

# Updates to Definitions: Who is a human subject?

Human subject means a living individual about whom an investigator conducting research

- (i) obtains information *or biospecimens* through intervention or interaction with the individual, *and uses, studies, or analyzes the information or biospecimens*; or
- (ii) obtains, uses, studies, analyzes, or generates identifiable private information *or identifiable biospecimens*.

# Updates to Definitions: Who is a human subject?

- **Same:** the individual still has to be “identifiable” – “identity may be readily ascertained”
- **Change:** definition now includes biospecimens
- Federal agencies are required to reexamine the meaning of “identifiable” within 1 year of the final rule and then at least every 4 years

# Categories of Activities that are Explicitly Not Research

1. Certain scholarly and journalistic activities
2. Public health surveillance
3. Criminal justice activities
4. Authorized operations to support national security