

Changes to Informed Consent Requirements and Forms

- Goal: improve understandability
- New regulations require a “concise and focused presentation” at the beginning of the consent form
- Level of detail should provide what a reasonable person would want to know to make an informed decision

Four New Elements/Requirements of Informed Consent

- Use (or not) of identifiable information/ biospecimens for future research
- Biospecimen commercial profit disclosure
- Return of clinically relevant research results
- Whole genome sequencing