



OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Office of Research Integrity Update

COGR Meeting June 6-7, 2019

Loc Nguyen-Khoa

June 06, 2019



PREDECISIONAL AND DELIBERATIVE
CONTROLLED UNCLASSIFIED INFORMATION (CUI)

WHO WE ARE



OFFICE OF THE
DIRECTOR



DIVISION OF
INVESTIGATIVE
OVERSIGHT



DIVISION OF
EDUCATION &
INTEGRITY

OFFICE OF RESEARCH INTEGRITY

ORI Update

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight

Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity

Programs to Support the Research
Community



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



WHAT IS RESEARCH MISCONDUCT?

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results

fabrication | falsification | plagiarism

Research misconduct does not include honest error or differences of opinion

ORI Update

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight **Research Misconduct**

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity
Programs to Support the Research
Community



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



ORI Update

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity Programs to Support the Research Community

Home » ORI Policy on Plagiarism

 Printer Friendly

ORI Policy on Plagiarism

Although there is widespread agreement in the scientific community on including plagiarism as a major element of the PHS definition of scientific misconduct, there is some uncertainty about how the definition of plagiarism itself is applied in ORI cases.

As a general working definition, ORI considers plagiarism to include both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work. It does not include authorship or credit disputes.

The theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review.

Substantial unattributed textual copying of another's work means the unattributed verbatim copying of sentences and paragraphs which materially mislead the reader regarding the contributions of the author. ORI generally does not pursue the issue of nearly-identical phrases which describe a commonly-used methodology or procedure because ORI does not consider such use as substantially misleading to the reader of significance.

Many allegations of plagiarism involve disputes among former collaborators who participated in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive data, or other product of the joint effort. The ownership of the intellectual property in many cases is seldom clear, and the collaborative history among the scientists often supports a claim of implied consent to use the products of the collaboration by any of the collaborators.

For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution.

From ORI Newsletter, Vol 3, No. 1, December 1994

From ORI Newsletter, Vol
3, No. 1, December 1994

ORI Update

“ORI **generally** does not pursue the limited use of identical or nearly-identical phrases which describe a **commonly-used methodology** or previous research because ORI does not consider such use as substantially **misleading** to the reader or of great significance.”

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity Programs to Support the Research Community

Home » ORI Policy on Plagiarism

ORI Policy on Plagiarism

Although there is widespread agreement that plagiarism is a major element of the PHS definition of plagiarism itself.

As a general working definition, plagiarism is the misappropriation of intellectual work. It does not include authors.

The theft or misappropriation of intellectual methods obtained by a privileged community.

Substantial unattributed textual copying of another's verbatim copying of sentences and paragraphs without regard to the contributions of the author. ORI generally does not pursue the limited use of identical or nearly-identical phrases which describe a commonly-used methodology or previous research because ORI does not consider such use as substantially misleading to the reader or of great significance.

Many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators.

For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution.

From ORI Newsletter, Vol 3, No. 1, December 1994

ORI Update

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight
Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity
Programs to Support the Research
Community

authorship disputes ≠ plagiarism

credit disputes ≠ plagiarism

Home » ORI Policy on Plagiarism

Printer Friendly

ORI Policy on Plagiarism

Although there is widespread agreement in the scientific community on including plagiarism as a major element of the PHS definition of scientific misconduct, there is some uncertainty about the definition of plagiarism itself as applied in ORI cases.

As a general working definition, ORI considers plagiarism the misappropriation of intellectual property and work. It does not include authorship disputes.

The theft or misappropriation of methods obtained by a privileged source.

Substantial unattributed text or verbatim copying of sentences regarding the contributions of the author, nearly-identical phrases which describe the work, because ORI does not consider such use plagiarism of significance.

Many allegations of plagiarism involve disputes among former collaborators over the development or conduct of a research project, but which do not involve the use and made independent use of the jointly developed concepts, methods, or language, or other product of the joint effort. The ownership of the work in many such situations is seldom clear, and the collaborative history among the parties often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators.

For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution.

From ORI Newsletter, Vol 3, No. 1, December 1994

Is **Self-Plagiarism** Research Misconduct ?

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight **Research Misconduct**

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity
Programs to Support the Research
Community



Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity Programs to Support the Research Community

Is Self-Plagiarism Research Misconduct ?

"Plagiarism is the appropriation of **another person's** ideas, processes, results, or words without giving appropriate credit."

-- 42 CFR Part 93.103(c)



Sec. 93.319 Institutional standards.

- a) Institutions may have internal standards of conduct different from the HHS standards for research misconduct under this part. Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part's definition of research misconduct.
- b) An HHS finding or settlement does not affect institutional findings or administrative actions based on an institution's internal standards of conduct.

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity Programs to Support the Research Community



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



FABRICATION/FALSIFICATION OF IMAGES

ORI Update

Three Divisions

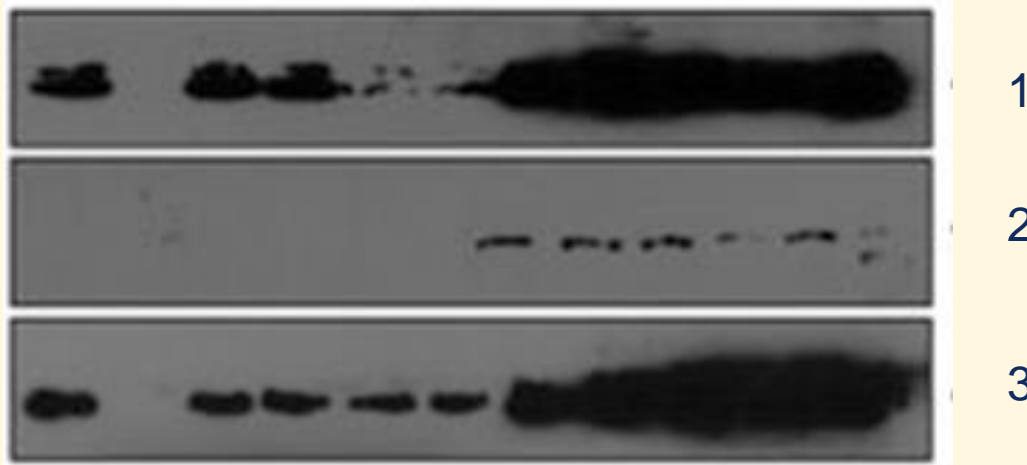
- OD / DIO / DEI

Division of Investigative Oversight **Research Misconduct**

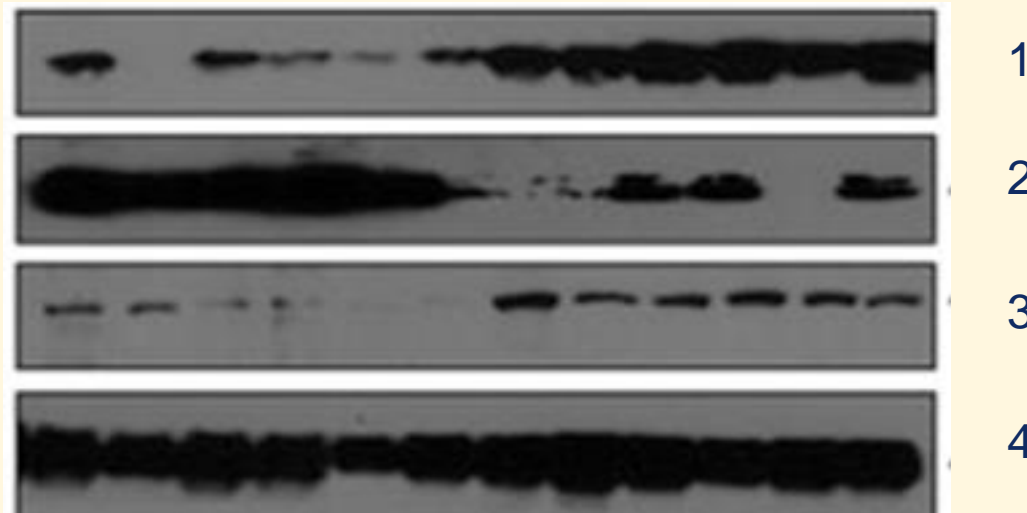
- Falsification/Fabrication/Plagiarism

Division of Education & Integrity
Programs to Support the Research
Community

A



B



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



FABRICATION/FALSIFICATION OF IMAGES

ORI Update

Three Divisions

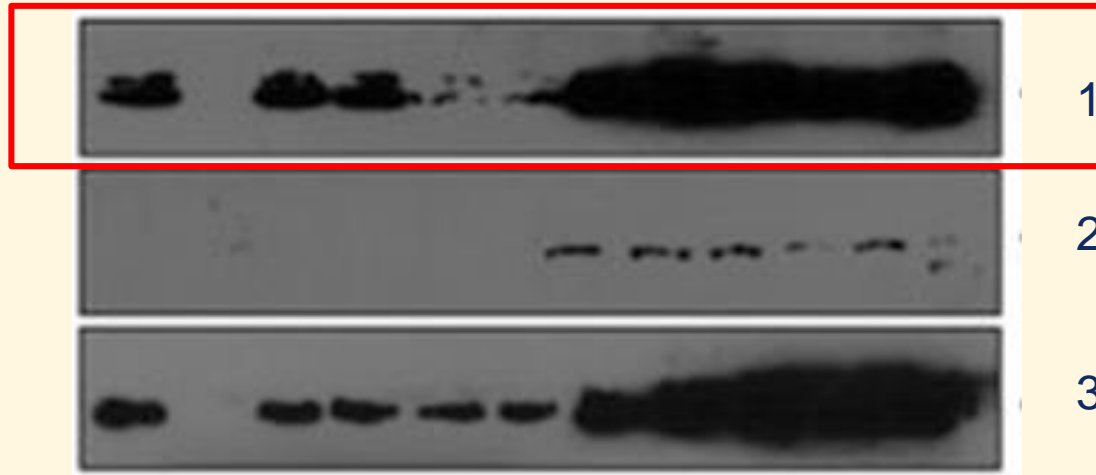
- OD / DIO / DEI

Division of Investigative Oversight **Research Misconduct**

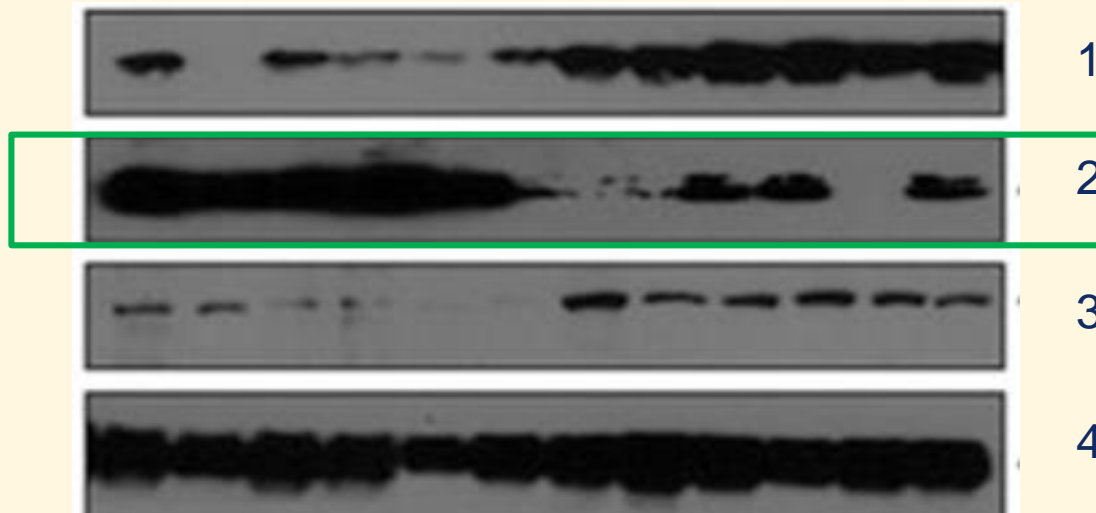
- Falsification/Fabrication/Plagiarism

Division of Education & Integrity
Programs to Support the Research
Community

A



B



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



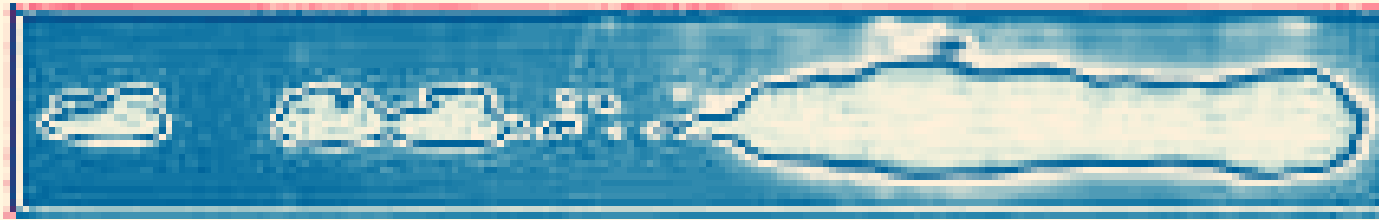
FABRICATION/FALSIFICATION OF IMAGES

ORI Update

Color Overlay



Gradient Map



Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity
Programs to Support the Research
Community



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



Nearly 5,000 Institutions Worldwide

ORI Update

PHS FUNDING AGENCIES



National Institutes
of Health



CENTERS FOR DISEASE
CONTROL AND PREVENTION



ASSURANCE

POLICY REVIEW

GRANTS

CONFERENCES

EDUCATION

PROGRAMS

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight
Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity
Programs to Support the Research
Community



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



Policy Review Checklist

ORI Update

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity Programs to Support the Research Community

ASSURANCE POLICY REVIEW GRANTS CONFERENCES EDUCATION PROGRAMS

CHECKLIST: Policies and Procedures for Handling Research Misconduct Allegations

This checklist is used by the U.S. Department of Health and Human Services, Office of Research Integrity (ORI) and is intended only to provide general information regarding ORI's review of institutional policies. It should not be used by institutions or relied on by them as a substitute for familiarity with the Federal laws and regulations applicable to research misconduct, including 42 U.S.C. 289b and 42 C.F.R. Part 93. The information presented in the checklist is not legal advice, is not to be acted on as such, may not be current, and is subject to change without notice.

A. Policies and Procedures Requirements Pursuant to §93.304. Institutions seeking an approved assurance must have written policies and procedures for addressing research misconduct that include the following:	
Page/Section	Criteria
	Consistent with Sec. 93.108, protection of the confidentiality of <input type="checkbox"/> Respondents, <input type="checkbox"/> Complainants, and <input type="checkbox"/> Research subjects identifiable from research records or evidence (§93.304(a)).
	A thorough, competent, objective, and fair response* to allegations of research misconduct consistent with and within the time limits** of 42 C.F.R. Part 93, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the <input type="checkbox"/> Complainant, <input type="checkbox"/> Respondent, or <input type="checkbox"/> Witnesses (§93.304(b)). *Ensuring a fair investigation <input type="checkbox"/> Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation (§93.310(f)). ** Time Limits <input type="checkbox"/> The institution must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period (§93.307(g)). <input type="checkbox"/> Within 30 days of finding that an investigation is warranted, provide ORI with the written finding by the responsible institutional official and a copy of the inquiry report (§93.309(a)). <input type="checkbox"/> Begin the investigation within 30 days after determining that an investigation is warranted (§93.310(a)). <input type="checkbox"/> An institution must complete all aspects of an investigation within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment in accordance with Sec. 93.312, and sending the final report to ORI under Sec. 93.315. (§93.311(a)).
	Written notice to the respondent(s), consistent with and within the time limits of this part (§93.304(c)) <input type="checkbox"/> At the time of or before beginning an inquiry, an institution must make a good faith effort to notify in writing the presumed respondent, if any (§93.307(b)). <input type="checkbox"/> If the inquiry subsequently identifies additional respondents, the institution must notify them (§93.307(b)). <input type="checkbox"/> The institution must notify the respondent whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to this part and the institution's policies and procedures adopted under its assurance. (§93.308(a)).

U.S. Off
<http://a>

<https://ori.hhs.gov/assurance-program>

→ Click Policy Review Checklist



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



“CHOOSE YOUR OWN ADVENTURE” VIDEO



THE LAB

Avoiding Research
Misconduct

Go to The Ethical
Decision Making
Tutorials

View Intro Video

Accessibility

Acknowledgments

Legal

PROGRAMS

ORI Update

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight
Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity
Programs to Support the Research
Community

<http://ori.hhs.gov/TheLab>



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



YOU'VE BEEN ACCUSED OF RESEARCH MISCONDUCT NOW WHAT?

Institutions, that receive Public Health Service biomedical research funding, must have written policies and procedures for addressing allegations of research misconduct and must respond to each allegation (§93.300(a-b)).

DEFINITION OF RESPONDENT: Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding (§93.225).

PROTECTING THE RIGHTS OF RESPONDENTS

PROTECTING IDENTITY

Disclosure of the respondent's identity is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law (§93.108).

PROTECTING REPUTATION

Institutions must make all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made (§93.304(k)).

RESPONDENT'S PARTICIPATION IN PROCEEDING

Federal regulation provides a meaningful opportunity for respondents to participate in the proceeding.

NOTICE OF INQUIRY

At the time of or before beginning an inquiry, an institution must make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the institution must notify them (§93.307(b)).

COMMENTING ON INQUIRY REPORT

The institution must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report (§93.307(f)).

The institution must notify the respondent whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to 42 C.F.R. Part 93 and the institution's policies and procedures adopted under its assurance (§93.308(a)).

NOTICE OF INVESTIGATION

Notify the respondent in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins (§93.310(c)).

NOTICE OF NEW ALLEGATIONS

The institution must give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation (§93.310(c)).

COMMENTING ON INVESTIGATION REPORT

The institution must give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the respondent on the draft report, if any, must be submitted within 30 days of the date on which the respondent received the draft investigation report (§93.312).

MISCONDUCT MUST BE PROVEN BY EVIDENCE

Allegations of research misconduct must be proven by a preponderance of evidence (§93.104(c)).

ACCESS TO RESEARCH RECORDS

Where appropriate, the institution must give the respondent copies of, or reasonable, supervised access to the research records (§93.305(b)).

PROTECTING THE RESEARCH RECORD

Taking custody of all the research records and evidence needed to conduct the research misconduct proceeding by the institution (§93.305(a)) is done to protect the integrity of the evidence and to develop a complete record of relevant evidence (§93.304(m)).



All citations refer to Public Health Service Policies on Research Misconduct; Final Rule, 42 C.F.R. Part 93

INFOGRAPHICS

ORI Update

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity Programs to Support the Research Community

PROGRAMS

“One of the most important educational products ORI has to offer”

--Loc Nguyen-Khoa

<http://ori.hhs.gov/infographics>



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



CONFERENCES AND WORKSHOPS

RIO Boot Camps

RCR Instruction Workshop

Conference for Senior Officials

World Conference on Research Integrity

PROGRAMS

ORI Update

Three Divisions

- OD / DIO / DEI

Division of Investigative Oversight
Research Misconduct

- Falsification/Fabrication/Plagiarism

Division of Education & Integrity
Programs to Support the Research
Community



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



TRENDS IN PROMOTING RESEARCH INTEGRITY

The Role of Research Integrity in Promoting Excellence:
Tools for College and University Leaders

Northwestern University
Chicago, IL



May 22-23, 2019

PROGRAMS

ORI Update

Trends

1. More involvement and support from senior officials
2. Evolution of RCR
3. RCR training will no longer be a compliance checkbox
4. Research community will take the lead



Culture Change



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH



Conclusion

- ORI functions best when it collaborates with the research community
- ORI handles fabrication, falsification, AND plagiarism
 - Authorship Disputes ≠ Plagiarism
 - Self-Plagiarism ≠ Research Misconduct
- ORI invests considerable resources to providing services to the research community to promote research integrity
- ORI is privileged to be part of a positive culture change



Thank You

Connect with ORI

- Twitter: @hhs_ori
- ORI Web: ori.hhs.gov
- Email Us: AskORI@hhs.gov

Loc Nguyen-Khoa

Loc.Nguyen-Khoa@hhs.gov



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH

