2017 Research Year in Review

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COLLABORATION DRIVES RESULTS

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2017 Research Year in Review

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21st Century Cures Act Update

December 13, 2016 Congress passed the 21st Century Cures Act with $4.8 billion dollars in funding and a purpose of speeding the development and approval of new medicines and medical devices the act has generated significant excitement and discussion.

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2017 FDA-21st Century Cures Act Deliverables

Section	Title	Public Website Notes		Section	Title	Public website Notes
1001	FDA innovation projects	Submission to Congress: Food & Drug Administration Work Plan and Proposed Funding Allocations of FDA Innovation Account		3057	CLIA waiver improvements	Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Wavier Applications for Manufacturers of In Vitro Diagnostic Devices - Draft Guidance for Industry and Food and Drug Administration Staff
2041	Task Force on research specific to pregnant women and lactating women	NIH held a two-day meeting of the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) on 8/21-22/2017.		3059	Cleaning instructions and validation data requirement	Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and Food and Drug Administration Staff
3002	Patient-focused drug development guidance	Plan for Issuance of Patient-Focused Drug Development Guidance		3060	Clarifying medical software regulation	FDA communicated its interpretation of this policy through final guidance titled "Medical Device Accessories--Describing Accessories and Classification Pathway for New Accessory Types"
3024	Informed consent waiver or alteration for clinical investigations	Guidance titled, "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects."		3073	Establishment of FDA intercenter institutes	FDA website: "Oncology Center of Excellence"
3034	Guidance regarding devices used in regenerative advance therapies	This draft guidance, and other guidance documents that are part of the comprehensive policy framework for the regulation of regenerative medicine products		3074	Scientific Engagement	2017 Annual Reports on Conferences
3051	Breakthrough Devices	Breakthrough Devices Program - Draft Guidance for Industry and Food and Drug Administration Staff				

https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/21stCenturyCuresAct/ucm562475.htm

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21st Century Cures Act and the FDA

Oncology Center of Excellence ("OCE")

- Launched 01.19.17 to "leverage the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices. (i.e., disease focused approach)
- Goal: expedite the development of oncology and hematology medical products
- In 2017 approved 16 new drug and biologic applications, 30 supplemental drug and biologic applications, 2 biosimilars, and several IVDs.
- Notable approvals:
  - The first cell-based gene therapies (CAR T-cell, tisagenlecleucel, and axicabtagene ciloleucel)
  - The first cancer drug product label update describing how patients should STOP taking nilotinib.
  - IVDs (Oncomine DX Target Test, IMPACT NGS tumor profiling, FoundationOne CDX NGS test)
- OCE held more than 30 academic symposiums

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21st Century Cures Act and the FDA

Some Key Provisions from 2017 FDA Work Plan for the 21st Century Cures Act Innovation Account Activities: Prepared for Review by the FDA Science Board

- **Section 3023, Protection of Human Research Subjects**
  - Harmonize, to the extent possible, FDA and HHS Common Rule within three years of enactment of the Cures Act.
- **Section 3051. Breakthrough Devices**
  - Expands FDA's Expanded Access Pathway program which will allow for expedited development and review of breakthrough devices.
- **Section 3031. Summary Level Review for Improving Access to Therapies and Information**
  - FDA will rely on qualified data summaries to support approval of a supplemental application for a qualified use of a drug.
- **Section 3002. Patient-Focused Drug Development**
  - FDA to issue guidance that addresses acceptable methodological approaches for collecting, measuring, and analyzing patient experience data.
- **Section 3021. Novel Clinical Trial Design**
  - FDA will assist sponsors in incorporating complex adaptive and other novel trial designs into proposed clinical protocols and applications for new drugs and biological products in order to facilitate more efficient product development.

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21st Century Cures Act and the NIH

Regenerative Medicine Innovation Project ("RMIP")

- The 21st Century Cures Act authorized $30 million over four years ($2 million for FY 2017) "for clinical research to further the field of regenerative medicine using adult stem cells."

2017 RMIP Awardees

- **Harvard University, Cambridge, Mass.**
  Production of Clinical-Grade Diabetes Patient-Specific Induced Pluripotent Stem Cell Lines Intended for Autologous Beta Cell Replacement Therapy
- **Maine Medical Center, Portland**
  Engineering Erythropoietin-Producing Cells
- **University of Colorado Denver**
  Testing the Therapeutic Potential of iPS Cells for Inherited Skin Diseases
- **Yale University, New Haven, Conn.**
  Optimizing Therapeutic Revascularization by Endothelial Cell Transplantation
- **Albert Einstein College of Medicine, New York**
  Optimization of Reagent Red Blood Cell Production
- **Boston Children's Hospital**
  ABCB5-Positive Stem Cells for Limbal Stem Cell Deficiency (LSCD) Therapy
- **Children's Hospital of Philadelphia**
  Optimization of Ex Vivo- and In Vivo-Generated Platelets
- **Columbia University Health Sciences, New York**
  Modeling, pathogenesis and treatment of idiopathic pulmonary fibrosis.

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FDA REGULATORY UPDATE

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FDA Clinical Trials Guidance Documents

- FDA and OHRP Issue Final Joint Guidance on IRB Written Procedures – 5/2018
- Draft: Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials Guidance for Industry – 4/2018
- FDA Guidance ICH E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry – 3/2018
- Waiver of IRB Requirements for Drug and Biological Product Studies - Information Sheet -10/2017
- IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects - 07/2017
- Minutes of Institutional Review Board (IRB) Meetings - Guidance for Institutions and IRBs - 09/2017
- FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions - Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff -12/2017
- Draft: Expanded Access to Investigational Drugs for Treatment Use — Questions & Answers -10/2017
- Draft: Use of Electronic Records and Electronic Signatures in Clinical Investigations Under Part 11 – Questions and Answers – 06/2017

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FDA Clinical Trials Guidance Documents

FDA and OHRP Issue Final Joint Guidance on IRB Written Procedures

- To enhance human subject protection and reduce regulatory burden, OHRP and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research
- The purpose of this guidance is to assist staff at institutions and IRBs who are responsible for preparing and maintaining written procedures
- The guidance includes a Written Procedures Checklist that incorporates the HHS and FDA regulatory requirements for written procedures for the IRB and recommendations on the type of operational details to include to support each of these requirements

FDA Clinical Trials Guidance Documents

Draft: Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials Guidance for Industry

- Provides recommendations about how and when to include pregnant women in drug development clinical trials for drugs and therapeutic biological products
- The scientific and ethical issues discussed in this guidance apply both to clinical trials that enroll pregnant subjects and to clinical trials that allow enrolled subjects who become pregnant to remain in the trial
- Some of the information provided in this guidance applies to drugs indicated to treat pregnancy specific conditions (e.g., preterm labor, pre-eclampsia), but the larger focus is on drugs indicated for conditions that occur commonly among females of reproductive potential

FDA Clinical Trials Guidance Documents

Guidance ICH E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry

Revisions in addendum include:

- Using a risk management approach in designing studies
- Promoting the use of risk-based and centralized monitoring in managing studies
- Addressing the reporting and follow-up of significant noncompliance (including conducting a root cause analysis, and creating a corrective and preventative action plan)
- Addressing technology issues (for example, specifying that electronic systems should be validated, backed-up, and safeguarded)
- Specifying oversight responsibilities of sponsors and investigators
- Improving data integrity (for example, requiring that source data are attributable, legible, contemporaneous, original, accurate, and complete)
- Ensuring both investigators and sponsors have access to study data and documents

FDA Clinical Trials Guidance Documents

Waiver of IRB Requirements for Drug and Biological Product Studies - Information Sheet

- Update to January 2006 Guidance Document
- Clarified that a sponsor does not need to apply for a waiver of local IRB review when a centralized IRB review process is used
- Added new section (section VIII) which states that a waiver of IRB review is appropriate for individual patient expanded access INDs when the physician obtains concurrence by the IRB chairperson before treatment use begins

FDA Clinical Trials Guidance Documents

IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects

- FDA will not object to an IRB waiving or altering informed consent requirements for certain minimal risk clinical investigations
- FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent
- Title III, section 3024 of the 21st Century Cures Act amended the FD&C Act to provide FDA with the authority to permit an exception from informed consent requirements for minimal risk clinical investigations

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https://www.fda.gov/RegulatoryInformation/Guidances/ucm566474.htm

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FDA Clinical Trials Guidance Documents

Use of Electronic Records and Electronic Signatures in Clinical Investigations Under Part 11 – DRAFT

- Provides recommendations on the use of electronic records and electronic signatures under part 11 in clinical investigations of medical products
- The goals of the draft guidance are to clarify and update recommendations for applying and implementing part 11 requirements and to encourage the use of electronic records and systems to improve the quality and efficiency of clinical investigations.

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM563785.pdf

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FDA Clinical Trials Guidance Documents

Minutes of Institutional Review Board (IRB) Meetings - Guidance for Institutions and IRBs

- Joint FDA & OHRP guidance
- provides recommendations on the type and amount of information to include in IRB meeting minutes
- Guidance focuses on the five required items that must be included in the minutes:
  - Attendance at the meetings;
  - Actions taken by the IRB;
  - The vote on these actions, including the number of members voting for, against, and abstaining;
  - The basis for requiring changes in or disapproving research; and
  - A written summary of the discussion of controverted issues and their resolution

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https://www.fda.gov/RegulatoryInformation/Guidances/ucm470046.htm

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FDA Clinical Trials Guidance Documents

Expanded Access to Investigational Drugs for Treatment Use — Qs & As –DRAFT

- Update to June 2016 guidance
- Clarifies the IRB review requirements for individual patient expanded access treatment use of investigational drugs
- Describes how the Agency reviews adverse event data in the expanded access context
- References the 21st Century Cures Act requirement that expanded access policies be publicly posted

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM351261.pdf

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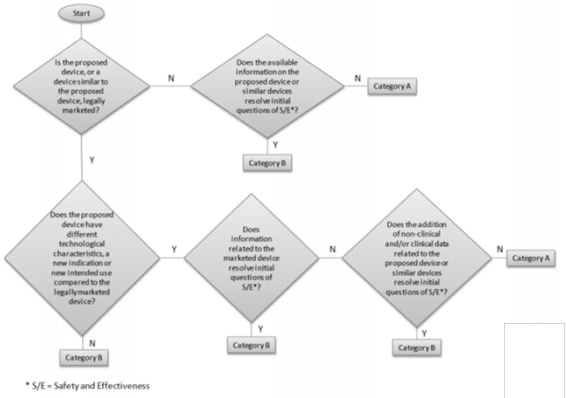
FDA Clinical Trials Guidance Documents

FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions -

- Guidance explains the framework that FDA follows for categorization of investigational devices



https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM504091.pdf

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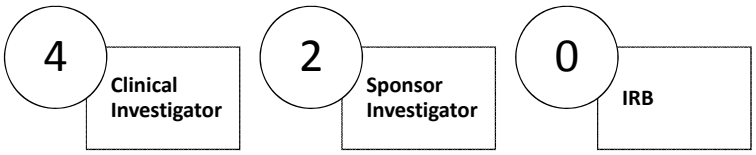
2017 FDA Warning Letters



All issued by the Center for Drug Evaluation and Research

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https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126500.pdf

2017 FDA Clinical Investigator Warning Letters

Cassandra E. Curtis, M.D. 01/27/2017

- Failed to ensure that the investigation was conducted according to the investigational plan.
- Failed to maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.
- Failed to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects.

Adolfo Kaplan, M.D. 04/20/2017

- Failed to ensure that the investigation was conducted according to the investigational plan.

Laveeza (nmi) Bhatti, M.D. 08/04/2017

- Failed to ensure that the investigation was conducted according to the investigational plan.
- Failed to retain records required to be maintained under 21 CFR Part 312 for a period of two years following the date a marketing application is approved for the drug for the indication for which the drug is being investigated; or, if no application is filed or if the application is not approved for such indication, until two years after the investigation is discontinued.

Sohail M. Khan, M.D. 10/10/2017

- Failed to retain records required to be maintained under 21 CFR Part 312 for a period of two years following the date a marketing application is approved for the drug for the indication for which the drug is being investigated; or, if no application is filed or if the application is not approved for such indication, until two years after the investigation is discontinued.

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2017 FDA Sponsor-Investigator Warning Letters

Merrill D Benson, M.D. 03/20/2017

- Failed to ensure that the investigation was conducted according to the investigational plan [21 CFR 312.60].

Kang Zhang, M.D., PhD. 01/05/2017

- Failed to ensure that the investigation was conducted according to the investigational plan [21 CFR 312.60].
- You failed to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects [21 CFR 312.62(a)].

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NIH REGULATORY UPDATE

Key Notices of NIH Policy Changes

- Notice of the Publication of the Final Rule on the Federal Policy for the Protections of Human Subjects (Common Rule): NOT-OD-17-038
- New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018: NOT-OD-17-062
- NIH and FDA Release Protocol Template for Phase 2 and 3 IND/IDE Clinical Trials: NOT-OD-17-064
- Guidance on Exceptions to the NIH Single IRB Policy: NOT-OD-18-003
- Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research: NOT-OD-18-014
- NIH Enforcement of Closeout Policies: NOT-OD-18-107

Key 2016 NIH Policy Changes with Effective Dates in 2017 or 2018

- Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research: NOT-OD-16-094
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information: NOT-OD-16-149
- Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials: NOT-OD-16-148

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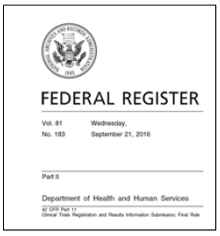
ClinicalTrials.gov

- September 2016 Final Rule published to expand registration and results information requirements of FDAAA 801. The Final Rule:
  - Clarifies which trials must be submitted, when they must be submitted, and whether compliance has been achieved.
  - Clarifies the definition of an Applicable Clinical Trial and provides structured criteria for determining which studies are considered to meet the definition.
  - Expands the FDAAA 801 requirements by requiring the submission of results information for trials of unapproved products
- Effective date: January 18, 2017
- Compliance date: April 18, 2017


FEDERAL REGISTER

Vol. 81 Wednesday,
No. 183 September 21, 2016

Part II

Department of Health and Human Services

42 CFR Part 11
Clinical Trials Registration and Results Information Submission; Final Rule

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NIH & ClinicalTrials.gov

- September 2016 NIH issued a final policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov*
- The final policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at ClinicalTrials.gov, and that results information of these trials is submitted to ClinicalTrials.gov
- Effective date: January 18, 2017
- Compliance date: April 18, 2017

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*https://www.clinicaltrials.gov/ct2/about-site/history#FinalRuleFDAAA801

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Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality

- NOT-OD-17-109
- Release Date: September 7, 2017
- Effective Date: October 1, 2017
- Policy Scope: Applies to all research funded by the NIH that collects or uses identifiable, sensitive information.
- Policy completes the requirement to implement Section 2012 of the 21st Century Cures Act
- Effective October 1, 2017, all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of the Policy is deemed to be issued a Certificate
- The policy defines identifiable sensitive information to mean means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:
  - An individual is identified; or
  - For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

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https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

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NIH and FDA Release Protocol Template for Phase 2 and 3 IND/IDE Clinical Trials

- NOT-OD-17-064
- Release Date: May 2, 2017
- The NIH and FDA developed a clinical trial protocol template with instructional and example text for NIH-funded investigators to use when writing protocols for phase 2 and 3 clinical trials that require IND or IDE applications.
- The NIH also released a secure web-based e-Protocol Writing Tool that allows investigators to generate a new protocol using the NIH-FDA Phase 2 and 3 IND/IDE Clinical Trial Protocol Template.

NIH Single IRB (sIRB) Policy

- Effective Date: January 25, 2018
- Policy published in NIH Guide and Federal Register: June 21, 2016
  - Full Policy: NOT-OD-16-094
  - Notice of Extension: NOT-OD-17-076
  - Cost Scenarios: NOT-OD-16-109
  - Implementation: NOT-OD-18-004
  - Exceptions: NOT-OD-18-003

NIH Single IRB (sIRB) Policy

- Applies to NIH-funded multi-site domestic studies involving non-exempt human subjects research are expected to use a single IRB
- Policy does not apply to:
  - Foreign sites
  - Career development (K), institutional training (T), and fellowship awards (F)
  - Current awards
- Exceptions:
  - Policy-based Exceptions: when Federal, State, Tribal, local laws/regulations/policies require local review
  - Time Limited Exceptions: When ancillary studies are part of ongoing studies or parent studies
  - Compelling Justification or Other Exceptions: When there is a compelling justification for local IRB review

https://grants.nih.gov/sites/default/files/Single%20IRB%20%26%20Exceptions%20Process%20Webinar%20October%2018%202017.pdf

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OHRP UPDATES

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OHRP Updates

The Revised Common Rule

- Original effective and compliance date: January 19, 2018
- Interim final rule to delay the effective and compliance date published January 17, 2018
  - The federal departments and agencies listed on the interim final rule are in the process of developing a proposed rule to further delay implementation of the 2018 Requirements
- New effective and compliance date: July 19, 2018
- Effective date for single IRB remains January 20, 2020

Institutional Review Board Written Procedures: Guidance for Institutions and IRBs

(As stated under FDA Updates, effective May 2018)

- Replaces OHRP'S July 1, 2011 guidance titled, "Guidance on Written IRB Procedures."

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OIG UPDATES

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OIG Active Work Plan Items

Announced/ Revised	Report No.	Agency	Title	Summary	Impact
Dec-17	W-00-18-35804	CMS	Review of CMS Systems Used to Pay Medicare Advantage Organizations	Medicare Advantage (MA) organizations submit to CMS diagnoses on their beneficiaries; in turn, CMS categorizes certain diagnoses into groups of clinically related diseases called hierarchical condition categories (HCC). For instances in which a diagnosis maps to a HCC, CMS increases the risk-adjusted payment. CMS has designed its Medicare Part C systems to capture the necessary data in order to make these increased payments to MA organizations. As CMS transitions to a new data system to make these payments, OIG will conduct analysis to inform both use of current systems and the transition to a new system. We will review the continuity of data maintained on current Medicare Part C systems. Specifically, we will review instances in which CMS made an increased payment to an MA organization for a HCC and determine whether CMS's systems properly contained a requisite diagnosis code that mapped to that HCC.	Could impact reimbursement for SOC items/services for beneficiaries enrolled in Medicare Advantage programs
Dec-17	OEI-03-16-00420; OEI-03-17-00410	CMS	Data Briefs Regarding Financial Relationships Reported to the Open Payments Program	The Physician Payments Sunshine Act (from the Patient Protection and Affordable Care Act § 6002) requires that manufacturers disclose to the Centers for Medicare & Medicaid Services payments made to physicians and teaching hospitals. Manufacturers and group purchasing organizations must also report ownership and investment interests held by physicians. We will analyze 2015 data extracted from the Open Payments website to determine the number and nature of financial interests. We will also determine how much Medicare paid for drugs and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) ordered by physicians who had financial relationships with manufacturers and group purchasing organizations. We will determine the volume and total dollar amount associated with drugs and DMEPOS ordered by these physicians in Medicare Parts B and D for 2015.	Indication that CMS is finally acting on the financial relationship disclosure requirements set forth in the Affordable Care Act Sunshine provisions. It is important for providers organizations to know whether PI disclosures comport with Sponsor/Manufacture published payment lists.

OIG Active Work Plan Items (continued)

Announced/ Revised	Report No.	Agency	Title	Summary	Impact
Dec-17	W-00-16-35745; W-00-18-35745	CMS	Payment Credits for Replaced Medical Devices That Were Implanted	Certain medical devices are implanted during inpatient or outpatient procedures. Such devices may require replacement because of defects, recalls, mechanical complication, and other factors. Under certain circumstances, Federal regulations require reductions in Medicare payments for inpatient, outpatient, and ambulatory surgical center (ASC) claims for the replacement of implanted devices due to recalls or failures (42 CFR §§ 412.89, 419.45, and 416.179). Prior OIG reviews have determined that Medicare administrative contractors made improper payments to hospitals for inpatient and outpatient claims for replaced medical devices. We will determine whether Medicare payments for replaced medical devices were made in accord with Medicare requirements.	May impact payments received for category B medical devices that have been explanted and/or replaced
Jun-17	W-00-17-59422; A-04-17-04059	NIH	NIH Compliance with Federal Requirements for Indirect Cost Rate Setting	In fiscal year 2016, HHS awarded contracts to commercial organizations totaling over $5.9 billion. Indirect costs make up a significant portion of award costs. The National Institutes of Health (NIH) Division of Financial Advisory Services (DFAS) is the cognizant Federal agency responsible for negotiating and establishing indirect cost rates for commercial organizations that receive the preponderance of their Federal contract awards from HHS. We will determine whether DFAS established indirect cost rates for applicable commercial organizations in accordance with Federal requirements.	Indirect Cost Rate calculations are under scrutiny. Ensure that your organizations methodology is sound and document your negotiations with the NIH.

OCR UPDATES

OCR Updates

The HHS Office for Civil Rights continues to investigate and pursue issues related to health information privacy.

In the past year, OCR has identified a number of privacy violations including:

- Breaches
- Impermissible disclosure of sensitive information
- Disclosure of PHI without an authorization
- Transfer of PHI without a Business Associate Agreement in place
- Impermissible access of PHI
- Lack of timely breach notification

These violations resulted in the forced implementation of formal corrective action plans and financial penalties ranging from $100K to $5.5 million.

DOJ UPDATES

DOJ Updates

3/2018 - CFO of New Haven Biotech Firm Charged with Embezzling Nearly $1 Million

- Upon further review of payroll and other financial records, firm's CEO discovered that, for several years, CFO had been writing checks to himself that were disguised as bonuses, that he had been giving himself unauthorized additional salary payments, that he had been using the firm credit card for personal expenditures, and that he had used the firm's funds to make unauthorized donations to an organization that CFO personally supported. A subsequent forensic audit revealed that, between 2012 and 2016, CFO had embezzled approximately $950,000 from the firm.

2/2018 - University of North Texas Health Science Center to Pay $13 Million to Settle Claims Related to Federal Grants

- UNTHSC has agreed to pay the United States $13,073,000.00 to settle claims that it inaccurately measured, tracked and paid researchers for effort spent on certain NIH-sponsored research grants.

11/2017 - Yiheng Percival Zhang Charged with Seven Felonies in Relation to Federal Grants

- The former Virginia Tech professor is charged with one count of conspiring to defraud the United States, three counts of making false statements within the jurisdiction of the United States, and three counts of making false claims to the United States.

8/2017 - Former Deputy Executive Director of USAID Contractor Sentenced for Theft of Grant Funds

- Eugene Sickle, the former deputy executive director of a South African research institute, was sentenced today to seven months of incarceration and ordered to pay $206,250 in restitution for a scheme in which he stole grant funds originating with the U.S. Agency for International Development (USAID).

https://www.justice.gov/usao/pressreleases

DOJ Updates

5/2017 - Dr. Jian Dong Sentenced to Seventy Months for Grant Fraud

- Dr. Jian Yun Dong, aka John Dong, was sentenced to seventy months imprisonment for multiple fraud-based convictions and ordered to pay over three million dollars in restitution.

4/2017 - Partners Healthcare and Brigham and Women's Hospital Agree to Pay $10 Million to Resolve Research Fraud Allegations

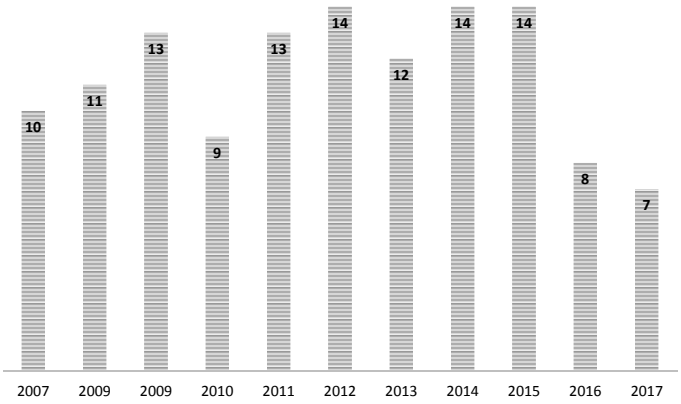
- Partners HealthCare System and one of its hospitals, Brigham and Women's Hospital (collectively, BWH), have agreed to pay $10 million to resolve allegations that a BWH stem cell research laboratory run by Dr. Piero Anversa fraudulently obtained grant funding from the National Institutes of Health (NIH). BWH disclosed these allegations to the government.

2/2017 - Jackson State University Agrees to Pay $1.17 Million to Settle False Claims Act Allegations

- JSU has agreed to pay the United States $1.17 million to settle allegations that JSU mismanaged National Science Foundation (NSF) Grants, announced U.S. Attorney Gregory K. Davis and Allison Lerner, Inspector General at the National Science Foundation.

ORI UPDATES

Cases with Research Misconduct by ORI



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https://ori.hhs.gov/case_summary

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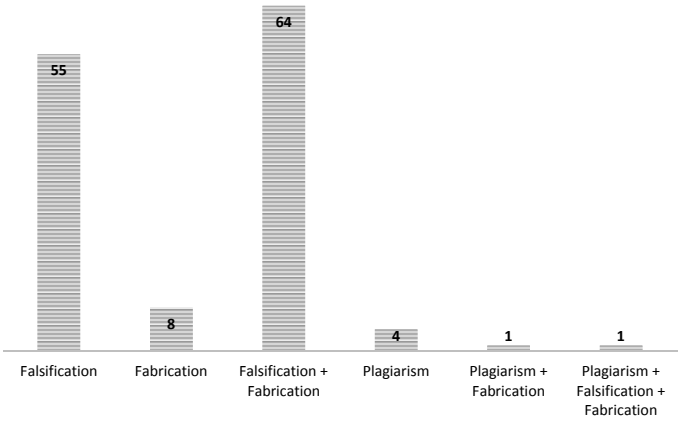
Types of Misconduct



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Cases with Research Misconduct by ORI

2018 (Q1):

- Skau, Colleen T.:
  - ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly reporting falsified and/or fabricated data and/or falsifying and/or fabricating data in two (2) papers.
  - ORI found that Respondent engaged in research misconduct by intentional, knowing, or reckless falsification and/or fabrication of the research record by selectively reporting by inappropriate inclusion/omission or alteration of data points in ten (10) figures and falsely reporting the statistical significance based on falsified data in ten (10) figures across the two (2) papers and supplementary material.
  - ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsely claiming in the methods and results to have performed validation of deletion/re-expression of FMNR2 levels in genetically modified B16 cell lines when that genetic modification was not validated for data reported in Figures 7 and 7S of Paper 1.
  - ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsely reporting a larger number of data points than actually were collected in fourteen (14) figures across the two (2) papers and supplementary materials.
  - ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly fabricating results and/or falsely labelling experimental results that arose from alternate experimental conditions/experiments in seven (7) figures across the two (2) papers and supplementary materials.

Cases with Research Misconduct by ORI

2017:

- Baughman, Brandi:
  - ORI found that falsified and/or fabricated data were included in eleven (11) figures in PLoS One 11(10):e0164378, 2016
- Chegini, Nasser
  - ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying data that were included in: J Reprod Immunol 73(2):118-29, 2007
- Chetram, Mahandranauth Anand
  - ORI found that Respondent engaged in research misconduct at GU by falsifying Western blot images and polymerase chain reaction (PCR) data included in an unfunded grant application, R01 CA193344-01A1, and in a manuscript submitted to Cancer Cell ("The DNA Repair Protein, NTHL1 Functions as an Oncoprotein by Activating the Canoncial Wnt Pathway."
  - Respondent engaged in research misconduct at ESOM and falsified RT-PCR data on Excel spreadsheets in the research record and in a figure generated from the false data included in an unpublished manuscript submitted to and withdrawn from Scientific Reports
- El-Remessy, Azza
  - ORI found that he engaged in research misconduct in research supported by National Eye Institute, National Institutes of Health, National Heart, Lung, and Blood Institute, and National Cancer Institute.
  - ORI found that Respondent intentionally, knowingly, or recklessly used the same false, Western blot bands to represent different experimental results

Cases with Research Misconduct by ORI

2017:

- Endo, Matthew
  - ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly causing false data to be recorded, falsifying and/or fabricating data and related images by alteration and/or reuse and/or relabeling of experimental data, and reporting falsified and/or fabricated data in one (1) manuscript subsequently submitted for publication
- Mirchandani, Alec
  - ORI found that Respondent engaged in research misconduct by knowingly and intentionally:
  - (1) fabricating the results of the T-maze behavioral experiment for control mice, (2) falsifying the laboratory and vivarium entry logs in an effort to cover up his actions, and (3) reporting the fabricated and falsified data to his laboratory supervisors
- Sauer, Frank
  - ORI found that the Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating images in seven (7) submitted NIH grant application and three (3) published papers by manipulating, reusing, and falsely labeling images.
  - Specifically, the Respondent falsified and/or fabricated images representing controls or experimental results

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https://ori.hhs.gov/case_summary

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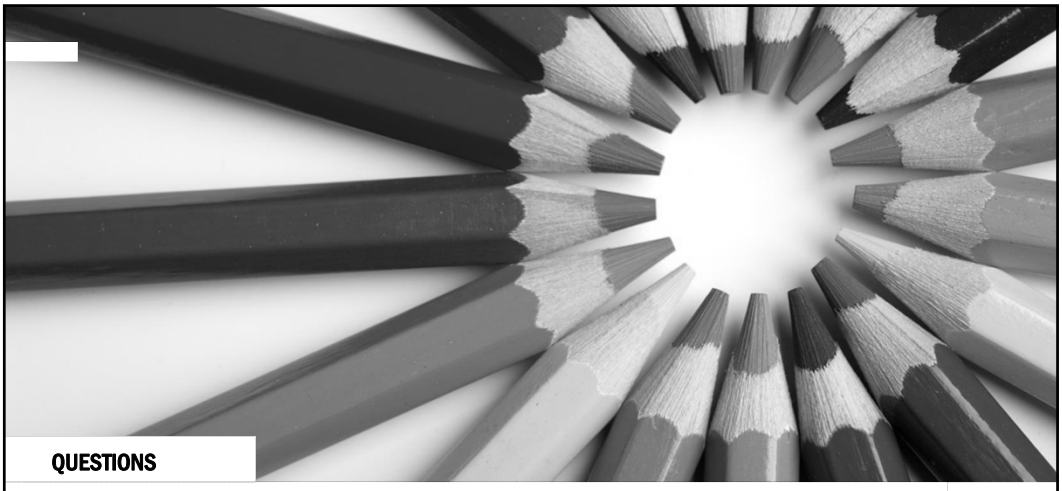

QUESTIONS

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