Creating CITI-Japan Program
for Web-based Training,
Where Ethicists, Law and Science Experts Meet

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In an attempt of create a Web-based training program
for Japanese researchers . . .

<table>
<thead>
<tr>
<th></th>
<th>U. S. A.</th>
<th>Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. Med Sch</td>
<td>160</td>
<td>80</td>
</tr>
<tr>
<td>Faculty/Sch</td>
<td>1</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Japan:

1) does not have critical mass of collaborating educators.
2) does not have widely accepted ethics standard.
3) historically, does not have strong civilian initiative.
4) is not receptive to what appears to be US-centric.
### Humanitarian response to the 2004 Indian Ocean earthquake

#### Government vs. Private Donation

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>German</th>
<th>JPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Govern’t</td>
<td>277</td>
<td>82</td>
<td>539</td>
</tr>
<tr>
<td>Private</td>
<td>1,875</td>
<td>580</td>
<td>34</td>
</tr>
</tbody>
</table>

*Million USD*

- [http://www2.ttcn.ne.jp/honkawa/0920.html](http://www2.ttcn.ne.jp/honkawa/0920.html)
We recommend not to directly apply Euro-American rules to Japanese researchers as they do not have autonomy comparable to…

Lack of Autonomy
- No Penalty
- No Court Ruling
- No Official Record

poor ethical basis

no history to teach

Science Council of Japan

July 21, 2005
Regulation learning

Japan, today

"Why" "Do", "Don't"

Research Ethics Education in Japan

Ethics learning
No learning

We are busy, just tell me what we should do!

臨床研究に関する倫理指針（平成20年7月31日全部改正）
厚生労働省

第2 研究者等(*)の責務等

1 研究者等の責務等

（6）研究者等は、臨床研究の実施に先立ち、臨床研究に関する倫理その他臨床研究の実施に必要な知識について講習その他必要な教育を受けなければならない。

* 研究責任者、臨床研究機関の長その他の臨床研究に携わる者をいう。

Ethics Guideline for Clinical Studies
July 31, 2008

Health, Labour and Welfare Ministry

It is now mandated to take ethics education.
Expertise:
- What
- To whom
- To what extent
- How

1. Selection of Topics
2. Search for Original Modules in CITI etc
3. Translation
4. Japanize
   - Legal
   - Culture
   - History
5. Review by Japanese expert(s)
6. Review by CITI
   - Assurance for globality
7. Uploading
8. Revision based on public comments
The Collaborative Institutional Training Initiative (CITI) was founded in March 2000 as a collaboration between the University of Miami and the Fred Hutchinson Cancer Research Center to develop a web based training program in human research subjects protections. In response to the June 2000 education policy announcement, the collaboration was expanded to include content experts from 10 institutions who provided the content for the first 12 biomedical modules. In addition to the “Basic” content, the CITI model provides the opportunity for institutions to post additional instructional materials specific to their institution. The first version of the CITI Course in The Protection of Human Research Subjects, hosted at the University of Miami, was rolled out to the participants on September 3, 2000. In December 2000, the CITI Course site was made available to institutions by subscription.

In Spring 2004, the CITI Program was migrated to a new software platform developed at the VA by Mike Fallon, DVM, PhD, and Stephanie Manuel, MSME. In January 2007, with the help of Dr. Fallon and Ms. Manuel a software upgrade was implemented to permit the program to broaden it’s scope and to expand the courses offered to our participating institutions and organizations around the world.

The CITI Program, co-founded by Karen Hansen and Paul Braunschweiger PhD, is now on it’s 7th iteration and includes:

- Basic Courses in the Protection of Human Research Subjects.
- Biomedical Focus
- Social and Behavioral Focus.
- Refresher Courses
- Good Clinical Practice Course.
- Health Information Privacy and Security Course (HiPS)
- Laboratory Animal Welfare Courses for investigators and IACUC Members
- Responsible Conduct of Research (RCR).

A multi-language site, targeting international researchers was made available at http://www.irbtraining.org in Fall 2004. This multi-language capability has been added to the current CITI platform. A Spanish and Portuguese language site will be added in November 2007.

As of October 2007, the CITI Program is used by over 830 participating institutions and facilities from around the world.
ようこそ

CITI Japanログインおよび登録ページ

現在メインテナンスの途中です。一部不具合が生じるかもしれませんがご容赦ください。

CITI Japanプログラムは研究関連団体のすべての方に研究倫理教育を提供している登録制のサービスです。すべてのサービスに参加するために、受講者はCITI Japanに参加する機関に属している必要があります。

CITI Japanプログラムは保護されたサイトです。あなたがCITI Japanに参加している機関に属する新規の受講者の場合、ユーザ名とパスワードを作成するために登録手続きを完了し、その上でサイトにアクセスする必要があります。

登録済みのユーザーは下記からログイン

ユーザ名
パスワード

ユーザ名・パスワードを忘れられた方

良いなレスポンスを確保するために、同時アクセスユーザ数は現在2500名に制限されています。ログイン出来ない場合は、他のユーザがログオンした際にログインすることが可能になります。現在、このサイトには611名がログインしています。

注意：CITI JapanプログラムはMicrosoft Internet Explorer ver.5.0以降、またはFirefox ver.1.5以降でご利用下さい。
Japanese researchers are trustworthy because they have the highest self-esteem.