Understanding the New Common Rule and Its Impact to Industry

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Impact to Industry

Common Rule Applies only to Federally Funded Research

> Institutions will apply certain standards to all research

> 21st Century Cures Act compels FDA to harmonize regulation
Impacts to Industry – Some Positive, Some Not

Neutral or Negative
> New consent comprehension and reasonable person requirements
> Consent posting requirement
> Limitations on use of identifiable biospecimens and information

Potentially Positive
> Less continuing review for minimal risk/expedited research
> Requirement for all domestic sites to use single IRB

Big Unknown: Will FDA harmonize 50 & 56?
New Consent Requirements

- “Reasonable person” standard
- “Facilitates comprehension” standard
- Concise summary requirement
- Secondary use of biospecimens and information
- Posting to ‘government website’
New “Reasonable Person” Standard

The Common Rule establishes a new consent standard: To provide information that a reasonable person would want to have in order to make an informed decision about whether to participate.*

> “Reasonable person” is undefined, subject to interpretation

> Who determines the “reasonable person”
  
  • IRB
  • Sponsor
  • Investigator
  • Lawyers

*(§.116(a)(4)) emphasis and paraphrased
New “Facilitates Understanding” Standard

The Common Rule establishes a new consent standard: Information presented in sufficient detail, and organized and presented in a way that facilitates subject’s understanding of reasons why one might or might not want to participate; not merely provide lists of isolated facts*

> No guidance on “sufficient detail”

> Implies a consent comprehension test may be necessary
  • Who would develop and administer test?
  • What standard would be used?
  • “Facilitates Understanding” standard also incorporated in**

*($\_\_116(a)(5)(ii)$) emphasis and paraphrased
**($\_\_116(a)(5)(i)$)
Other Changes

Additional major new consent requirements:

> “Concise and focused” summary of “key information”*
  • Must appear at beginning on consent document
  • “Key information” is not defined in regulation, guidance pending

> Disclosure regarding future use of biospecimens and identifiable information**

> Consent must be posted to “Federal web-site within 60 days of last study visit
  • Unclear which version is posted—first signed, last approved?
  • Redaction of “proprietary information” is allowed
  • Posting is responsibility of “awardee” institution
  • “Federal website” is pending (likely clinicaltrials.gov)

*§.116(a)(5)(i)  **§.116(b)(9)
Impact to Industry

> **Consent template updates**
  - Company standard organization and language
  - Existing language negotiated with sites and IRBs

> **Legal considerations**
  - Reasonable person
  - Comprehension assessments
  - Public posting ~ media concerns
  - Contract updates

> **Other?**
New “Broad Consent” Process

The Common Rule establishes an entirely new alternative consent process for “Storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens”*

> No option for waiver of consent later on if subject refuses a “broad consent”
> Unclear what happens if subject refuses broad consent but also agrees to a study specific consent which includes future use of identifiable biospecimens

**Insight**

Depending on FDA harmonization language

Should *not* impact sponsors practice of using *de-identified* information and biospecimens collected during research

**Side Note**

Original NPRM proposed that any biospecimen would be considered identifiable

Final Common Rule dropped that position, left open changes in future

*(§116(d)) emphasis and paraphrased
Impact to Industry

> Broad Consent

- Limitations on biospecimen collection for pharmacokinetic and other common sponsor sub-studies and follow-up research
- Confusion at sites regarding status of biospecimens and data sharing with sponsors
- Differing standards on de-identification practices at sites
- Varying practices across sites
- Unknown FDA harmonization

> Other?
Reduced IRB Review

The new common rule drops several categories of research from the requirements of annual Continuing Review by the IRB*

> Research qualifying for expedited IRB review (e.g. minimal risk)
  - Applies to some phase 4, observational, and in vitro diagnostic device research

> Research qualifying for the new “limited” IRB review process (e.g. secondary use )
  - Would apply to some registry, biobanking, and post-marketing research

> Research reaching data analysis phase

> FDA regulations have not yet changed—50 and 56 still require continuing review at least annually
Single IRB for Multi-Site Research

> NIH policy on single IRB—effective September 2017
  • Applies only to NIH funded multi-site research
  • Domestic performance sites must use designated single IRB

> New Common Rule single IRB mandate—effective January 2020
  • Applies to all Common Rule agency funded multi-site research
  • Domestic performance sites must use designated single IRB*

> FDA harmonized regulation—effective…?
  • Would presumably apply to any FDA-regulated research
  • If following OHRP model, all performance sites must use the designated single IRB

*(§_.114(b)(1))
Impact to Industry

- Reduced requirement for IRB review
  - Obvious advantage in cost and efficiency

- Mandate for single IRB
  - Improved consistency through more sites using single IRB
  - Academic centers must use designated central IRBs
  - Sponsors may get to designate the single IRB for all sites
  - Remove resistance from sites to use commercially administered single IRBs

- Other?
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Big unknown – When will FDA harmonize?