資料3

研究者の行動規範に関する国際標準教育をめざす

CITI Japan プロジェクトとは

信州大学医学部特任教授
Vanderbilt大学医学部小児科学・内科学教授

市 川 家 國

CITI: "***C***ollaborative ***I***nstitutional ***T***raining ***I***nitiative"

研究者行動規範教育

利益相反に関して：

本講演に当たり、講演者には利益相反として
開示すべき事項はありません。

平成25年6月26日　市川家國

- 概要

  わが国での不正行為の現状
    - 内観
    - 外観

  わが国における対応策
    - 内観
    - 外観

- （欧）米における対応策
- わが国の現状と対応
- わが国の研究者主導の動き
  ＝ CITI Japan プロジェクト　23-39
- FAQ

＜背景＞

世界：　繰返される**ミスコンダクト**

欧米：　**取締りから教育へ**重点の移行

日本：　**教育カリキュラムの欠如**

＜戦略＞

・**大学院・研究機関**での**行動規範教育**

・**国際標準**を満たし、Up-dateし続ける教育内容

・**e-learning**　による均一教育の全国普及

米国

CITI Program

(Collaborative Institutional Training Initiative)

・全ての研究者に義務付けられている行動規範教育コンテンツを提供

・ほぼ全ての大学(top 100大学中99大学)・研究機関による利用

共同開発（国際標準）

CITI Japan プロジェクト

文部科学省「大学間連携共同教育推進事業」

研究者育成の為の行動規範教育の標準化と教育システムの全国展開

連携６大学＊ ＋ 連携機関 ＋ 協力教員多数

国際標準の教材作成

・全米教員団体の協力のもとでの教材作成
・協力教員による妥当性の精査と加筆修正
・関連事業との連携
・パブリック・コメント
・ユーザーミーティング

【教材例】
責任ある研究行為・ミスコンダクト・利益相反・公的研究費の取り扱い・倫理審査委員会による審査・個人情報の扱い・オーサーシップ　他

広報活動

・日本医学会
・全国医学部長病院長会議
・宇宙航空研究開発機構
・全国遺伝子医療部門連絡会議等との連携

Web運営
窓口サービス
受講認定

利用機関拡大

＊信州大学・東京医科歯科大学・福島県立医科大学
北里大学・上智大学・沖縄科学技術大学院大学

国際標準とされる行動規範を理解した研究者の全国的育成

グローバルな
ミスコンダクトの減少

海外共同研究者も

REQUIRED EDUCATION IN THE PROTECTION OF H N RESEARCH PARTICIPANTS

Release Date: June 5, 2000 (Revised August 25, 20

NOTICE: OD-00-039 National Institutes of Health Polic

Beginning on October 1, 2000, the NIH will require education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. Background To bolster the Federal commitment to the protection of h

participants, sev
strengthen gove
medical researc
HHS Secretary
This announcem
institutions of th
oversee their cli
institutional revi

One of the new initiatives addresses

日本の倫理専門家の方々は「論文発表」と称して、文献検索のペーパーを沢山出されていますが、教育には無頓着ですね。

Ethics Education in Asia

Country	GCP Adoptions	HRP Education
Japan	ICH (1998)	Optimistic & confident
Singapore	Yes (1998)	10 sites
South Korea	Yes (2001)	CITI - Korea
Hong Kong	ICH	
Taiwan	Yes (1997)	CITI - Taiwan
Indonesia	Yes (2001)	
Malaysia	Yes (1999)	
Philippines	Yes (1993)	
Thailand	Yes (2000)	Thai GCP
China	Yes (1999)	In Progress
India	Yes (2001)	CITI - India

日本の方々は楽観的で、
自信過剰のようです

By the courtesy of Capt. Melody Lin

U.S.Department of Health & Human Services www.hhs.gov

ORI research integrity

Office of Research Integrity

US Department of Health and Human Services

（研究公正局）

Division of Investigative Oversight (DIO)

取締り

Division of Education and Integrity (DEI)

教育

Policy

NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research. This policy will take effect with all new and renewal applications submitted on or after January 25, 2010, and for all continuation (Type 5) applications with deadlines on or after January 1, 2011. This Notice applies to the following programs: D43, D71, F05, F30, F31, F32, F33, F34, F37, F38, K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K99/R00, KL1, KL2, R25, R36, T15, T32, T34, T35, T36, T37, T90/R90, TL1, TU2, and U2R. This policy also applies to any other NIH-funded programs supporting research training, career development, or research education that require instruction in responsible conduct of research as stated in the relevant funding opportunity announcements.

Instructional Components

NIH recognize… …ughout the research trai… …riences and the best pract… …truction in responsible c…

1. Forma… …ons (e.g. case s… …ses can be a valua… …lan that employ… …erm training progra…
2. Subjec… …into most accept…
   a.
   b.
   c.
   d.
   e.
   f.
   g.
   h.
   i. …ntific

2010年1月25日以降

「責任ある研究行為」に関する倫理学習を義務とする

対象者： 学部学生、修士課程学生、博士課程学生、
ポスドク、新任教員

学習時間： 4年毎に 8時間以上

形式： Web教材だけでなく、講義＋2方向性授業

内容： a→i (+研究の安全性、環境への配慮、社会的責任)

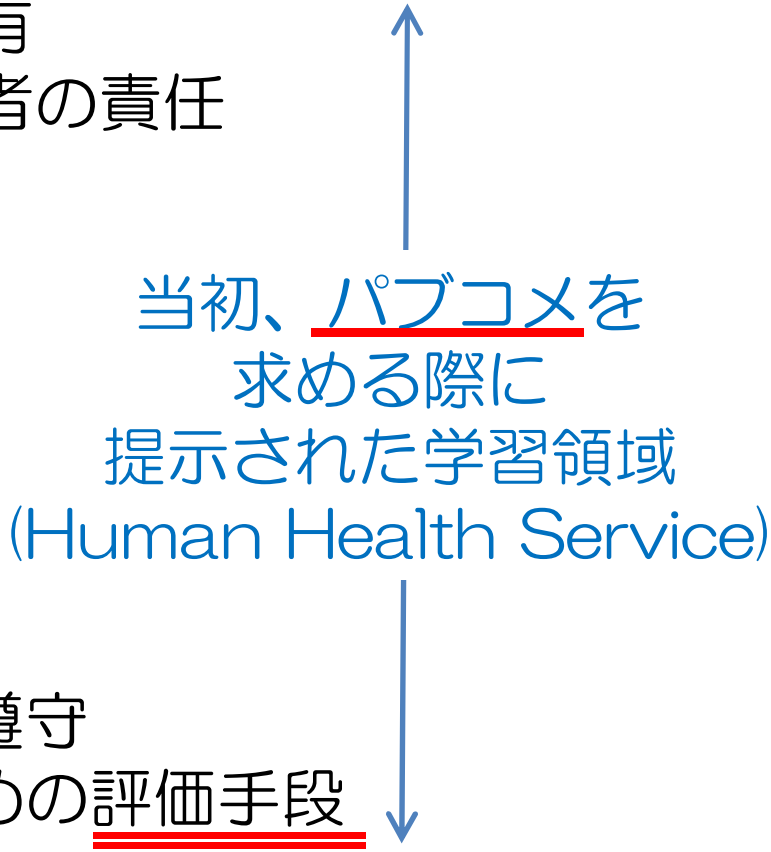
While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all of the above topics. Additional detail regarding subject matter is available under Resources.

3. **Faculty Participation:** Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.

4. **Duration of Instruction:** Instruction should involve substantive contact hours between the trainees/fellows/scholars/participants and the participating faculty. Acceptable

「責任ある研究行為（RCR）」教育の項目

1. データの収集、管理、共有。所有
2. 研究を指導する者および受ける者の責任
3. 論文発表と著者の責任
4. ピアレビュー
5. 共同研究
6. ヒトを対象とした研究
7. 動物を用いた研究
8. 研究における不正行為
9. 利益相反と責務
10. 法令・指針および施設内規則の遵守
11. 上記に関する習得を確保するための評価手段
12. 研究における安全対策
13. 研究者の社会的義務
14. 内部告発
15. 国外搬送と国の安全保障
16. 研究費の取り扱い



Dr. Donald WRIGHT (USA)
MD, M.P.H.
Deputy Assistant Secretary, Healthcare Quality
Acting Director, Office of Research Integrity, U.S. Department of Health and Human

Dr. Jan TAPLICK (GERMANY)
Deputy Director, European Molecular Biology Organiza

Dr. John C. GALLAND (USA)
Director, Division of Education and Integrity, Office of Research Integrity

Makoto ASASHIMA (Japan)
Tokyo University

Dr. John E. DAHLBERG (USA)
Director, Division of Investigative Oversight, Office of R

Dr. John M.
Founder & VP Pr

TIN (GERMANY)
r Biology Organization (EMBO)

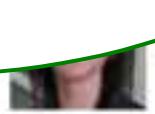
Dr. Paul BRAUNSCHWEIGER (US
University of Miami, CITI Program

Dr. Sabine KLEINERT (UK)
Senior Executive Editor, The Lancet
Vice Chair, Committee on Publication Ethics (

Epigeum, United Kingdo

ERMANY)
ular Biology Organization Journal

Ms. Allison C. LERNER (USA)
Inspector General, Office of Inspector General, National Science Foundation

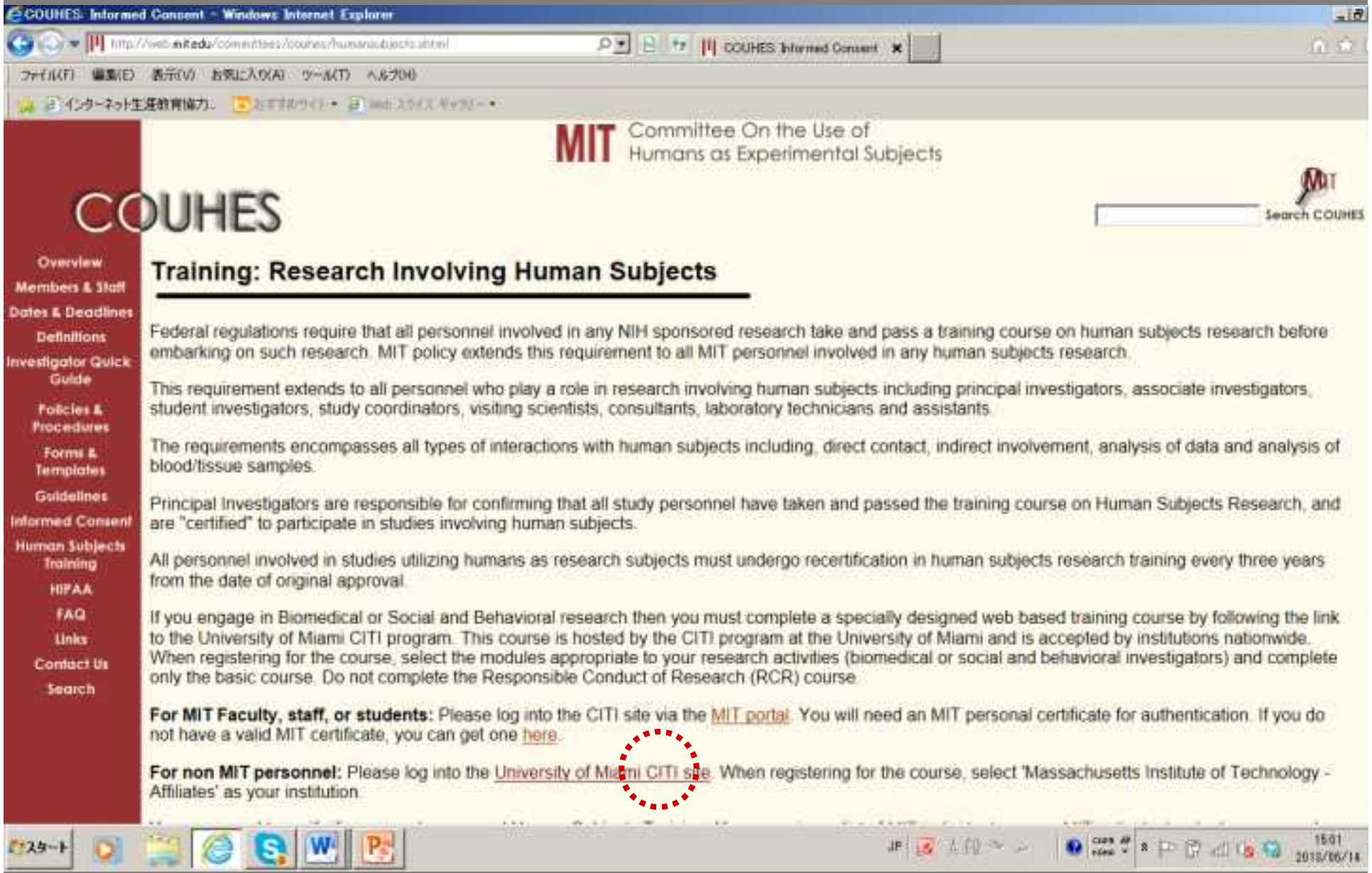


Diane M. SULLENBERGER (USA)
Executive Editor, Proceedings of the National Acade

アメリカでは
教員NPO団体の教材が
殆どの大学等で
使われています

イギリスでは
企業作成教材が10施設で
利用され始めています。

Harvard
http://www.hsph.harvard.edu/ohra/human-subjects-training-requirements/
MIT
http://web.mit.edu/committees/couhes/humansubjects.shtml
Stanford
http://researchcompliance.stanford.edu/hs/new/resources/training/index.html
Vanderbilt
https://www4.vanderbilt.edu/irb/
NASA
http://irb.nasa.gov/?p=crResearchGuidance
Rockefeller
http://rucares.rockefeller.edu/clinicalresearch/dept/crso/education
M.D. Anderson Cancer Center
http://www3.mdanderson.org/calendar/event/Human_Subjects_Protection_Training_18589.htm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MIT Committee On the Use of Humans as Experimental Subjects
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Dates & Deadlines
Definitions
Investigator Quick Guide
Policies & Procedures
Forms & Templates
Guidelines
Informed Consent
Human Subjects Training
HIPAA
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Training: Research Involving Human Subjects
Federal regulations require that all personnel involved in any NIH sponsored research take and pass a training course on human subjects research before embarking on such research. MIT policy extends this requirement to all MIT personnel involved in any human subjects research.
This requirement extends to all personnel who play a role in research involving human subjects including principal investigators, associate investigators, student investigators, study coordinators, visiting scientists, consultants, laboratory technicians and assistants.
The requirements encompasses all types of interactions with human subjects including, direct contact, indirect involvement, analysis of data and analysis of blood/tissue samples.
Principal Investigators are responsible for confirming that all study personnel have taken and passed the training course on Human Subjects Research, and are "certified" to participate in studies involving human subjects.
All personnel involved in studies utilizing humans as research subjects must undergo recertification in human subjects research training every three years from the date of original approval.
If you engage in Biomedical or Social and Behavioral research then you must complete a specially designed web based training course by following the link to the University of Miami CITI program. This course is hosted by the CITI program at the University of Miami and is accepted by institutions nationwide. When registering for the course, select the modules appropriate to your research activities (biomedical or social and behavioral investigators) and complete only the basic course. Do not complete the Responsible Conduct of Research (RCR) course.
For MIT Faculty, staff, or students: Please log into the CITI site via the MIT portal. You will need an MIT personal certificate for authentication. If you do not have a valid MIT certificate, you can get one here.
For non MIT personnel: Please log into the University of Miami CITI site. When registering for the course, select 'Massachusetts Institute of Technology - Affiliates' as your institution.

HARVARD School of Public Health

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Investigator Manual

Human Research Protection Program Plan

Forms/Instructions

OHRA Definitions

Human Research Training Requirements

Quality Improvement Program (QIP)

Department Assignments

IRB Meetings/Deadlines

For HSPH Student Researchers

Education

Resources/Useful Links

For Research Participants

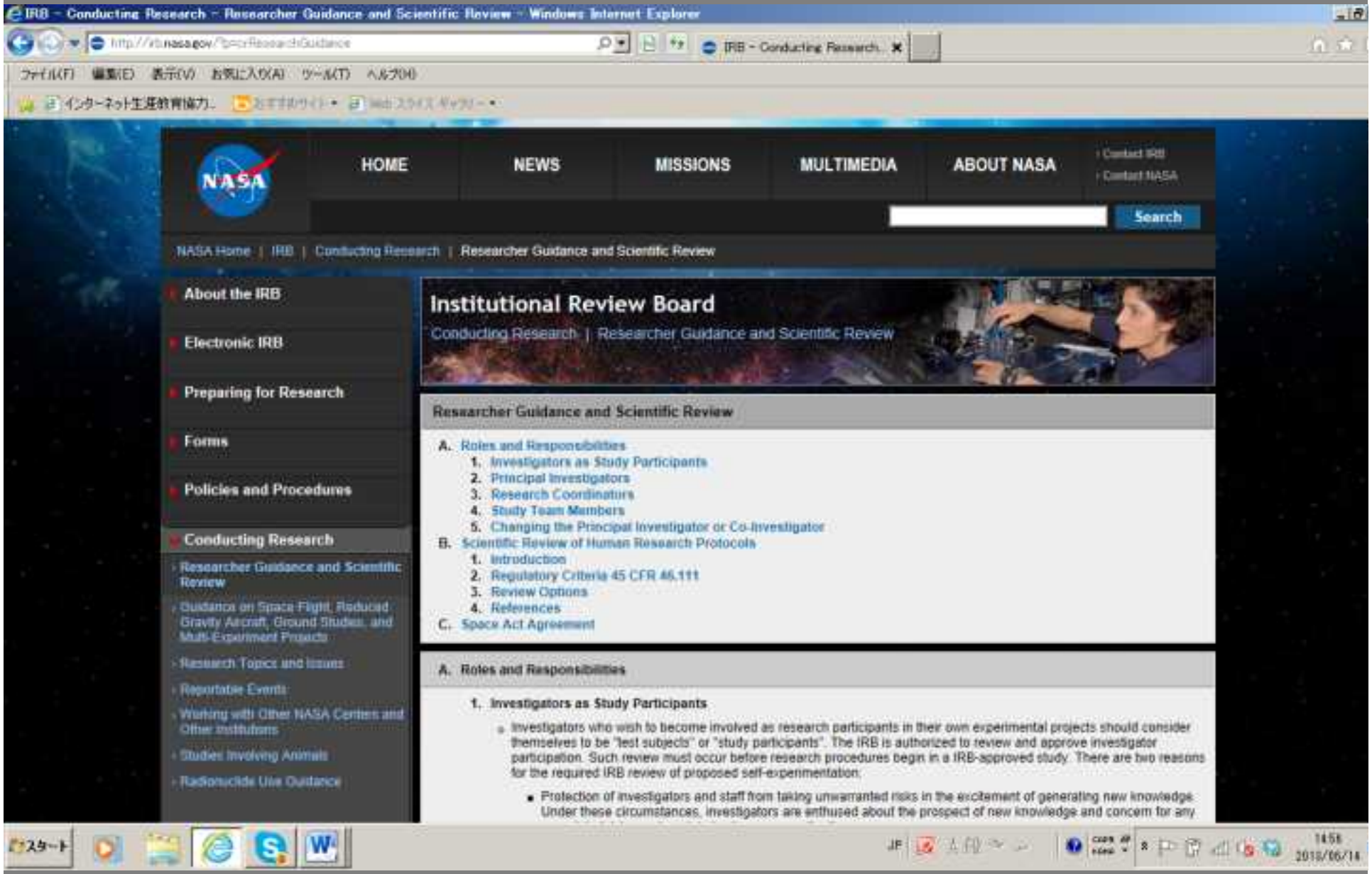
Office of Human Research Administration

Human Research Training Requirements

OHRA is pleased to offer Collaborative Institutional Training Initiative (CITI) Program as Harvard's online human research training curriculum. Effective June 2010, our former training program, HETHR (Harvard Ethics Training in Human Research), will no longer be available. Existing HETHR trainees, however, can continue to log in to HETHR to access their training record and/or certificate.

If you are a new learner who needs to complete human research training for the first time or have previously completed HETHR training and now need to complete refresher training, please visit CITI.

For individuals who have an existing CITI account	If you have previously completed CITI through your affiliation with another Institution, you may continue to log in under this account information and complete CITI to satisfy Harvard's human research training requirements. You will not be required to complete Harvard's CITI curriculum. Of note, unless you update your CITI profile to designate Harvard [Harvard Medical School and Harvard School of Dental Medicine; Harvard School of Public Health, or Harvard University (Cambridge/Allston campus)] as one of your affiliated institutions, you will need to provide the IRB with a hard copy CITI training certificate.
	For individuals who are new to CITI, you must register as a "New User." As part of the registration process, you will be asked to choose your affiliated institution or organization.


IRB - Conducting Research - Researcher Guidance and Scientific Review - Windows Internet Explorer
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Guidance on Space Flight, Reduced Gravity Aircraft, Ground Studies, and Multi-Experiment Projects
Research Topics and Issues
Reportable Events
Working with Other NASA Centers and Other Institutions
Studies Involving Animals
Radionuclide Use Guidance
Institutional Review Board
Conducting Research | Researcher Guidance and Scientific Review
Researcher Guidance and Scientific Review
A. Roles and Responsibilities
1. Investigators as Study Participants
2. Principal Investigators
3. Research Coordinators
4. Study Team Members
5. Changing the Principal Investigator or Co-Investigator
B. Scientific Review of Human Research Protocols
1. Introduction
2. Regulatory Criteria 45 CFR 46.111
3. Review Options
4. References
C. Space Act Agreement
A. Roles and Responsibilities
1. Investigators as Study Participants
Investigators who wish to become involved as research participants in their own experimental projects should consider themselves to be "test subjects" or "study participants". The IRB is authorized to review and approve investigator participation. Such review must occur before research procedures begin in a IRB-approved study. There are two reasons for the required IRB review of proposed self-experimentation:
Protection of investigators and staff from taking unwarranted risks in the excitement of generating new knowledge. Under these circumstances, investigators are enthused about the prospect of new knowledge and concern for any

Responsibilities for Safety and Welfare of Research Subjects

- Conduct the study in an ethical manner, including protecting the rights and welfare of human participants who are involved in the research protocol;
- Report any corres… …ngs) to the IRB;
- Respond to partic… participant compl…
- Designing and ca…
  - Data and Sa…

Responsibilities for Training and …

- Ensure that all participating … …bserve pertinent regulations and institutional policies and guidelines;
- Ensure that key personn… …ning the study are qualified, appropriately trained and adhere to the provisions of the IRB-approved protoc…

Responsibilities for Adherence to Regulatory and IRB Requirements and Guidance

- Complete CITI training, and be sure to select NASA as the Institution. Save a copy and attach it to your Board Review Application.
  - Collaborative Institution…
- Ensure that all research involv… …ent of the research, including screening…
- Seek IRB guidance when in d…
- Comply with all IRB decisions…
- Obtain IRB review and appro…
  - Review Process - Conditions of Approval
- Ensure that no test subject is involved in the research prior to obtaining his d…
- Ensure the adequacy of the informed consent process;
- Ensure that protocols receive at least yearly continuing IRB review and approva…
- Provide financial disclosure information or any other potential conflicts of interest… …affect the relationship with the research subject or the outcome of the research.

3. **Research Coordinators**

Responsibilities for Research

The Research Coordinator (RC) works with and under the direction of the PI. Although the… …legally responsible for all aspects of the research study, the RC often handles the bulk of the daily study activities an… …ys a key role in the study conduct and management. The RC is frequently responsible for organizing the documentati… …nd files pertaining to a study

CITI教材の中からNASAが指定する教科を選んで、学習を済ませ、修了証を取得して、それを研究審査申請書に付して提出しなさい。

JAXAの研究者は、CITI Japanの教材の中からJAXAが指定する学習を済ませることが必須となります。

CITI Collaborative Institutional Training Initiative

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Português
Español
Chinese
Russian
Japanese
Thai
French
Korean

Welcome

CITI Login and Registration Page

The CITI Program is a subscription service providing research ethics ed
members of the research community. To participate fully, learners must
with a CITI participating organization.

The CITI course is a protected site. If you are a new learner at a participating organization you must register to create your own username and password and gain access to the site.

New Users Register Here

Already Registered? Login Below

Username

Password

Submit

Forgot login information

To ensure that all users enjoy rapid response times, access is temporarily limited to 2500 concurrent users. As learners log off others will be permitted to log on. **There are**