

Compliance Programs in Academic Medical Centers

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Regulatory Affairs Oversight

- (1) Human Subject Protection
- (2) HIPAA Privacy
- (3) Animal Care and Use
- (4) Conflict of Interest
- (5) Research Integrity
- (6) Institutional Biosafety
- (7) Radiation Safety



Research Compliance

→ Institutional Review Boards

- staffing/resource
- Membership
- Quality and Timeliness of Review
- Informed Consent Documents
- CIRB (www.ncicirb.com)
 - ✓ Joint initiative between NCI and OHRP

→ Institutional Biosafety Committee

- Gene Therapy/Recombinant DNA – Office of Biotechnology Activities (301-496-9838) (www4.od.nih.gov/oba/)
- Select agents (www.cdc.gov/od/sap/) (see the interim final rule on the Possession, Use and Transfer of Select Agents and Toxins – 42CFR Part 73)



Human Subject Protection in Research Training Alternatives

Certification that one has completed training in human subject protection in research is required of all Georgetown University faculty, investigators, study coordinators and other individuals directly involved in human subject research. An individual may complete this training, which should be updated annually, by:

1 - taking the on-line NIH course (<http://cme.nci.nih.gov>). This on-line program prints a completion certificate at the end of the program.

A copy of the certificate needs to be forwarded to Dorothea Hudley, Grants Assistant, Research and Technology Development Services, 177 Building D, so she can record in her GU database that you have completed the training. This course may be used to comply with either the Basic or the Refresher training required by Georgetown.

or



Human Subject Protection in Research Training Alternatives [continued]

2 – attending the Basic (for first-time trainees) or Refresher training session, or viewing the applicable videotape of these PricewaterhouseCoopers training sessions; the videotapes are kept on the GCRC (General Clinical Research Center), 7 Main Hospital. To view either of these tapes, phone the GCRC Nursing Station, ext. 4-0796, to schedule a convenient time for viewing in a room on their unit. After completion of the tape, you complete a form that provides information for the GU training database.

or

3 – viewing the **OHRP Investigator 101 Training Course** (PRIM&R copyright 2001) available on CD-ROM. To borrow a copy of the CD-ROM and User's Manual, please contact either the Biomedical Institutional Review Board (IRB) office at ext. 7-2618 or ext. 7-1928, or the Social-Behavioral IRB office at ext. 7-5594. You will be asked to complete a training course sheet when you return the CD-ROM and manual to the applicable IRB office.

In any case, contact Dorothea Hudley (ext. 7-1701, or e-mail: dmh42@georgetown.edu) when you need to request a copy of your Georgetown certificate of completion.



Research Compliance [Continued]

→ HIPAA and Research

- role of IRB

- tissue banks—unspecified future use

- Authorization for Disclosure/Consent

→ Resources

- HHS/OCR Guidance

 - (www.hhs.gov/ocr/hipaa/privacy.html)

- American Council on Education

 - (www.acenet.edu, “Impact of the HIPAA Privacy Rule on Academic Research”)



Conflict of Interest

→ Financial Conflicts of Interest Policy

→ disclosure forms

→ Conflict of Interest Information Resources available on the web

✓ <http://grants2.nih.gov/grants/policy/coi/resources.html>



Research Compliance [Continued]

- *Clinical Trials Office*
- *Grants Management*
- *University Counsel*
- *Internal Audit*



Professional Associations

→ AAMC – Association of American Medical Colleges

→ www.aamc.org

→ exculpatory language

→ COGR – Council on Governmental Relations
(association of research universities)

<http://206.151.87.59/>

✓ Army Grants

✓ compensation for injury

✓ publication of research results -- government
clearance/confer and consult



Examples of Exculpatory Language

- By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all rights, title, and interest to said items.
- By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.



Examples of Acceptable Language

- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
- This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.
- This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.



Re: US Army Medical Research & Military
Command (USAMRMC)

Change in reimbursement restrictions for
research related injury or illness

Ask your grant/contract officer at Fort Detrick
to contact Robert Charles about the changes
in reimbursement restrictions:

Robert.Charles@DET.AMEDD.ARMY.MIL



Computerized Adverse Event Reporting (CAER)

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CAER Background

→ The Computerized Adverse Event Reporting (CAER) project was created to require the establishment of processes for the reporting, analysis, and prevention of Serious Adverse Events (SAEs), and the implementation of a system that includes conducting analysis when an adverse event occurs, and developing strategies to reduce the risk of similar incidents occurring in the future. The requirements for CAER were gathered by interviewing various user groups including principal investigators, administrators, nurses, Georgetown University IRB reviewers and executive members, and the NIH Office of Biological Activities.



Business Case

- **Patient/Subject safety and compliance with regulatory requirements**
 - Reporting of SAEs is an important component of the Data Safety Monitoring Plan (DSMP). The prompt review of SAEs is required to determine whether a study should be discontinued or whether additional patient care resources should be added.
 - Adverse event data volume is increasing steadily and the need for quick and easy access to trial data is becoming critical. CAER offers extensive features that expedite the management and reporting of adverse event data while maintaining regulatory compliance.
- **Central repository of adverse events**
 - This will facilitate cross-trial analyses, searches for specific variables, and identification of trends.
 - CAER provides both “Ad Hoc” and “Pre-formatted” reports for the generation of in-depth queries and to permit analyses.
 - ✓ For example, CAER database can be queried by type of adverse event, disease, phase of study, protocol, principal investigator, etc.
- **Controlled Vocabulary**
 - CAER is integrated with MedDRA (Medical Dictionary for Regulatory Activities). This is essential for cross-trial analyses.



CAER Users

- CAER will be used by all research initiatives that are under the oversight of GU IRB.
- CAER has been designed with flexibility in mind. The system uses the personalization technology to tailor the interface for the use at a specific institution with specific needs.



Summary of CAER Features

- Allows for the electronic submission of internal and external Serious Adverse Event (SAE)
- Allows to create both a new report and a follow-up report
- Allows for incremental saving
- Validates data for completeness and consistency
- Uses MedDRA as standard medical vocabulary
- Allows for trend and root cause analyses



Built-in Messaging Component

- Notifies the recipients (e.g., IRB, RSA, PI) of the availability of an AE report.
 - When a report is finished processing, the server sends a formatted mail message to the recipients, notifying that the AE report is available. The recipient can then view the report using the URL provided in the mail message
- Sends reminders to the users, notifying them to complete the AE report form.
 - When an AE is submitted as 'Initial', the server sends a formatted mail message to the user every 7 days (or as specified), reminding them of completing the form.



User Access

- Supports system administration tool for user profiling and defining user displays
- Defines editing privileges depending on user type; grants or denies user access to different modules
- Provides user access via the Internet using SSL
 - Access via GU NetID and Password
- Supports concurrent user access



System Security

- Development, Testing, and Production Servers compliant with 45CFR142 – security and electronic signature standards
- Includes encrypted passwords, user lockout after a predefined number of unsuccessful logons
- Sessions will be suspended after a specified period of inactivity and require password to be re-entered
- Audit trail records user access to each data record and any modifications made
- Version control tracks changes as required by GCP guidelines



Compliance with Standards

- Controls medical vocabulary
 - Uses MedDRA terms for the coding of adverse events, allowing for consistent use of medical terminology
- Is compliant with Section 508
- *Has the potential of using HL7 standards to submit pre- and post marketing SAE reports to the FDA (contingent upon FDA approval)*



