



2018- 2019
Research Year-in- Review

May 5, 2019

ankura 

ankura.com 1

1

Research Year-in-Review



Lisa Murtha
Senior Managing Director
Philadelphia
lisa.murtha@ankura.com
+1.267.386.4980 Direct

RESEARCH CONSULTING, COMPLIANCE, INVESTIGATIONS & PROCESS IMPROVEMENT

- JD
- Certifications: CHC, CHRC
- More than 30 years of healthcare, research, fraud and abuse, HIPAA privacy, and compliance experience.
- Provided operational and compliance consulting services to life sciences organizations, research sites, CROs, and investigators across the globe.
- Served as in-house counsel to two nationwide healthcare organizations and as chief compliance officer for both an insurer and an university and its health system.



Nicole Visyak
Director
Boston
nicole.Visyak@Ankura.com
+1.904.472.4095 Direct

CLINICAL RESEARCH AND COMPLIANCE EXPERT

- MS, MA
- Certifications: CRC
- Over 11 years of clinical research and compliance experience as a researcher, clinical coordinator, and consultant.
- Previously served as a clinical research program manager and clinical research coordinator at Boston Children's Hospital.
- Provide research consulting services to academic medical centers, community hospitals, independent research organization, and hospital/ health systems related to clinical research billing compliance, research operations, good clinical practice, and the protection of human subjects.

ankura 

2

2

Table of Contents	
FDA Regulatory Updates	4
NIH Regulatory Updates	9
OHRP Updates	11
OIG Updates	14
OCR Updates	19
DOJ Updates	21
ORI Updates	29

ankura

3

3

FDA REGULATORY UPDATE	
-----------------------	--

ankura

4

4

A Risk-Based Approach to Monitoring of Clinical Investigations: Questions and Answers

- Published March 15, 2019
- **Comments due by May 14, 2019**
- Guidance to industry on a risk-based approach to monitoring of investigational studies of human drug and biological products, medical devices, and combinations thereof.
- Provides clarifications and additional guidance to facilitate and encourage sponsors' implementation of risk-based monitoring.
- FDA's recommendations for planning a monitoring approach, developing the content of monitoring plans, and addressing and communicating monitoring results.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/risk-based-approach-monitoring-clinical-investigations-questions-and-answers>

Proposed Rule: IRB Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations

- Published November 15, 2018
- The Proposed Rule, if finalized, permits an IRB to waive the requirement to obtain informed consent for some minimal risk clinical investigations.
- Under the proposed exception, an IRB may waive informed consent when:
 - The clinical investigation involves no more than minimal risk to the subjects;
 - The waiver of informed consent will not adversely affect the rights and welfare of the subjects;
 - The clinical investigation could not be carried out without the waiver; and
 - The subjects are provided with additional "pertinent" information after participating in the study.

<https://www.govinfo.gov/content/pkg/FR-2018-11-15/pdf/2018-24822.pdf>

Civil Money Penalties Relating to ClinicalTrials.gov Data Bank

- Published September 20, 2018
- Civil Money Penalties (CMPs) for parties that fail to submit data or submit false or misleading data to the ClinicalTrials.gov data bank.
- FDA will utilize a “risk-based approach” to decide when to issue a Pre-Notice Letter and will focus enforcement on:
 - Parties that fail to submit data;
 - Parties having pattern of previous non-compliance; and
 - Clinical trials with multiple issues of statutory and/or regulatory non-compliance.
- Parties are given 30 days to remedy non-compliance.
- Parties may be assessed a CMP of \$10,000 per violation and \$10,000 for each day the non-compliance is not remedied.

<https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM607698.pdf>

Final Rule: Acceptance of Clinical Data Obtained Outside the U.S.

- Published February 21, 2018
- Updated standards for accepting clinical data from investigations conducted outside the U.S when submitted to support an IDE or a device marketing application.
- Final Rule does not apply to clinical data from investigations conducted outside the U.S. and submitted for other purposes.
- Submitted data is subject to the reporting requirements found at 21 CFR 812.28(b), viz. names and qualifications of the investigators, summary of the protocol, results, how informed consent was obtained, and any incentives offered to subjects.
- Sponsors may request FDA to waive these requirements after explaining why compliance with the requirements is unnecessary or cannot be achieved.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.28>

NIH REGULATORY UPDATE

9

NIH Single IRB (sIRB) Policy

- Effective Date: January 25, 2018
- 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

10

OHRP UPDATES

ankura

11

11

OHRP Update

The Revised Common Rule

FINAL REVISIONS TO THE COMMON RULE WENT INTO EFFECT ON JANUARY 21, 2019

Major areas of change are related to:

- Definitions [§46.102]
- Informed consent requirements [§46.116]
- Single IRB Review [§46.114]
- Continuing Review [§46.109]
- Exempt Categories [§46.104]

<https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html>

ankura

12

12

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."
- Goal: to assist Institutional and IRB staff in preparing/maintaining written procedures.
- Includes written procedure checklist incorporating HHS and FDA regulatory requirements for written procedures, operational recommendations and topics for consideration when developing P&P.

<https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm512761.pdf>

OIG UPDATES

OIG Update

OIG Advisory Opinion No. 18-13

- Charitable trust suggested making a significant donation to a Research Institute partnered with a health care system.
 - The Research Institute does not bill Federal health care programs – the health care system does.
 - The trustees have ownership/financial interests in long-term care facilities that have long-standing business relationships with the health care system.
- Anti-kickback Statute implications - affiliation with health care system can generate business for trustee's long term care facilities
 - Knowing and willful offense to offer, pay, solicit or receive any remuneration to induce/reward referrals of items/services
 - Potential self-dealing: the trustees want to donate (remuneration) to an entity that could indirectly generate business (financial relationship) for the trustee's business.
- Conclusion: low risk under AKS

<https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-13.pdf>



15

15

OIG Update

OIG Advisory Opinion No. 19-02

- Pharmaceutical manufacturer's proposal to loan limited-function iphone to financially needy patients lacking the technology necessary to receive data from sensor embedded in digital medication (DM).
 - Patch records patient ingestion of drug and indicators of patient rest patterns/activity, which must be accessed through smartphone.
- Beneficiary Inducement Implications of Civil Monetary Penalties Law: would remuneration (loaner device) likely influence beneficiary to select provider/practitioner/supplier (prescriber/pharmacy)?
 - Yes-prescriber completes paperwork for patient to obtain device → patient could believe that he/she must continue receiving care from provider while using loaner device.
 - Meets Access to Care Exception: 1) promotes access to care and 2) low risk of harm.
- AKS Implications: would remuneration influence beneficiary to select item/service reimbursable by Fed. health care programs?
 - Device integral to and only available (temporarily) to those needing the drug and would otherwise be unable to use the drug without the technology.
 - Not advertised → patients unlikely to suggest DM solely to receive device
 - No imposition AKS sanctions (no requisite intent to induce referrals)

<https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-02.pdf>



16

16

OIG Update

OIG Active Work Plan: February 2019

- OIG will examine NIH's oversight and monitoring of the financial conflicts of interest reported by grantee institutions.
- Grantee institutions must submit sufficient information that would enable NIH to both:
 - 1) Understand the nature and extent of a researcher's financial conflict of interest and;
 - 2) Assess the appropriateness of the grantee institution's plan to manage this conflict.
- [NIH's Implementation of Financial Conflict of Interest Regulations](#)
- [NIH Monitoring of Extramural Researchers' Financial Conflicts of Interest](#)



17

17

OIG Update

OIG Active Work Plan: February 2019

- OIG will examine NIH's oversight of its grantees' compliance with NIH policies, including NIH efforts to ensure the integrity of its grant application and selection processes.
- OIG will conduct audits at NIH's Institutes and Centers to review their:
 - 1) Pre-award process for assessing risk of potential recipients of Federal funds
 - 2) Post-award process for overseeing and monitoring of grantees on the basis of risks identified during the pre-award process.
- [NIH's Oversight of its Grantees' Compliance with NIH Policies](#)
- [NIH's Peer Review Process for Evaluating Grants](#)



18

18

OCR UPDATES

19

OCR Updates

ALJ Rules in Favor of OCR – MD Anderson to pay \$4.3 million in penalties for HIPAA violations

- 3 separate OCR investigations in 2012-2013 involving the theft of an unencrypted laptop from the residence of a MD Anderson employee and the loss of two unencrypted thumb drives containing ePHI 33,500 individuals.
- Investigation showed that MD Anderson had written encryption policies and that MD Anderson's own risk analyses identified high-risk in the lack of device-level encryption. MD Anderson eventually adopted a device-level encryption solution, but it failed to encrypt the entire inventory of devices.
- ALJ upheld penalties for each day of MD Anderson's non-compliance with HIPAA and for each record breached.
- MD Anderson claimed that the ePHI at issue was for "research" and thus not subject to HIPAA's nondisclosure requirements. ALJ objected; nothing in regulations supports argument and argument ignores fact that there is mechanism to separate research function from clinical function.

<https://www.hhs.gov/sites/default/files/alj-cr5111.pdf>

20

DOJ Enforcement Updates

21

DOJ Update

Duke University Agrees to Pay U.S. \$112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct

- March 25, 2019
- The settlement resolves allegations that between 2006 and 2018, Duke knowingly submitted claims to the NIH and to the EPA that contained falsified or fabricated data or statements in thirty (30) grants.
- The allegations were originally brought in a lawsuit filed by Joseph Thomas, a former Duke employee, under the qui tam, or whistleblower, provisions of the False Claims Act, which permit private individuals to sue on behalf of the government and share in any recovery. The Act permits the government to intervene in and take over the whistleblower's suit, or, as in this case, for the whistleblower to pursue the action on the government's behalf. Mr. Thomas will receive \$33,750,000 from the settlement.

https://www.justice.gov/usao/pressreleases?keys=research&items_per_page=25&f%5B0%5D=field_or_date%3A2019

22

DOJ Update

UT Health Science Center Pays More than \$2.3 Million to Resolve Allegations

- January 31, 2019
- The settlement resolves allegations that the UTHSC Human Genetics Center misappropriated funds under an NIH grant related to sequencing the human genome.
- According to the source, the center wanted to draw down a substantial portion of the money remaining on the grant before the end of the grant period so that it would not have to return unused funds to the NIH. To accomplish this, the source claimed the center placed an order for a large quantity of genetic sequencing material from Illumina Inc. just prior to the end of the subject grant. They then allegedly stopped shipment of that material and had Illumina establish a credit for the material, from which the Genetics Center then used to purchase goods and services after the close out of the grant. This resulted in UTHSCH underreporting by that amount the unobligated federal funds remaining on the grant which were not returned to NIH.

<https://www.justice.gov/usao-sdtx/pr/ut-health-science-center-pays-more-23-million-resolve-allegations>



23

23

DOJ Update

Texas A&M Research Foundation Pays \$750,000 to Settle Claims Alleging Improper Charges to Federal Grants

- September 20, 2018
- The settlement is the result of an investigation that began after a *qui tam*, or whistleblower, lawsuit was filed under seal on June 6, 2013. The whistleblowers are employed by TAMRF and alleged that during their employment they witnessed TAMRF allow personnel to ignore federal restrictions and permitted the overcharging of salaries, which inflated grant expenses. The whistleblowers also alleged TAMRF engaged in cost shifting; allowed academic employees to wrongfully receive longevity pay; violated salary caps; and improperly charged grants for expenses not incurred or not covered.
- The United States also concluded that TAMRF improperly charged various federal grants for expenses not properly allocable to them, including salaries and wages for individuals not working on the grants and supplies and equipment unrelated to the grants. TAMRF also improperly charged various federal grants for unallowable costs such as travel expenses unrelated to the objectives of the grants or for unaffiliated parties not working on the grants.

<https://www.justice.gov/usao-sdtx/pr/texas-am-research-foundation-pays-750000-settle-claims-alleging-improper-charges>



24

24

DOJ Update

Drug Maker Pfizer Agrees to Pay \$23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks

- May 24, 2018
- Pharmaceutical company Pfizer, Inc. (Pfizer) agreed to pay \$23.85 million to resolve claims that it used a foundation as a conduit to pay the copays of Medicare patients taking three Pfizer drugs, in violation of the False Claims Act.
- Under the Anti-Kickback Statute, a pharmaceutical company is prohibited from offering, directly or indirectly, any remuneration—which includes paying patients' copay obligations—to induce Medicare patients to purchase the company's drugs.
- The government alleged that Pfizer used a foundation as a conduit to pay the copay obligations of Medicare patients taking three Pfizer drugs: Sutent and Inlyta, which both treat renal cell carcinoma, and Tikosyn, which treats arrhythmia in patients with atrial fibrillation or atrial flutter. The government alleged that, in order to generate revenue, and instead of giving Sutent and Inlyta to Medicare patients who met the financial qualifications of Pfizer's existing free drug program, Pfizer used a third-party specialty pharmacy to transition certain patients to the foundation, which covered the patients' Medicare copays.

<https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks>



25

25

DOJ Update

Advanced Thermal Technologies and CEO Agree to Pay \$100,000 for Failing to Account for Federal Research Funds

- March 20, 2018
- Advanced Thermal Technologies, LLC (ATT), and its President and Chief Operating Officer, James W. Connell, of Upton, Mass., agreed today to pay \$100,000 to resolve allegations that they failed to account for a portion of federal research grants they received and that they used a portion of the funds unlawfully.
- The government's complaint alleges that on multiple occasions from 2007 to 2016, Connell personally certified to NSF and DOE that: (1) ATT maintained an adequate financial system to account for the award funds as required by regulations, (2) ATT would comply with the award terms and conditions, and (3) ATT spent the award funds and performed the research in accordance with the terms and conditions. The complaint alleges that these certifications were often false because ATT and Connell failed to prepare and maintain documentation substantiating that they used the funds for the awarded research projects, and, on occasion, that they claimed and received funds for NSF projects that were already completed.

<https://www.justice.gov/usao-ma/pr/advanced-thermal-technologies-and-ceo-agree-pay-100000-failing-account-federal-research>



26

26

DOJ Update

University of Pittsburgh Professor Pays \$132,000 and Agrees to Exclusion to Resolve Allegations of False Claims for Federal Research Grants

- March 21, 2018
- Christian Schunn, Ph.D., a professor at the University of Pittsburgh since 2001, has agreed to pay the United States \$132,027 to resolve allegations that he violated the False Claims Act by submitting false documents to the National Science Foundation (NSF) in order to obtain federal grants to fund his research.
- From 2006-2016, Schunn allegedly created false IRB approvals and submitted them to NSF in connection with multiple proposals for NSF funding totaling more than \$2.3 million.
 - NSF awarded funding to the University of Pittsburgh (Schunn as Principal Investigator) and award funds were drawn down.
 - Schunn then allegedly made, or caused others to make, false claims for payment by certifying that the drawdowns were in accordance with the terms and conditions of the awards (when no proper IRB approval had been in place).
 - The United States contended that Schunn also made false certifications in connection with annual and project reports associated with these awards.

<https://www.justice.gov/usao-wdpa/pr/university-pittsburgh-professor-pays-132000-and-agrees-exclusion-resolve-allegations>



27

27

DOJ Update

CFO of New Haven Biotech Firm Charged with Embezzling Nearly \$1 Million

- March 27, 2019
- 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.

<https://www.justice.gov/usao-ct/pr/cfo-new-haven-biotech-firm-charged-embezzling-nearly-1-million>

University of North Texas Health Science Center to Pay \$13 Million to Settle Claims Related to Federal Grants

- February 16, 2018
- UNTHSC has agreed to pay the United States \$13,073,000 to settle claims that it inaccurately measured, tracked and paid researchers for effort spent on certain NIH-sponsored research grants.

<https://www.justice.gov/usao-ndtx/pr/university-north-texas-health-science-center-pay-13-million-settle-claims-related>



28

28

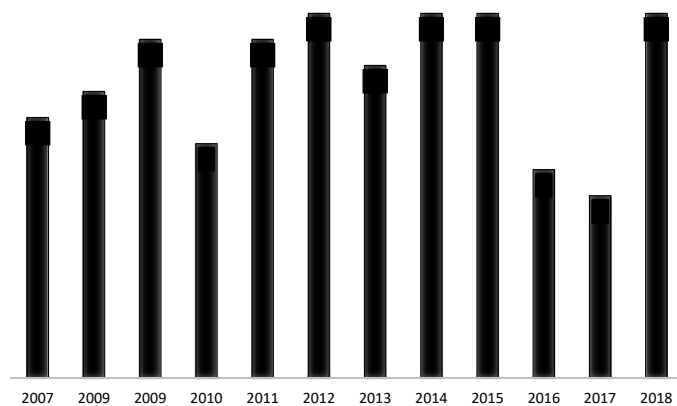
ORI UPDATES

29

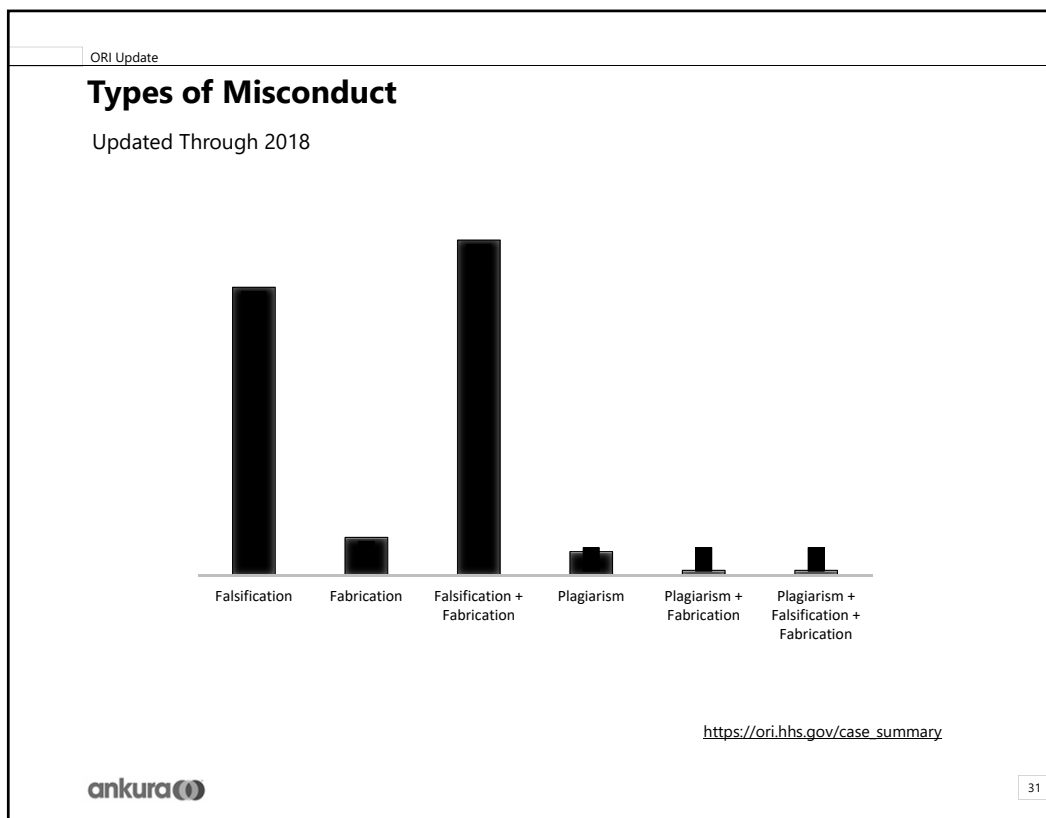
ORI Update

Cases with Research Misconduct by ORI

Updated through 2018


https://ori.hhs.gov/case_summary

30



31

ORI Update

Cases with Research Misconduct by ORI

Murthy, Krishna H.M.: Falsification/ Fabrication

- Former Research Associate Professor, University of Alabama at Birmingham
- Intentionally, knowingly, or recklessly engaging in research misconduct by falsifying and/or fabricating X-ray crystallographic data.
- Falsified and/ or fabricated research was reported in ten (10) journal articles and also referenced in five (5) NIH grant applications.
- Administrative Law Judge (ALJ) issued a recommended decision in favor of ORI:
 - Debarment for 10 years from eligibility for any contracting or subcontracting with any agency of the U.S. Government and from eligibility for or involvement in non-procurement programs of the U.S. Government.
 - Prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of ten (10) years; and
 - Notice to journals requiring correction/retraction.

https://ori.hhs.gov/case_summary

ankura

32

32

ORI Update

Cases with Research Misconduct by ORI

Srivastava, Rakesh: Plagiarism

- Former Professor, University of Kansas Medical Center
- ORI found that Respondent intentionally committed research misconduct by including plagiarized words in the submission of a grant application to NIH.
- Final notice Issued-Administrative Action:
 - Two year debarment from contracting or subcontracting with any agency of US Government and eligibility/involvement in non-procurement programs of the US government; and
 - Two year prohibition from serving in any advisory capacity to PHS.

https://ori.hhs.gov/case_summary

ankura

33

33

ORI Update

Cases with Research Misconduct by ORI

Elqutub, Maria Cristina Miron: Falsification/Fabrication

- Research Interviewer, University of Texas MD Anderson Cancer Center
- Respondent engaged in research misconduct by intentionally and knowingly falsifying and/or fabricating data by recording dates and providing her own blood samples to cause samples to be falsely labeled as samples from 98 study subjects that were included in two (2) published papers and two (2) grant progress reports submitted to NIDCR.
- Respondent entered into a Voluntary Settlement Agreement and agreed:
 - to have her research supervised for a period of 3 years;
 - to certify to ORI that the data provided by Respondent are based on actual experiments;
 - if no supervisory plan is provided to ORI, to provide certification to ORI on an annual basis that she has not engaged in, applied for, or had her name included on any application, proposal, or other request for PHS funds without prior notification to ORI;
 - to exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of 3 years; and
 - to correct journal submissions.

https://ori.hhs.gov/case_summary

ankura

34

34

ORI Update

Cases with Research Misconduct by ORI

Baughman, Brandi M., Ph.D.: Falsification


- Postdoctoral, University of North Carolina Chapel Hill
- Engaged in research misconduct by falsely reusing and relabeling 14 individual Western blot images from an unrelated experiment conducted in September 2013
- Dr. Baughman entered into a Voluntary Exclusion Agreement in which she agreed:
 - to exclude herself voluntarily from any contracting or subcontracting with any agency of the U.S. Government and from eligibility or involvement in non-procurement programs of the U.S. Government and
 - to exclude herself voluntarily from serving in any advisory capacity to the U.S. Public Health Service (PHS) including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

https://ori.hhs.gov/case_summary

ankura

35

35



Questions?

Lisa Murtha: Lisa.Murtha@Ankura.com
 Nicole Visyak: Nicole.Visyak@Ankura.com

ankura

36

36