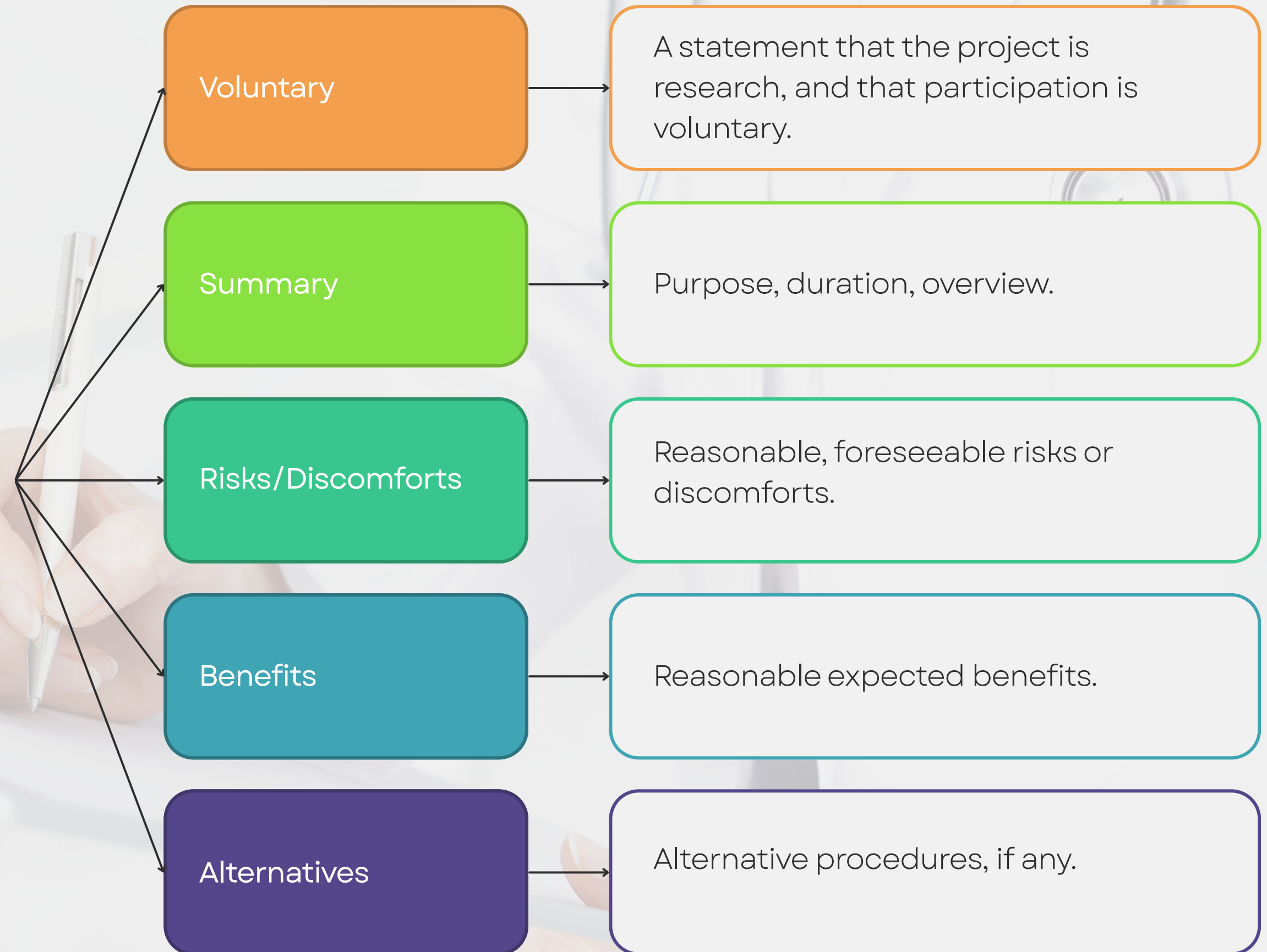
The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

Broad Consent:
Federal regulations permit broad consent for limited secondary research uses of identifiable private information or identifiable biospecimens; however, MUSC does not currently allow use of the Common Rule broad consent pathway.

No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

KEY INFORMATION: 5 FACTORS IDENTIFIED IN THE COMMON RULE

Key information must appear at the beginning of the consent, and be presented concisely in a way that helps the subject understand why they may or may not want to participate.



EXCULPATORY LANGUAGE

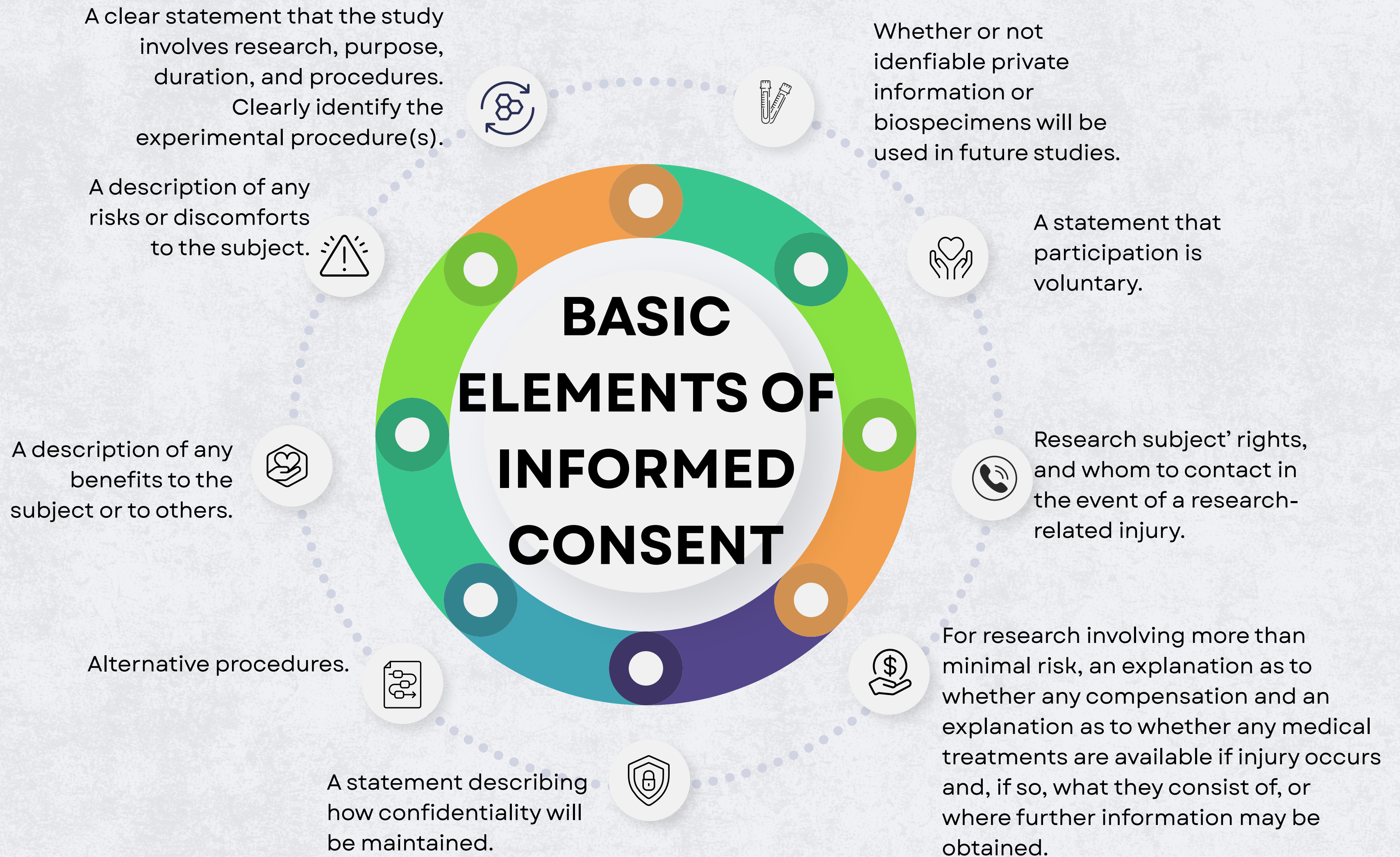
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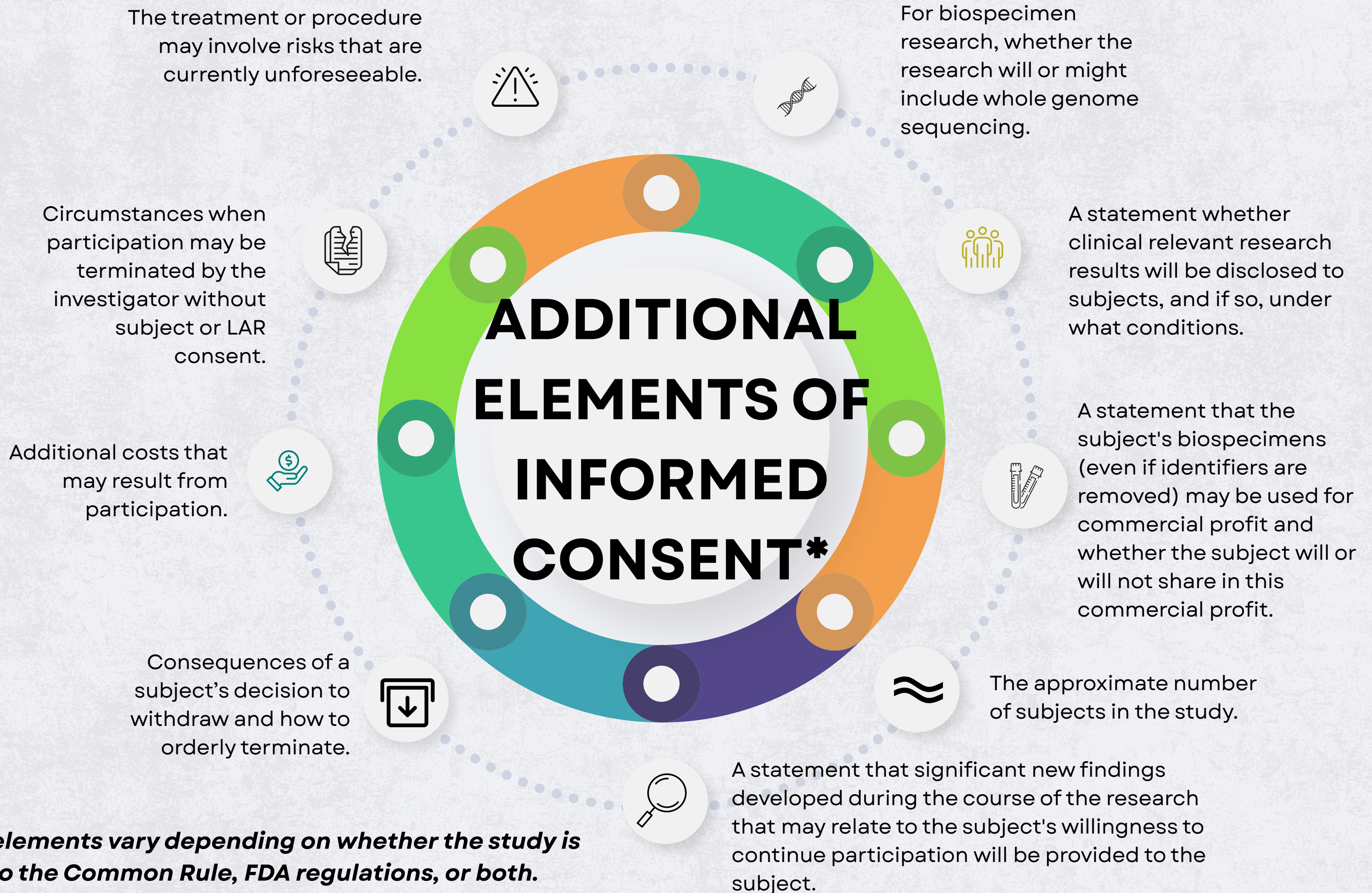
Exculpatory

I waive any possibility of compensation, including any right to sue, for injuries that I may receive as a result of participation in this research.

Acceptable

Because of hospital policy, the hospital is not able to offer financial compensation should you be injured as a result of participating in this research. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.





CONSENT: A PROCESS, NOT JUST A FORM



Informed consent is not a single event or a document. It is an ongoing process involving the study team and research subject. Informed consent consists of a full discussion of the research:

- nature of the research
- subject's role in that research
- understanding of that role by the potential subject
- subject's voluntary choice to join the study

INVESTIGATOR'S ROLE

PI has ultimate responsibility to determine how and who conducts the process. Plan who needs to be present on both sides of the table:

- Subject only?
- One/two parents?
- Proxy?
- Primary Investigator?
- Co-Investigator?
- Others?

Subject may want family or friends involved.

Investigator may want colleague, coordinator, or other research staff involved.

RECONSENTING: WHEN DO WE HAVE TO NOTIFY OR RECONSENT SUBJECTS?

Consent as an ongoing process demands dissemination of new information concerning the subject's participation.

New Findings

- Could it affect current subjects desire to participate? (if yes, reconsent)
- Is it something that former subjects would need to know? (notification)

Study Procedure Change

If subjects are unaffected by the change (i.e. past that point of the study), they do not need to reconsent for the new procedures. They may need notification depending on the reason.

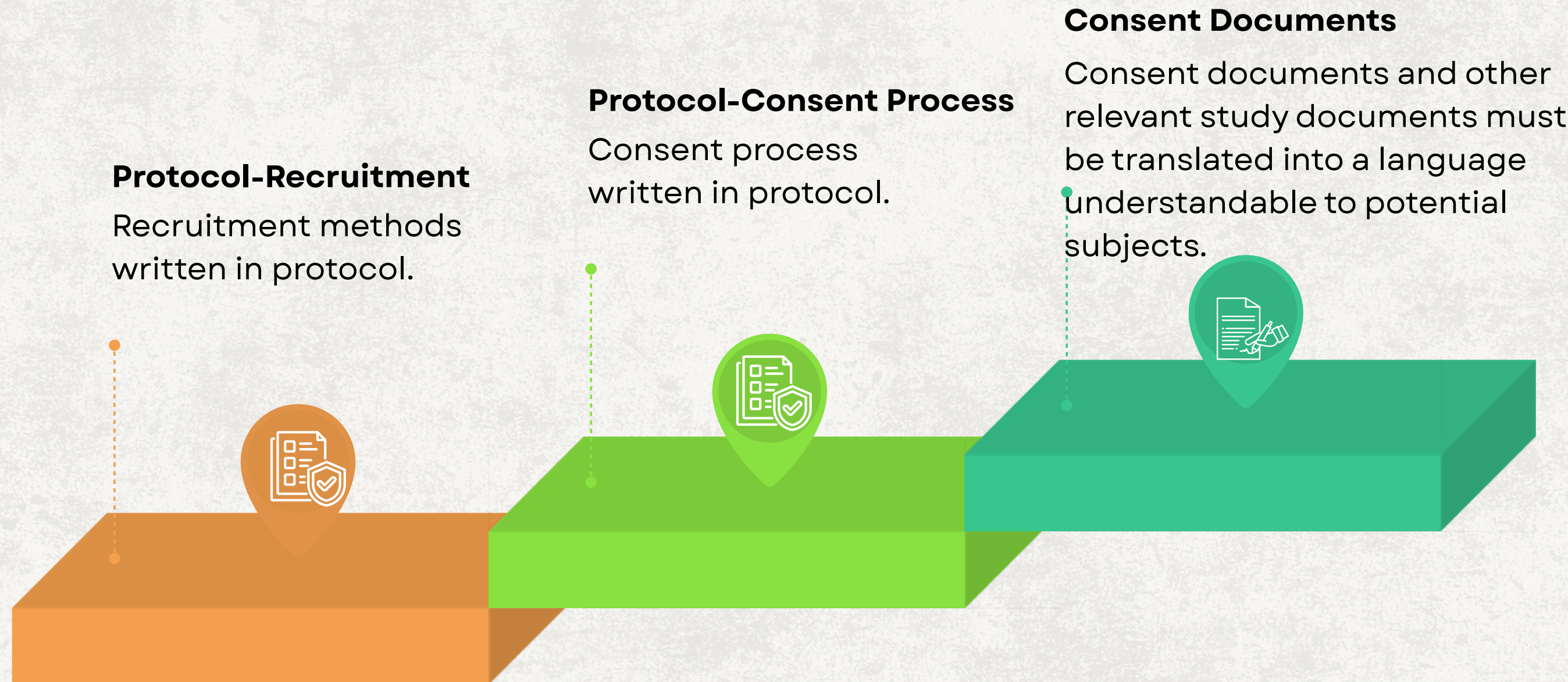
Risk (new or changed)

- Completed subjects may need notification of late developing risks.
- Current subjects may need reconsent if they haven't yet assumed the risk.

Reconsent: Use when subjects have to decide whether or not to proceed with additional study procedures.

Notification: Use when information needs to be conveyed but there is nothing to 'reconsent' to.

NON-ENGLISH SPEAKING PARTICIPANTS



Short Form:

If a non-English speaking participant is enrolled, unexpectedly, an IRB-approved 'short form' consent can be utilized. The short form must be written in a language understandable by the subject/LAR. Under 45 CFR 46.117(b)(2), the IRB must approve a written summary.

- There must be a witness to the oral presentation
- The subject/LAR signs the short form
- The person obtaining consent signs the summary
- The witness signs both the short form and summary
- Copies of both are provided

Planned enrollment of non-English speaking participants should use translated consent materials.

WAIVER OR ALTERATION OF INFORMED CONSENT

- For minimal risk research, the IRB may approve a request to waive all or some of the required elements of informed consent under specific circumstances.
- Waivers or alterations of informed consent are primarily requested for projects involving secondary analysis of existing data or in projects involving deception.



The research involves no more than minimal risk to subjects.



The research could not be carried out practicably without the waiver or alteration.



If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format.



The waiver or alteration will not adversely affect the rights and welfare of the subjects.



Where appropriate, the subjects will be provided with additional information about their participation.
Note: The intent of this waiver criterion is to require debriefing for participants in deception research.

WAIVER OF DOCUMENTATION OF INFORMED CONSENT

The IRB may approve a request to waive documentation of informed consent for some research projects. Subjects must be provided with information about the research project; however, the study team is not required to obtain the subject's signature on an informed consent document.

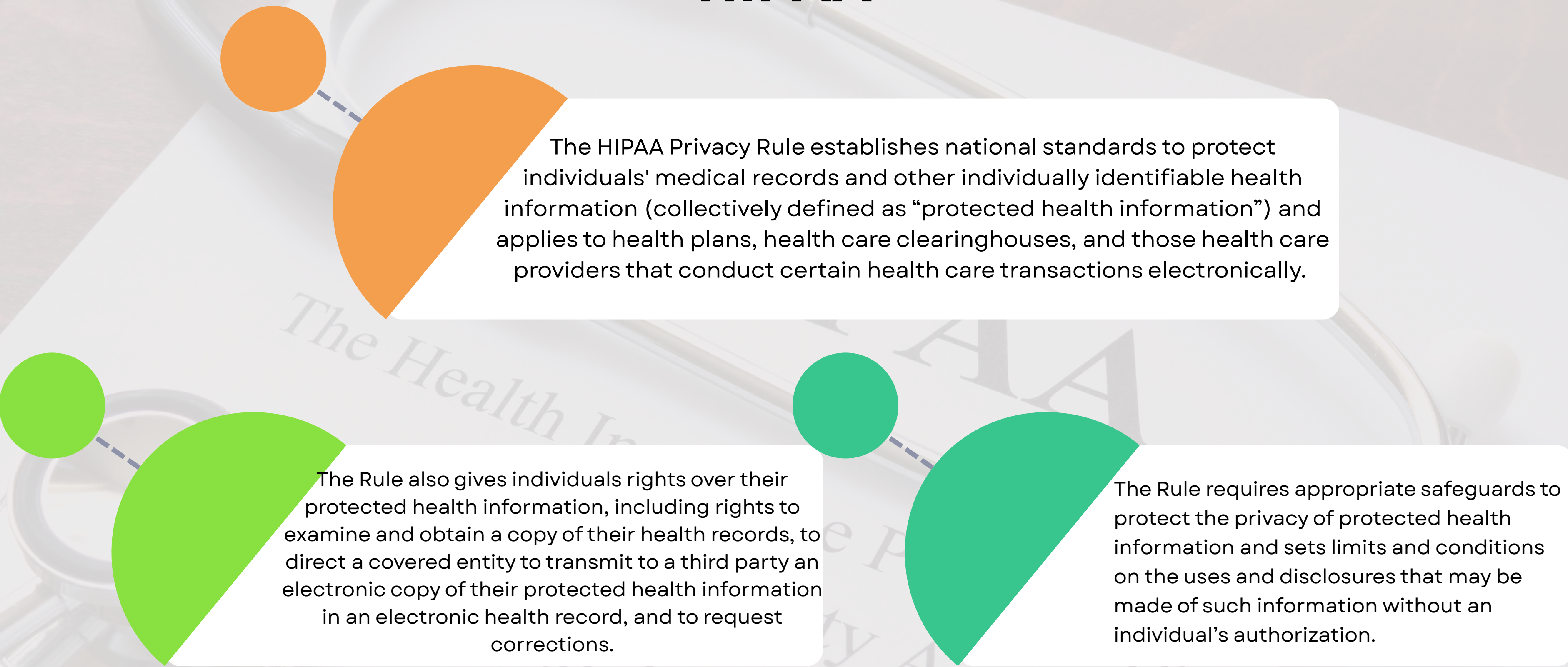
A waiver of documentation is permissible when:

The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality.

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

The subjects or LARs who are members of a distinct cultural group or community in which signing forms is not the norm, provided the research is no more than minimal risk, and there is an appropriate alternative mechanism for documenting consent.

HIPAA



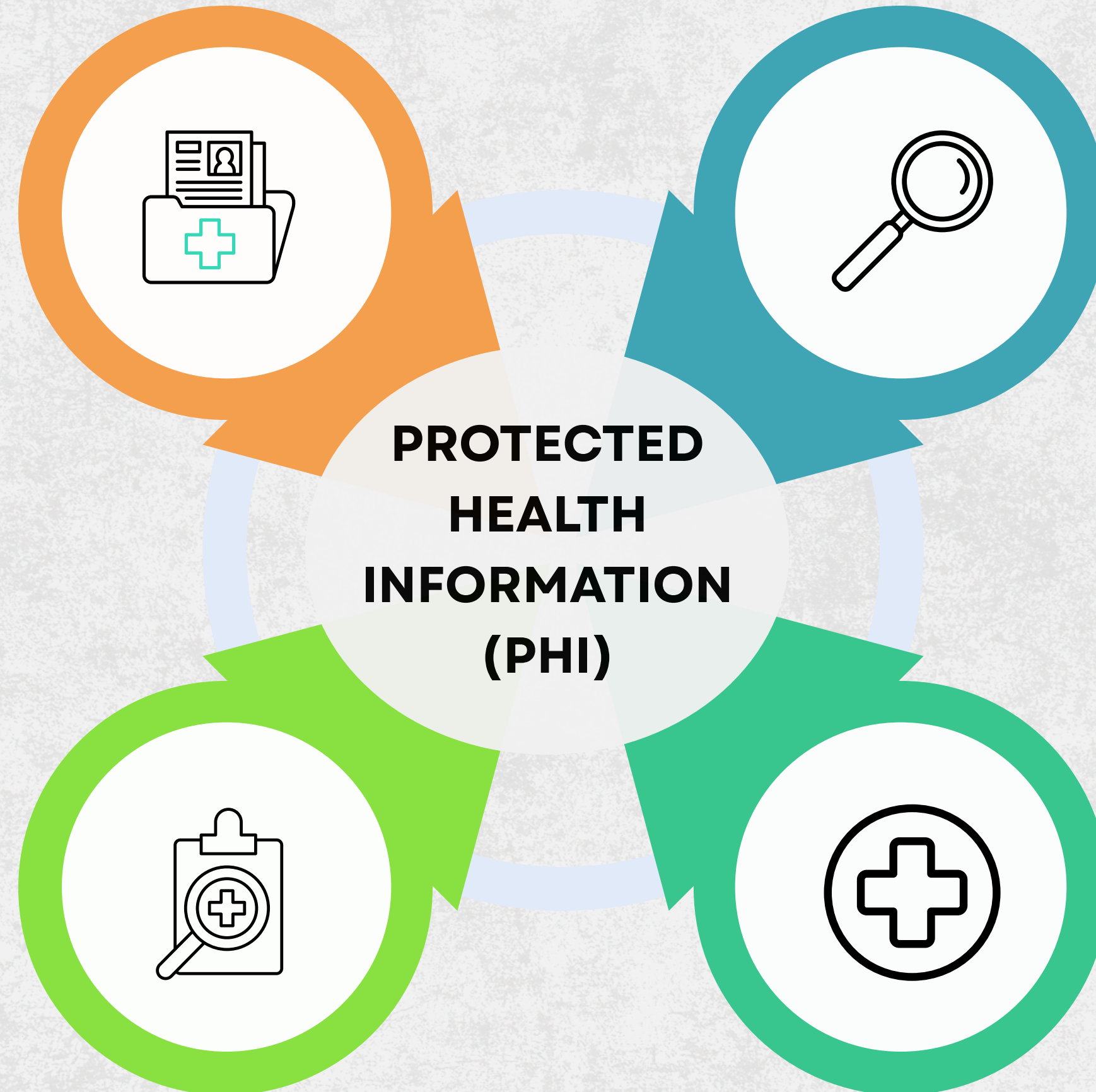
The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other individually identifiable health information (collectively defined as “protected health information”) and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically.

The Rule also gives individuals rights over their protected health information, including rights to examine and obtain a copy of their health records, to direct a covered entity to transmit to a third party an electronic copy of their protected health information in an electronic health record, and to request corrections.

The Rule requires appropriate safeguards to protect the privacy of protected health information and sets limits and conditions on the uses and disclosures that may be made of such information without an individual’s authorization.

- Is individually identifiable health information, whether oral or recorded in any form or medium (e.g., narrative notes; X-ray films or CT/MRI scans; EEG / EKG tracings, etc.), that may include demographic information, and

- Is created or received by a 'covered entity,' and



- Identifies the individual directly or contains sufficient data so that the identity of the individual can be readily inferred
- Relates to the past, present, or future physical or mental health or condition of an individual, to the provision of health care to that individual, and/or to payment for health care services, and

18 PHI (PROTECTED HEALTH INFORMATION) IDENTIFIERS

- Names
- All elements of date (except year) for dates directly related to an individual (DOB, admission date, discharge date, date of death)
- All geographic subdivision smaller than a state including street address, city, county, precinct, zip code, and/or equivalent geocodes.
- Medical record number
- Telephone Numbers
- Fax Numbers
- Account numbers
- Certificate/license numbers
- Health plan beneficiary number
- Vehicle identifiers and serial numbers, including license plate numbers
- Web Universal Resource Locators (URLs)
- Social security numbers
- Device identifiers and serial numbers
- Electronic mail addresses
- IP address numbers
- Full face photographic images and any comparable images
- Biometric identifiers, including finger and voice prints
- Any other unique identifying number, characteristic or code

HIPAA



Researchers are obligated to comply with HIPAA when they access, use, disclose, and/or create “Protected Health Information” (PHI).



Accessing identifiable medical records for research requires a signed HIPAA Authorization or a waiver.



Exempt studies using PHI require authorization or waiver of HIPAA authorization.



WHAT IS A WAIVER OF HIPAA AUTHORIZATION?

A HIPAA waiver for research is a special permission that allows researchers to use or access a person's private health information without getting their written consent. This is only allowed only under certain conditions such as:



01

Disclosure of PHI for research purposes is minimal risk to the subject.



02

The research cannot practicably be done without access to the PHI.



03

The research can't be conducted without the waiver.

REQUIREMENTS FOR WAIVER OF HIPAA



Include the plan to protect the identifiers from improper use or disclosure.



Justify why the nature and amount of PHI is felt to be the minimum necessary.



Justify why the research couldn't practicably be conducted without access and use of the PHI.



Justify why the research couldn't practicably be conducted without the waiver.



Written assurances that the PHI will not be used or disclosed to others (entity or person), except by law, authorized oversight, or other permitted use or disclosure.



Include the plan to destroy the ID log at the earliest opportunity, unless justified to retain.



Questions?

Rebekah Whichard
IRB Administrator for Education & Training
richreb@musc.edu