

NOTICE OF REVISION TO UTPA IRB HUMAN SUBJECTS TRAINING REQUIREMENTS

Posted by: Grant Benham on 11/13/2007

Today's Date: 11/19/2007

NOTICE OF REVISION TO UTPA IRB

HUMAN SUBJECTS TRAINING REQUIREMENTS:

As part of a continuing effort to simplify the IRB process, the human subjects protection training requirements have recently been revised.

Information about these revisions is provided in the accompanying guidance document. The document also provides step-by-step instructions on how to register and complete the course.

Additional guidance about IRB policies and procedures can be found at <http://www.utpa.edu/orsp/irb.html>

If you have any questions after having read the available guidance documents, please contact the UTPA IRB Chair, Dr. Grant Benham, at gbenham@utpa.edu.

**NOTICE OF REVISION TO UTPA IRB
HUMAN SUBJECTS TRAINING REQUIREMENTS:**

As part of a continuing effort to simplify the IRB process, the human subjects protection training requirements have recently been revised. Human subjects protection training will still be completed via the online CITI course, but the social-behavioral course (“learner group”) has been modified as described below.

The social behavioral learner group now contains fewer REQUIRED modules, as listed below:

University of Texas-Pan American Module	REQUIRED
Introduction	REQUIRED
History and Ethical Principles - SBR	REQUIRED
Defining Research with Human Subjects - SBR	REQUIRED
The Regulations and The Social and Behavioral Sciences - SBR	REQUIRED
Assessing Risk in Social and Behavioral Sciences - SBR	REQUIRED
Informed Consent - SBR	REQUIRED
Privacy and Confidentiality - SBR	REQUIRED
Records-Based Research	REQUIRED
Research With Protected Populations - Vulnerable Subjects: An Overview	REQUIRED

As before, researchers will need to obtain at least an 80% average on module quizzes in order to obtain a basic social-behavioral CITI certificate.

Researchers are also **required** to complete certain “OPTIONAL” modules *if the modules apply to their research*. For example, researchers conducting studies in elementary schools must complete both the “*Research in Public Elementary and Secondary Schools – SBR*” and the “*Research with Children – SBR*” modules. Researchers must score 100% on any of these “OPTIONAL” modules and should submit a printout of their CITI grades along with the CITI completion certificate. IRB protocols will not be reviewed until any necessary applicable “OPTIONAL” modules have been passed.

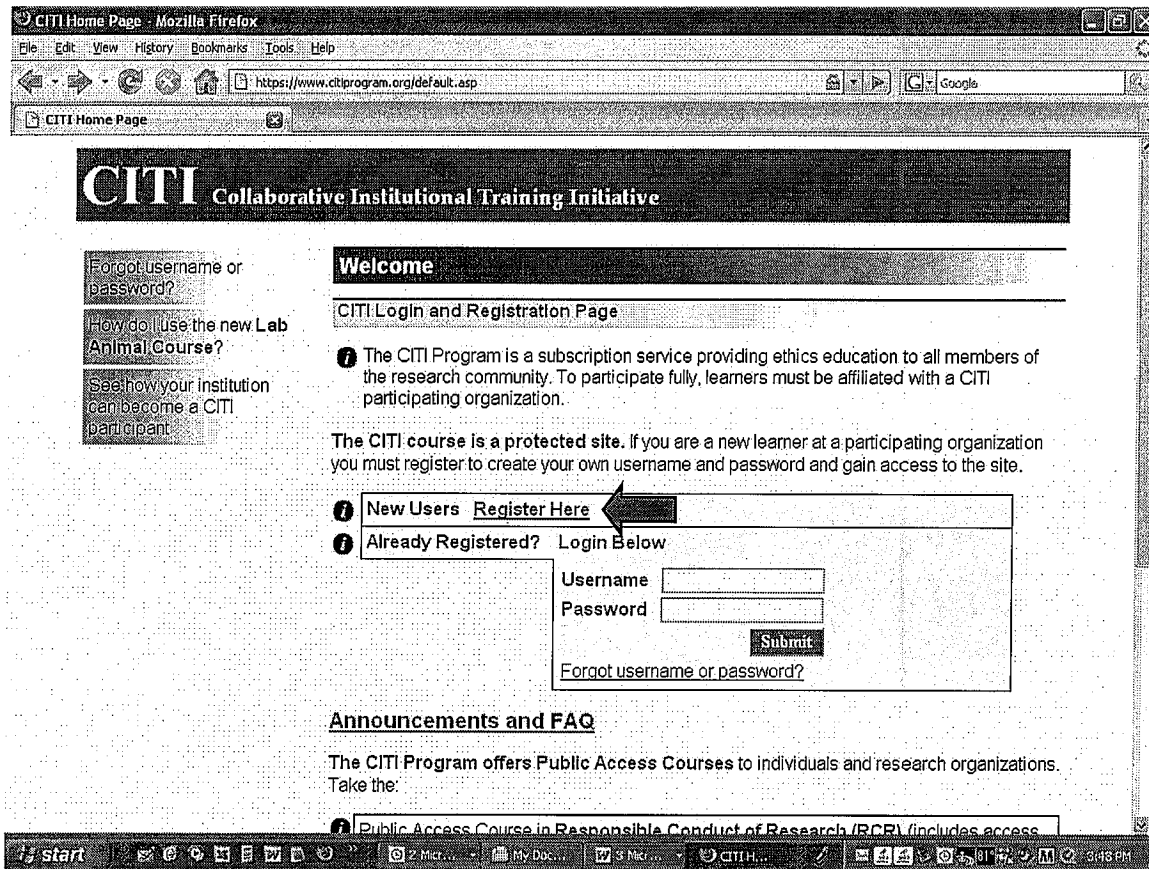
The “OPTIONAL” modules are listed below:

Research in Public Elementary and Secondary Schools - SBR	“OPTIONAL”
Research with Children - SBR	“OPTIONAL”
Internet Research - SBR	“OPTIONAL”
International Research - SBR	“OPTIONAL”
HIPAA and Human Subjects Research	“OPTIONAL”
Research with Prisoners - SBR	“OPTIONAL”
Workers as Research Subjects-A Vulnerable Population	“OPTIONAL”
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	“OPTIONAL”
Group Harms: Research With Culturally or Medically Vulnerable Groups	“OPTIONAL”
FDA-Regulated Research	“OPTIONAL”
Genetic Research in Human Populations	“OPTIONAL”

Instructions for Completing the UTPA IRB Human Subjects Protection Training: Online CITI Course

Detailed instructions, with screen shots, are provided below. The first section explains how to register and take the basic course. The second section explains how to take the "OPTIONAL" modules.

- 1) Go to the CITI website at www.citiprogram.org
- 2) Click on "Register Here"




3) Select "University of Texas-Pan American" from the drop-down box, click "Submit"

CITI Collaborative Institutional Training Initiative

Select your institution or organization

Choose your institution from the appropriate dropdown menu then click **SUBMIT**. If you are affiliated with more than one institution, you will be able to select additional institutions after providing the information required.

Participating Institutions: 

Veterans Affairs:

Department of Energy:

HIV/AIDS Network Coordination (HANC):

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4) Enter a username and a password (can be **different** from your UTPA username/password), reenter password to verify, and click "Submit"

CITI Select Username and Password - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://www.citiprogram.org/register/login.asp?affiliation=733

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Select Your Username and Password

Your username should consist of 4 to 50 characters. Acceptable characters include letters, numbers, and the symbols "@", ".", and "_". No spaces or other characters are allowed. Your username is **not case sensitive**; "A12B34CD" is the same as "a12b34cd".

Username:

Your password should consist of 8 to 12 characters. Letters and numbers are the only acceptable characters. No spaces or other characters are allowed. Your password is **not case sensitive**; "A12B34CD" is the same as "a12b34cd".

Password:

Verify Password:

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5) Enter the requested user information (as you want it to appear on your completion certificate) and click "Submit"

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Name and Email Address

Enter your first name, last name, and preferred email address in the fields below.

First Name:

Last Name:

E-mail:

Confirm E-mail:

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6) For the first question, select "Social Behavioral Researcher Investigators and Key Personnel", for the second question select "I have not previously completed an approved Basic Course", and click "Submit".

Note: this learner group option is the most common at UTPA. If you believe the biomedical course is more appropriate to your area of research, you may elect to complete that course. However, the human subjects training will be more biomedically oriented. DO NOT select the IRB Reference Resource – this is only for IRB members and staff. If you are in any doubt, please contact ORSP at 384-5004 before selecting your learner group.

Select Groups - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://www.citiprogram.org/register/selectgroups.asp?strKeyID=4BA43CA2-8C92-4207-ADF2-3E5B73C

Select Groups

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Select Groups - University of Texas-Pan American

Question 1 Select the group appropriate to your research activities.

Choose one answer

- Biomedical Research Investigators and Key Personnel.
- Social Behavioral Research Investigators and Key Personnel:
- IRB Reference Resource: All CITI modules are available for ongoing use and reference when you join this Learner Group. If you are required to complete the CITI modules as a prerequisite for conducting human subjects research, you should enroll in a Learner Group listed above and complete all requirements. If you enroll in this group you will be required to complete ALL CITI modules. You may change your Learner Group status to "IRB Reference Resource" later to access review any of the CITI modules.

Question 2 Select the group for which you have previously completed an institutionally approved Basic Course in the Protection of Human Research Subjects.

Choose one answer

- Biomedical Research Investigators and Key Personnel.
- Social Behavioral Research Investigators and Key Personnel:
- IRB Reference Resource: All CITI modules are available for ongoing use and reference when you join this Learner Group. If you are required to complete the CITI modules as a prerequisite for conducting human subjects research, you should enroll in a Learner Group listed above and complete all requirements. If you enroll in this group you will be required to complete ALL CITI modules. You may change your Learner Group status to "IRB Reference Resource" later to access review any of the CITI modules.
- I have not previously completed an approved Basic Course.

start

3:51 PM

7) Click "No"

CITI Registration Select Institution - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://www.citiprogram.org/register/selectanother.asp?strKeyID=3E0821A1-4ACE-488A-A39E-09DACE

CITI Registration Select Institution...

CITI Collaborative Institutional Training Initiative

Select your institution or organization

You have registered with the following institution(s):

- ▶ University of Texas-Pan American

At this point you can register with another institution. This could be very useful if:

- ▶ You are required to complete the requirements for a VA Medical Center.
- ▶ You are collaborating with an investigator at another institution or organization that uses the CITI Program.
- ▶ You are planning to move to another institution that uses the CITI Program.
- ▶ You want to review CITI courses (e.g., RCR or HIPS) that may not be offered by your institution.

If you want to add the training requirements for another institution, you may do it now.

Check "Yes" to affiliate with another institution.

Check "No" to continue with your current selection.

Yes No

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8) You are at the "Learner's Menu". To start the training course, click on "Enter" under the "My Courses" heading.

CITI Main Menu - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://www.citiprogram.org/members/mainmenu.asp?strKeyID=E56EB632-AB9D-4C18-9D7C-4A

CITI Main Menu utpatester3 utpatester3 (ID 726243) Tuesday, November 6, 2007

CITI Collaborative Institutional Training Initiative

Announcements and Frequently Asked Questions (FAQ) Main Menu | Logoff

Learner's Menu

- This is the email address we have for you: g@utpa.edu. If this is not correct, please [edit or change your address](#) now.
- You are affiliated with 1 participating institution(s) on the CITI website. You will have at least one grade book per institution to track your progress in meeting the institution's coursework requirements (see below).

[Affiliate with another institution](#) | [Change username or password](#) | [CME/CEU credits](#)

University of Texas-Pan American (ID: 7323) [View University of Texas-Pan American instructions page](#)

Your responses to the University of Texas-Pan American enrollment question(s) have established the courses shown immediately below for you to complete. If this is *incorrect* use the "Add a course or update your learner group" link below to return to the enrollment questions.

My Courses	Status	Completion Reports
Basic/Refresher Course - Human Subjects Research	Not Started - Enter	Not Earned

[Add a course or update your learner groups for University of Texas-Pan American](#)

University of Texas-Pan American Learner Utilities

- [Optional Modules](#) (completion is completely voluntary and will not count toward a completed course)
- [Update my profile information](#) for University of Texas-Pan American
- [Previous Coursework Completed](#)
- [CME/CEU credits](#) for human subjects protection coursework
- [Remove my affiliation](#) from University of Texas-Pan American

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start CITI Main Me... CITI Main Me... Microsoft HSC NEWS 9:37 PM

9) You are now at the listing of required modules for the Social-Behavioral Basic Course. The required modules must be completed in the order listed. Each time you complete a module, you may move on to the next module (most modules will have short quizzes at the end). You will need at least an 80% average on quizzes to print the Basic Course completion certificate. If you score poorly on any quizzes, you may retake them.

Your performance is stored in the CITI database, so you do not have to complete all modules in one sitting. You can log off and on again. When you log on, you will be directed to the "Learner's Menu" simply "re-enter" the course to continue the training.

CITI Gradebook - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://www.citiprogram.org/members/learners/gradebook_v3.asp?strKeyID=593A8741-6B55-4F1... CITI Guidelines oral history Interview

CITI Gradebook

UTPA Tester 4 (ID: 736031) Wednesday, November 7, 2007

CITI Collaborative Institutional Training Initiative

[Announcements and Frequently Asked Questions \(FAQ\)](#) [Main Menu | Logoff](#)

Basic/Refresher Course - Human Subjects Research Gradebook

Take the next required module, [University of Texas-Pan American Module](#).

Required Modules	Data	Score
▶ University of Texas-Pan American Module (ID: 1189)	Incomplete	
Introduction (ID: 757)	Incomplete	
History and Ethical Principles - SBR (ID: 493)	Incomplete	
Defining Research with Human Subjects - SBR (ID: 491)	Incomplete	
The Regulations and The Social and Behavioral Sciences - SBR (ID: 522)	Incomplete	
Assessing Risk in Social and Behavioral Sciences - SBR (ID: 523)	Incomplete	
Informed Consent - SBR (ID: 504)	Incomplete	
Privacy and Confidentiality - SBR (ID: 505)	Incomplete	
Records-Based Research (ID: 5)	Incomplete	
Research With Protected Populations - Vulnerable Subjects: An Overview (ID: 7)	Incomplete	

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10) If your study only requires completion of the basic CITI course, then you have completed the requirements. When all required modules have been completed you will be able to print out the completion certificate/report from the Main Menu page.

If you need to complete additional "OPTIONAL" modules, read the following instructions (next page).

CITI Main Menu - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://www.citiprogram.org/members/mainmenu.asp?strKeyID=FCBC7F70-B425-488B-90F6-307

CITI Main Menu

UTPA Tester 4 (ID: 73001)

Wednesday, November 7, 2007

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Announcements and Frequently Asked Questions (FAQ) [Main Menu](#) | [Logout](#)

Learner's Menu

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- You are affiliated with 1 participating institution(s) on the CITI website. You will have at least one grade book per institution to track your progress in meeting the institution's coursework requirements (see below).

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University of Texas-Pan American [View University of Texas-Pan American instructions page](#)

Your responses to the University of Texas-Pan American enrollment question(s) have established the courses shown immediately below for you to complete. If this is *incorrect* use the "Add a course or update your learner group" link below to return to the enrollment questions.

My Courses	Status	Completion Reports
Basic/Refresher Course - Human Subjects Research	Passed - 11/07/07	Print

[Add a course or update your learner groups for University of Texas-Pan American](#)

University of Texas-Pan American Learner Utilities

- [Optional Modules](#) (completion is completely voluntary and will not count toward a completed course)
- [Update my profile information for University of Texas-Pan American](#)
- [Previous Coursework Completed](#)
- [CME/CEU credits for human subjects protection coursework](#)
- [Remove my affiliation from University of Texas-Pan American](#)

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11) If your research involves procedures, special populations, or other topics covered in the "OPTIONAL Modules" listed at the beginning of this document (and repeated on the following page), you will need to access the list of OPTIONAL modules then print out a completion report. You need to score 100% on each quiz taken for these optional modules. To access these modules, select "OPTIONAL Modules" from the Main ("Learner's") Menu.

CITI Main Menu - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://www.citiprogram.org/members/mainmenu.asp?strKeyID=FCBC7F70-B425-48BB-90F6-307

CITI Main Menu

UTPA Tester 4 (ID: 733021) Wednesday, November 7, 2007

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Learner's Menu

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[Affiliate with another institution](#) | [Change username or password](#) | [CME/CEU credits](#)

University of Texas-Pan American (ID: 733) View University of Texas-Pan American [instructions page](#)

Your responses to the University of Texas-Pan American enrollment question(s) have established the courses shown immediately below for you to complete. If this is *incorrect* use the "Add a course or update your learner group" link below to return to the enrollment questions.

My Courses	Status	Completion Reports
Basic/Refresher Course - Human Subjects Research	Passed - 11/07/07	Print

[Add a course or update your learner groups for University of Texas-Pan American](#)

University of Texas-Pan American Learner Utilities

- [Optional Modules](#) (completion is completely voluntary and will not count toward a completed course)
- [Update my profile information for University of Texas-Pan American](#)
- [Previous Coursework Completed](#)
- [CME/CEU credits for human subjects protection coursework](#)
- [Remove my affiliation from University of Texas-Pan American](#)

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12) Please note that CITI provides an extensive list of OPTIONAL modules, including "Refresher" modules. You should only choose from the following:

- Research in Public Elementary and Secondary Schools - SBR
- Research with Children - SBR
- Internet Research - SBR
- International Research - SBR
- HIPAA and Human Subjects Research
- Research with Prisoners - SBR
- Workers as Research Subjects-A Vulnerable Population
- Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero
- Group Harms: Research With Culturally or Medically Vulnerable Groups
- FDA-Regulated Research
- Genetic Research in Human Populations

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[Announcements and Frequently Asked Questions \(FAQ\)](#) [Main Menu](#) [Logout](#)

Optional Modules - University of Texas-Pan American

Note: Optional modules are provided for your general interest and suggested reading only!

- ▶ You do not receive "extra credit" for completing them.
- ▶ They do not show up on any completion reports.
- ▶ They will be credited in a grade book if you subsequently enroll in a course that includes them.
- ▶ A record of all modules you complete is maintained in the database. Follow the link to see your [previous coursework](#).

Optional Modules For Basic/Refresher Course - Human Subjects Research	Already Taken?	Score
Introduction	Taken 11/07/07	No Quiz
History and Ethical Principles - SBR	Taken 11/07/07	100
Defining Research with Human Subjects - SBR	Taken 11/07/07	100
The Regulations and The Social and Behavioral Sciences - SBR	Taken 11/07/07	100
Assessing Risk in Social and Behavioral Sciences - SBR	Taken 11/07/07	100
Informed Consent - SBR	Taken 11/07/07	100
Privacy and Confidentiality - SBR	Taken 11/07/07	100
Records-Based Research	Taken 11/07/07	100
Genetic Research in Human Populations	Optional	-
Research With Protected Populations - Vulnerable Subjects: An Overview	Taken 11/07/07	100
Research with Prisoners - SBR	Optional	-
Research with Children - SBR	Optional	-
Research in Public Elementary and Secondary Schools - SBR	Optional	-
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	Optional	-
International Research - SBR	Optional	-
Internet Research - SBR	Optional	-
Group Harms: Research With Culturally or Medically Vulnerable Groups	Optional	-
FDA-Regulated Research	Optional	-
Human Subjects Research at the VA	Optional	-
HIPAA and Human Subjects Research	Optional	-
Workers as Research Subjects-A Vulnerable Population	Optional	-
Hot Topics	Optional	-
Conflicts of Interest in Research Involving Human Subjects	Optional	-
The IRB Member Module - "What Every New IRB Member Needs to Know"	Optional	-
Refresher Course 101 Introduction	Optional	-

13) When you have completed an OPTIONAL module, you can return to the main menu and then select "OPTIONAL Modules" again. You will now see the additional quiz scores for the OPTIONAL module(s) that you completed. If your research requires completion of one or more of these OPTIONAL modules, you should complete the required modules and print out a copy of this page to include in your IRB submission (i.e. in addition to the Basic Course certificate). This allows IRB staff and reviewers to confirm that you have completed all additionally required modules.

In the example below, the researcher is conducting online surveys and has therefore completed the "Internet Research - SBR" module and quiz. **Remember, you must score 100% on each of the applicable required modules for them to count.**

Optional Modules - University of Texas-Pan American

Note: Optional modules are provided for your general interest and suggested reading only!

- ▶ You do not receive "extra credit" for completing them.
- ▶ They do not show up on any completion reports.
- ▶ They will be credited in a grade book if you subsequently enroll in a course that includes them.
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Optional Modules For Basic/Refresher Course - Human Subjects Research	Already Taken?	Score
Introduction	Taken 11/07/07	No Quiz
History and Ethical Principles - SBR	Taken 11/07/07	100
Defining Research with Human Subjects - SBR	Taken 11/07/07	100
The Regulations and The Social and Behavioral Sciences - SBR	Taken 11/07/07	100
Assessing Risk in Social and Behavioral Sciences - SBR	Taken 11/07/07	100
Informed Consent - SBR	Taken 11/07/07	100
Privacy and Confidentiality - SBR	Taken 11/07/07	100
Records-Based Research	Taken 11/07/07	100
Genetic Research in Human Populations	Optional	-
Research With Protected Populations - Vulnerable Subjects: An Overview	Taken 11/07/07	100
Research with Prisoners - SBR	Optional	-
Research with Children - SBR	Optional	-
Research in Public Elementary and Secondary Schools - SBR	Optional	-
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	Optional	-
International Research - SBR	Optional	-
Internet Research - SBR	Taken 11/07/07	100
Group Harms: Research With Culturally or Medically Vulnerable Groups	Optional	-
FDA-Regulated Research	Optional	-
Human Subjects Research at the VA	Optional	-
HIPAA and Human Subjects Research	Optional	-
Workers as Research Subjects: A Vulnerable Population	Optional	-
Hot Topics	Optional	-
Conflicts of Interest in Research Involving Human Subjects	Optional	-
The IRB Member Module - "What Every New IRB Member Needs to Know"	Optional	-
Refresher Course '10' Introduction	Optional	-
SBR 101 REFRESHER MODULE 1. History and Ethics	Optional	-
SBR 101 REFRESHER MODULE 2. Regulatory Overview	Optional	-
SBR 101 REFRESHER MODULE 3. Fundamental Issues	Optional	-
SBR 101 REFRESHER MODULE 4. Vulnerable Subjects	Optional	-

DON'T FORGET: IF YOU HAVE TAKEN ANY OPTIONAL MODULES YOU SHOULD PRINT OUT AND SUBMIT A COPY OF THIS PAGE WITH YOUR COMPLETION CERTIFICATE/REPORT

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Posted by: Grant Benham on 11/13/2007

Today's Date: 11/19/2007

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