Current Issues in Health Policy

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Regulatory Changes

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September 24, 2018

Common Rule Changes
Delayed until January 1, 2019 & 2020

19 January 2017  HHS Published Final Rule
19 July 2018 to 20 January 2019 Six-month delay period with three burden-reducing provisions allowed
21 January 2019 General Compliance Date for All Changes except cooperative research
20 January 2020 Compliance Date for Cooperative Research

Delay to Final Rule
A Final Rule published in 2016 (Federal Policy for the Protection of Human Subjects: Six-Month Delay of the General Compliance Date of Research Involving the Use of Human Subjects) further delayed the general compliance date for all cooperative research. Therefore, this delay was extended again, until January 2020, allowing for additional time to separate the two final rules: one for non-cooperative research – that remains 20 January 2019; and the other for cooperative research – that remains 20 January 2020. During this delay, institutions are allowed to apply new provisions from the revised Common Rule (2018 requirements) during the period from 19 July 2018 – 20 January 2019 (HHS 2018).
What is a human subject?

Under the changes, the definition for “human subject” now includes identifiable biospecimens.

What is a clinical trial?

A clinical trial is...
“a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.”

Informed Consent

- Key information upfront
- Additional elements added, if applicable
- IRB approved consent posted publicly
- Broad consent for identifiable samples or individual identifiable data acceptable

Institutional Review Board

- Single IRB
- Federalwide Assurance (FWA)
- Continuing Reviews
- Grant Application Review
- 4 new exempt categories
- Membership
- Vulnerable population coverage
ICH E6 Changes

Improve study design & conduct - Modernize

- Monitoring
- Sponsor Responsibilities
- Investigator Responsibilities
- ALCOAC

GDPR
General Data Protection Regulation

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References

https://about.citiprogram.org/en/resources/
http://www.irb.pitt.edu/GDPR

Current Issues in Health Policy Related to Cancer Research

Shimere Williams Sherwood, PhD
ASCO, Policy and Advocacy
Current and Ongoing Issues

- Federal Funding for Research
  - 21st Century Cures and Cancer Moonshot

- Right to Try/Expanded Access

- Protection of Human Subjects: Common Rule

Status of NIH Funding...End of Fiscal Year

Congress

- 2018 - Provided $37.1 billion; a $3 billion increase, the largest in 15 years.
- 2019 - Increase likely
  - Senate passed a $2 billion increase for NIH
  - House Appropriations Committee passed a $1.25 billion increase for NIH
  - House & Senate agreed on using the Senate numbers

Administration

- Proposed 7% cut to NIH for 2019.
- Proposed a 12% cut to NCI for 2019.
- Rejected by the House and Senate Appropriations Committees on a bipartisan basis.

Federal Funding and Continued Implementation of Cures

- NIH – $4.8 billion over 10 years in CURES Act
  - Precision Medicine Initiative ($1.5 billion)
  - Beau Biden Cancer Initiative ($1.8 billion)
  - FDA – $500 million

Advance medical research, promote innovation and the development of new treatments for cancer and other chronic diseases.

NIH Update

NIH Congressional Hearing Update on CURES

- Big Data
  - certificates of confidentiality
  - Data Commons Pilot rewards
  - Data sharing

- Inclusion across lifespan policy (begins January 2019)
- Next Generation of Researchers Initiative
- Precision Medicine Initiative - All of Us Research Program
- Cancer Moonshot
**FDA Update**

Implementation of Cures continues
- Clinical Trial Designs
  - Seamless clinical trials and make clinical endpoints more achievable
  - FDA released final guidance on use of RWE and EHRs
  - Draft guidances on modernizing clinical trials (expansion cohorts and use of placebos); ASCO is included in these discussions
- Establishing OCE – received funding to continue the implementation of the Center - organizing review divisions around disease types
- Expanded Access Improvements – simplified IRB review and RUF navigator

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**Advocacy on Federal Research Funding and Policies**

- Direct Lobbying
- Coalition Lobbying & Letters
- Grassroots/ACT Network
- Written Testimony
- Capitol Hill Events
- Social Media
- Traditional Media
- I Live to Conquer Cancer Campaign

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**ASCO ACT Network (Alert Congress Today)**

- ASCO.org/ACTNetwork
- The ACT Network matches you with your lawmakers
- Identify the issue/s you would like to contact your lawmakers about concerning cancer care
- Each alert contains background information on the issue and the current Congressional status
- Send editable letters to your lawmaker with one click

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**Right to Try/Expanded Access**

- As of May 2018, 39 states have enacted RTT laws
- May 30, 2018, Federal RTT legislation signed into law
  - Federal law pre-empts state laws
  - Impact on Providers and Patients
    - DO NOT require physicians to help patients seek access to investigational treatment
    - Physician liability protections
    - Lack patient protections
- ASCO continues to support FDA improvements to expanded access program
- ASCO Resources
  - FAQ on RTT
  - Podcast
  - Issue Brief
Protection of Human Subjects: Common Rule

- Release of final rule - January 19, 2017
- Implementation - Delayed till January 21, 2019
- HHS reviewing provisions institutions can implement during the delay period
- Elimination of continuing review for minimal risk studies
- Elimination of IRB approval for applications as part of the certification process (FWA is the only type of assurance OHRP approves)
- Definition of “research” which deems certain activities not to be research


Questions and Discussion

- Key takeaways from the three issues
  - Federal Funding continues to have a positive outlook considering the environment
  - Right to Try is more Right to Ask
  - Common Rule changes are coming - continue to prepare

ASCO ACT Network allows you to get involved by: