THE COMMON RULE

PROTECTION OF HUMAN SUBJECTS

The Common Rule (45 CFR 46) establishes federal protections for individuals, referred to as *human subjects,* who participate in research. It defines ethical and procedural standards — including requirements for informed consent and Institutional Review Board (IRB) oversight. It applies to **all research involving human subjects that is conducted, supported, or regulated by a federal department or agency.**

Key Definitions

Human subject:
A living individual about whom a researcher obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Identifiable private information:
Private information where the subject's identity is or may readily be determined by the investigator, or the information is linked to identifiable data.

Identifiable biospecimen:
A biological sample where the identity of the subject is or may readily be determined by the investigator, or is associated with identifiable information.

When The Common Rule Applies

Applies when researchers:

- Interact directly with people to collect information or samples.
- Use identifiable private information or identifiable biospecimens.
- Intend to re-identify previously deidentified specimens.

When Research May Be Exempt

Some low-risk activities are exempt. For example:

- Using publicly available information or biospecimens.
- Working with information for which the identity of the human subject cannot be readily ascertained directly or through identifiers linked to the subjects.

Application to Residual Dried Blood Spots (RDBS)

Residual dried blood spots (RDBS) are specimens leftover from newborn screening. They are regulated the same as any other biospecimen under the Common Rule.

- Deidentified residual biospecimens, including RDBS, are not considered human subjects as long as they remain deidentified. Research using these materials is not subject to the Common Rule.
- However, if a researcher intends to re-identify a deidentified biospecimen, including RDBS, the work becomes human subject research and is subject to the Common Rule provisions - including the requirement for informed consent prior to conducting the research.

Why It Matters

- ✅ Protects privacy and autonomy of research participants.
- ✅ Enables responsible use of deidentified data and biospecimens.
- ✅ Prevents misuse while allowing lifesaving public health and genetic research.

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