米国 CITI

World Health Organization

COLLABORATING CENTER IN ETHICS AND GLOBAL HEALTH POLICY

Collaborative Institutional Training Initiative

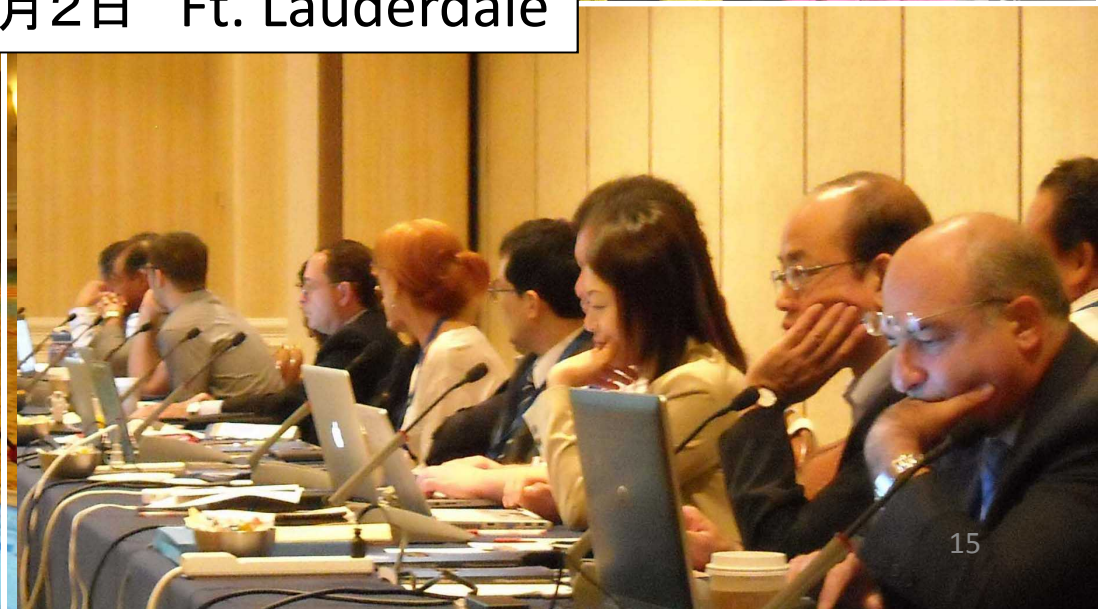
e-Learning 教材の作成と配信

- 現利用機関数：>1,800
- 利用者数：～1,000,000 (10/1/11-11/15/11)
- 30/50 トップ医学部（世界）
- 50/50 トップ大学（米国）

設立：2000年4月 – NPOボランティア教員団体

CITI 定例教材作成者会議

平成24年11月2日　Ft. Lauderdale



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 ce (audit findings) to the IRB;
- Respond to partic y significant participant compl
- Designing and ca priate
  - › Data and Sa

Responsibilities for Training an

- Ensure that all participatin observe pertinent regulations and institutional policies and guidelines;
- Ensure that key perso rming the study are qualified, appropriately trained and adhere to the provisions of the IRB-approved proto

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 invol ent of the research, including screening
- Seek IRB guidance when in
- Comply with all IRB decision
- Obtain IRB review and appro
  - › Review Process - Conditions of Approval
- Ensure that no test subject is involved in the research prior to obtaining his
- 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**

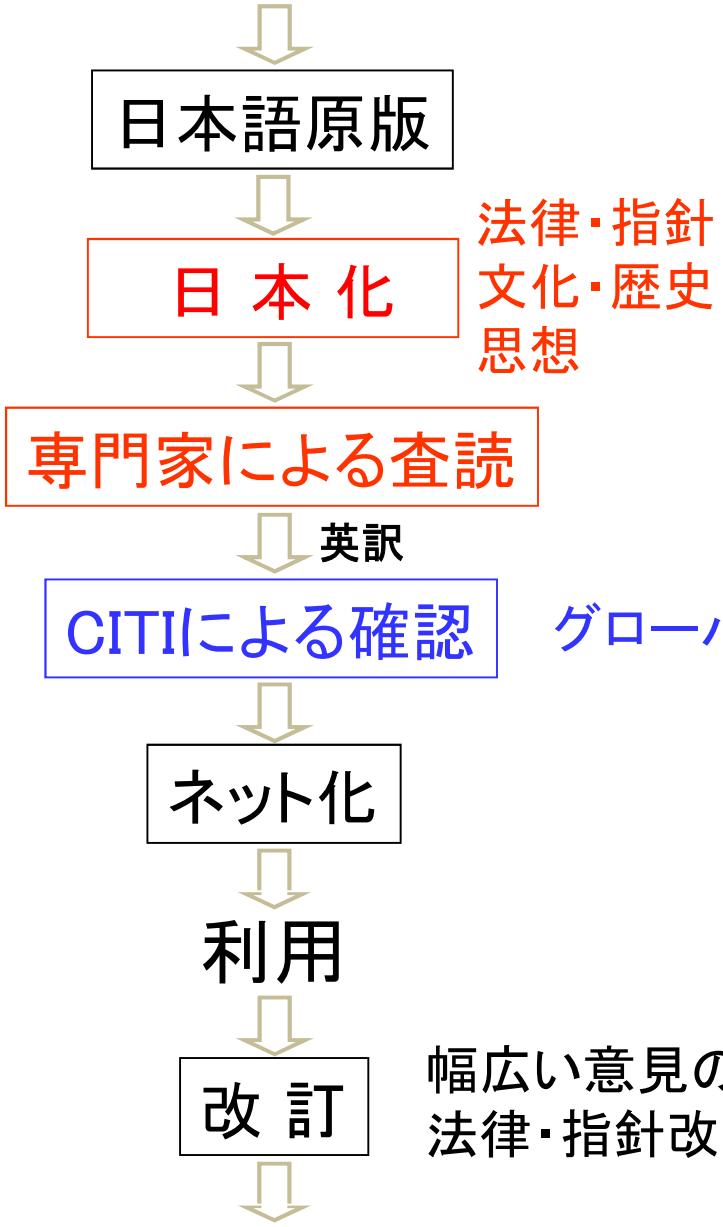
Responsibilities for Research

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 d files pertaining to a study

CITI教材の中からNASAが指定する教科の学習を済ませ、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。

「誰に」、「何を」、「どの程度」、「どのように」（教育技術）
をCITI等の教材から輸入



全国の研究機関・大学が使用する質の高い教材づくり

米国：　NPO全国的ボランティア団体

英国：　企業(Epigeum)

日本：　文科省支援下の大学連携
＋　全国規模の有志参加

CITI e-Learning

選択・配信・学習・習得評価・管理

大学・大学院・研究所・病院

「修得を確保するための評価手段の確保」

成績一覧

管理者
教学課
倫理審査委員会

CITI Japan Server

各教職員学生履修状況

対象者・学習内容

教材

成績

解答

講習・テスト

成績

成績

成績

成績

成績

教員・職員
学生・ポスドク

Maintenance of Data Integrity/Confidentiality	
Who will monitor research records?	
Where will research records be stored and how will it be secured?	
What will happen to data when study is complete?	

COMPLIANCE, DOCUMENTATION AND REPORTING			
Training			
All study personnel have completed Collaborative IRB Training Initiative (CITI) training:	Yes	No	
Adverse Event Reporting (Check all that apply.)			
Entities with adverse event reporting responsibilities:	PI ☑	Industry Sponsor	Other
Entities to which adverse events and, if applicable, DSMB reports will be reported: [NOTE: Adverse events must be reported to the RSA program in the same way (using the IRB approved adverse event form) and in the same timeframes as mandated by the IRB. MGH IRB guidelines are available at http://healthcare.partners.org/phsirb/adverse.htm. MIT IRB guidelines are available at http://web.mit.edu/committees/couhes/monitoringandreporting.shtml#adverse.]	RSA ☑	IRB ☑	FDA
	NIH	Industry Sponsor	DSMB
Documentation Requirements			
Protocol amendments that affect the clinical conduct of the study will be	Yes ☑	No	

本研究に参加する全ての研究者等はCITIの学習を修了していますか？

研究機関のホームページからCITIサイトへのリンク

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

CITI Japan プロジェクトにおける教材作成のガバナンス