

FINAL ODDS & ENDS

INFORMED CONSENT

CONSENT SCRIPT FOR EXEMPT HUMAN RESEARCH



That the activities involve research



The procedures to be performed



That participation is voluntary



The name and contact information for the investigator



RE-CONSENT OF RESEARCH SUBJECTS

Regulatory Requirement:

- Researchers must inform participants about significant new findings during research if it affects their willingness to continue

Factors Influencing Information Provision:

- Nature of the study and new information
- Urgency of the new findings
- Participant status (screening, intervention, long-term follow-up)

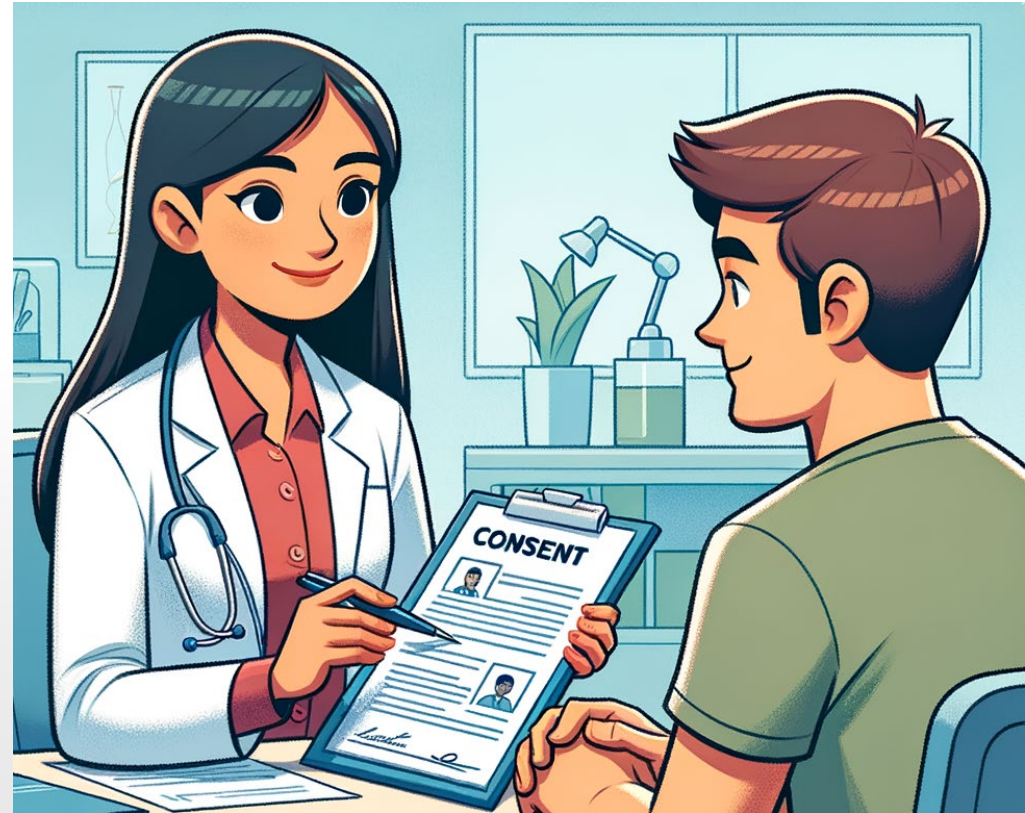
RE-CONSENT OF RESEARCH SUBJECTS

Instances Requiring Re-Consent:

- New research-related risks identified
- Increased frequency/magnitude of existing risks
- Unanticipated issues like data breaches
- Decrease in expected participation benefits
- Changes increasing burden/discomfort or duration
- Significant alterations in study design
- New uses for research specimens (e.g., genetic testing)
- Changes in financial burden or investigator conflicts

RE-CONSENT OF RESEARCH SUBJECTS

- Repeating the informed consent process with revised documentation
- Using an addendum to the original consent document
- Oral communication, documented in research records



CONSENT FOR SCREENING & RECRUITMENT

OBTAIN INFORMATION FOR SCREENING, RECRUITING, ELIGIBILITY WITHOUT CONSENT WHEN:

- The investigator will obtain information through oral or written communication with the prospective subject or LAR
- The investigator will obtain identifiable private information/biospecimens by accessing records or stored specimens



CONSENT & CONFLICT OF INTEREST



CONSENT & CONFLICT OF INTEREST

Sources of funding for the study

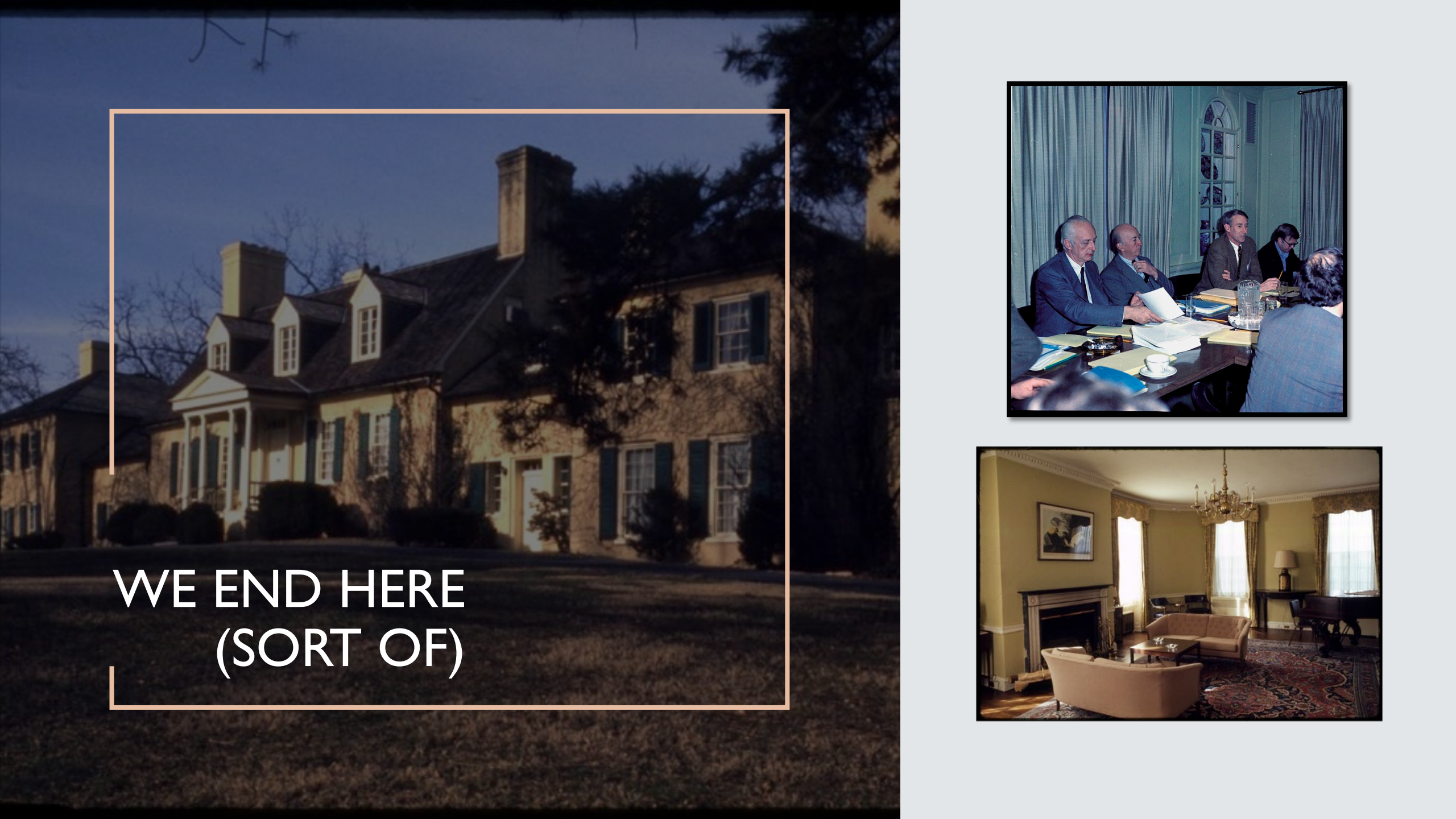
- Example: *This study is being funded by the National Institutes of Health (NIH) [or Industry Sponsor or Private Foundation].*

Investigator conflicts of interest

- Example: *Dr. John Smith, the principal investigator for this study, has a financial interest in the [product, drug, device, name of company] being studied.*

How to find out additional information

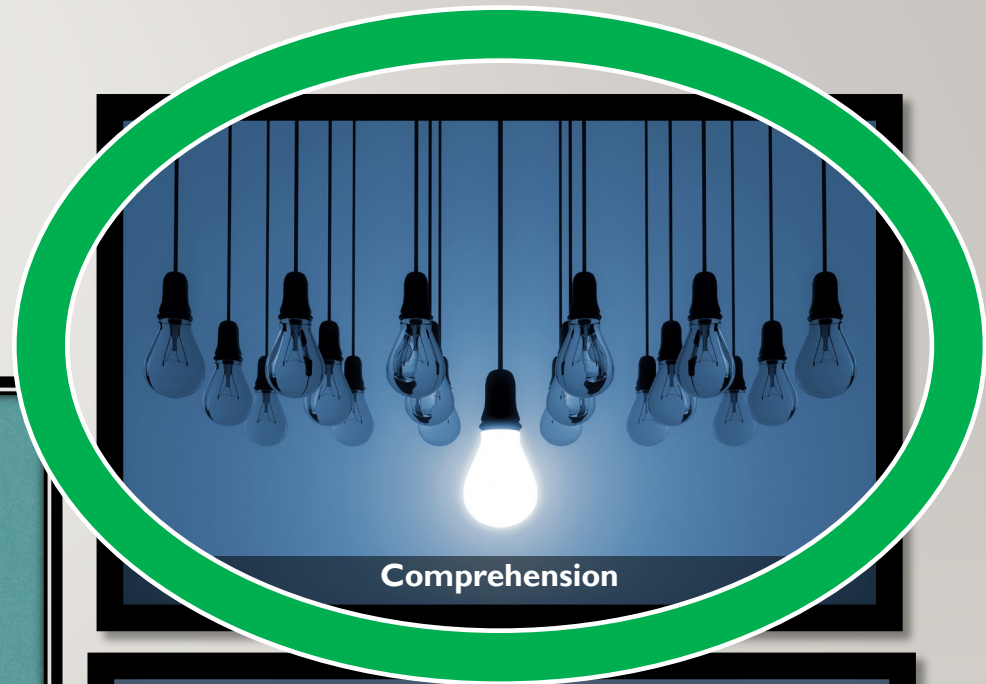
- Example: *This disclosure is made so that you may determine whether this relationship affects your willingness to participate in this study. If you have questions, please inform the study coordinator, and s/he will put you in touch with someone to talk to.*

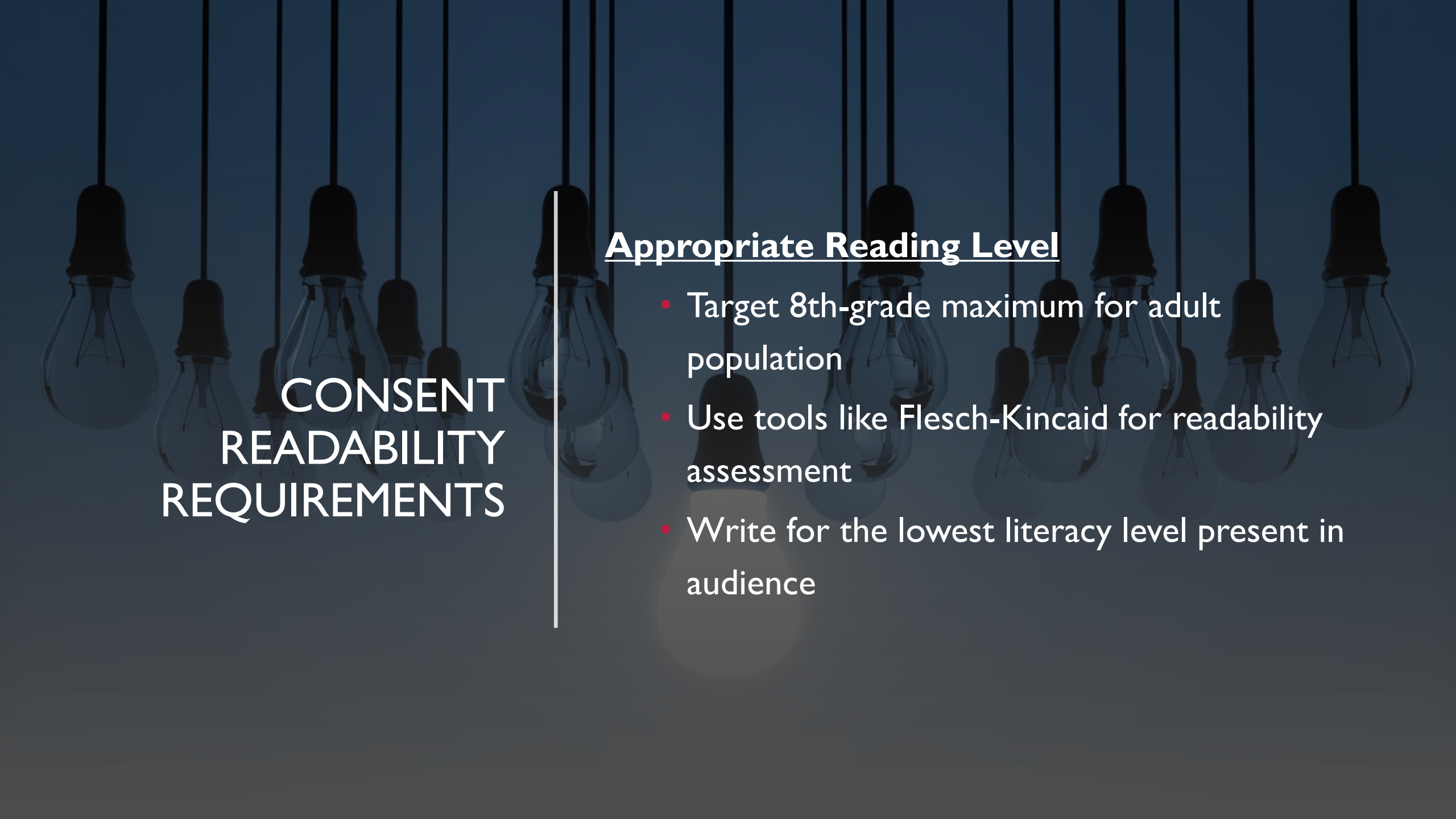


WE END HERE
(SORT OF)



PRINCIPLES APPLIED

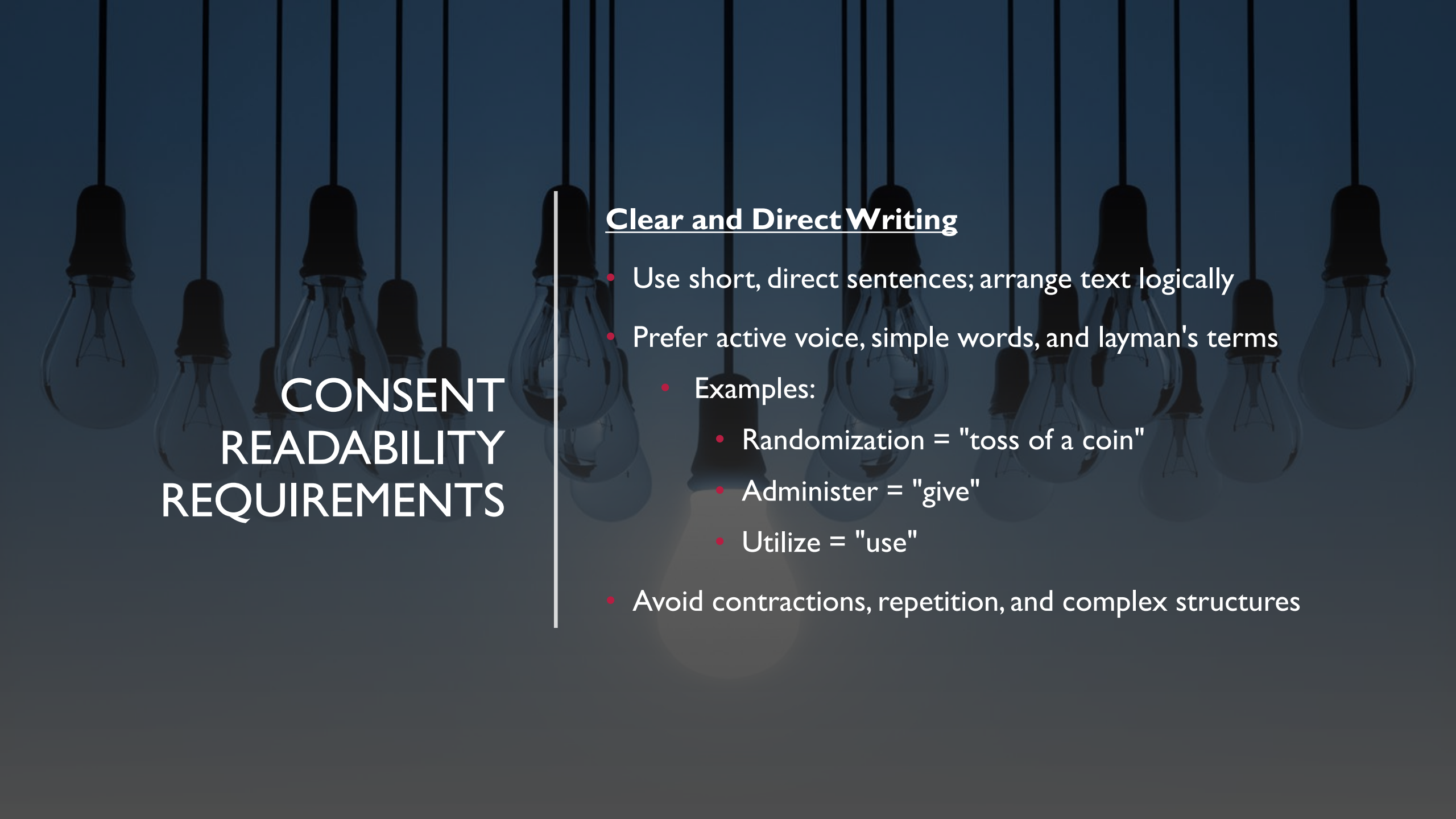


The background of the slide features a dark blue-grey gradient with several incandescent light bulbs hanging from thin black cords. The bulbs are arranged in a slightly irregular pattern, with some appearing more prominent than others. The overall aesthetic is modern and professional.

CONSENT READABILITY REQUIREMENTS

Appropriate Reading Level

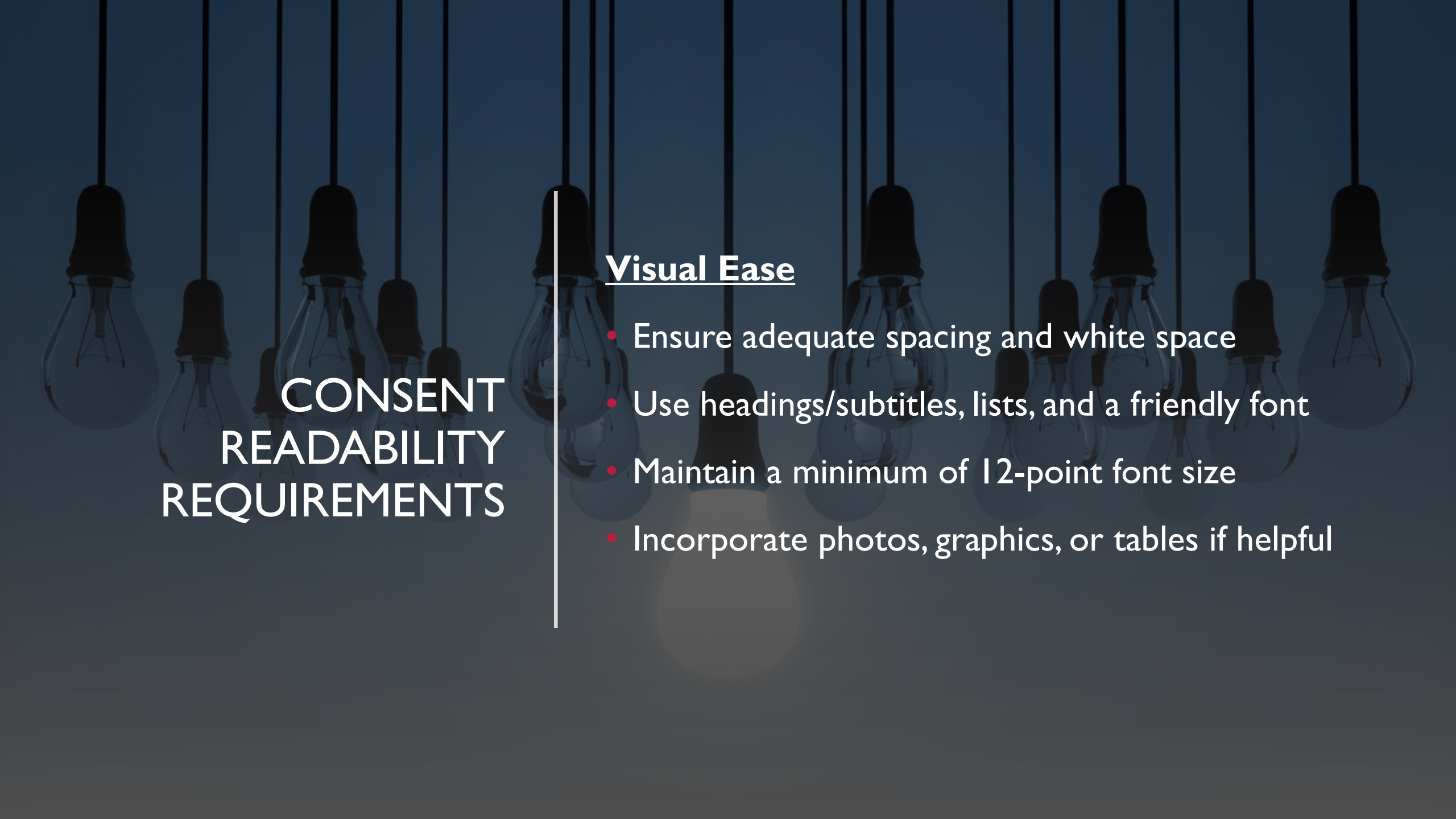
- Target 8th-grade maximum for adult population
- Use tools like Flesch-Kincaid for readability assessment
- Write for the lowest literacy level present in audience

The background of the slide features a dark blue-grey gradient with several incandescent light bulbs hanging from thin black cords. The bulbs are arranged in a slightly irregular pattern, with some appearing more prominent than others. The overall aesthetic is clean and modern.

CONSENT READABILITY REQUIREMENTS

Clear and Direct Writing

- Use short, direct sentences; arrange text logically
- Prefer active voice, simple words, and layman's terms
 - Examples:
 - Randomization = "toss of a coin"
 - Administer = "give"
 - Utilize = "use"
- Avoid contractions, repetition, and complex structures

The background of the slide features a dark blue-grey gradient with several incandescent light bulbs hanging from thin black cords. The bulbs are arranged in a slightly irregular pattern, with some appearing more prominent than others. The overall aesthetic is modern and minimalist.

CONSENT READABILITY REQUIREMENTS

Visual Ease

- Ensure adequate spacing and white space
- Use headings/subtitles, lists, and a friendly font
- Maintain a minimum of 12-point font size
- Incorporate photos, graphics, or tables if helpful

QUESTIONS?



INFORMED CONSENT