Tutorial Guide
For
ARIA Clinical Research Information Management System On LiNe
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Lesson 1

ARIA Web Site

In this lesson, you will learn how to:

- Access the ARIA web site

The ARIA database is accessed from the internet (Internet Explorer) by means of the ARIA web site or the UAMS Homepage.

1. The ARIA home page address is https://aria.uams.edu

Fig. 1.1
The ARIA homepage provides view of the ARIA system (fig. 1.1).

Embedded in the summary information are links to the Office of Research and Sponsored Programs (ORSP), and to the Institutional Review Board (IRB).

A navigation bar located at the top of the page, provides access to

2. The UAMS homepage is [http://uams.edu](http://uams.edu).
Select **RESEARCH / TECHNOLOGY** (fig. 1.2) from the left side of the page.

UAMS is the state’s premier center of research and the hub for scientific and medical innovation. Millions of dollars in grants and contracts are awarded each year for comprehensive studies in areas such as cancer, eye disease, substance abuse and Alzheimer’s disease, to mention a few. Our faculty of clinicians-scientists translate emerging and ever-changing research findings into better detection, treatment, management and prevention of disease. UAMS is a pioneer in biomedical and health-related research discovery, investigation and development, led by some of the nation’s top researchers and clinicians. Out of this research comes patents. UAMS BioVentures, a business accelerator geared toward technology-based enterprises, is attracting biotechnology companies to Arkansas and creating new opportunities for technology transfer. The Arkansas Biomedical Research Infrastructure Network, coordinated by UAMS faculty, is a statewide group of investigators and students at both institutions and private industries working together in a cooperative effort to further scientific discoveries.

Select **ARIA - Automated Research Information Administrator** (fig. 1.3) from the page.
Lesson 2
Log-In Process

In this lesson, you will learn how to:

- Access the ARIA login screen
- Obtaining an ARIA Web user account
- How to obtain a forgotten password?

To access ARIA click on the link located on the navigation bar.

ARIA WEB – Login Screen
Enter your username (last name first name) and password in the provided spaces (fig 2.1). Note: the username is not case sensitive.

Press Enter or click on the Login button to complete the login process.
Upon initial login, you may be prompted to update the Contact Profile data. See the Profile Update section lesson for additional information.

**How to Obtain an ARIA Username and Password**

In order to obtain an ARIA username and password you must complete the Human Subject Protection course offered by CITI. To access the online training and certification, go to [https://www.citiprogram.org/](https://www.citiprogram.org/). Choose University of Arkansas for Medical Sciences as your Participating Institution. Select Biomedical Research or Social/Behavioral Research under Question 1, depending on the nature of your research.

Upon completion of this course, fax your CITI completion report to the IRB office at 686-7265 along with a note that lists your email address and states that you are requesting an ARIA username and password. You must list your email address in order to be provided with a username and password. If you do not hear back via email with a password and username for the ARIA system shortly after faxing your training certificates, please contact the main IRB office at 501-686-5667 or IRB Director at 501-686-8062 and ask to speak to someone about obtaining your ARIA username and password.
Forgot your password? Click on the Forgot your password? link, if you cannot remember you username or password. Enter your email address in the space provided i.e., Name@uams.edu, and click Continue (fig 2.2). ARIA will automatically send you an email notification regarding your username and password. Do not respond to this email.

Fig 2.2
Lesson 3

Profile Update

Upon your initial login, you may be prompted to update your Contact Profile data. This area displays a profile summary. The profile section is used to maintain demographic information, education and a curriculum vitae summary.

Click on the **PROFILE** button on the Navigation bar to open the Review Profile. The Review Profile screen is divided into the following sections: Primary Contact Information, Education and Curriculum Vitae (fig 3.1).

![Fig 3.1](image-url)
Click **Continue** to return to the ARIA home page.

**Primary Contact Information**

This Contact Profile information is used for all notification regarding your protocols and documents. This information must remain current and accurate.

This section includes demographic information. Click on the **Edit** link to modify your primary contact information (fig 1.4). Once you update your Contact Profile information Click on Update to accept the changes or Reset to discard the changes.

**Education**

If you need to add education, click on the **Add New Education** link (fig 3.1). Provide the appropriate data. Click on **Continue** to complete the entry (fig 3.2).
Curriculum Vitae

To update your Curriculum Vitae information, Click on the Edit link (fig 3.1).

Click on Reset to discard the changes or Click on Continue to return to the ARIA home page after editing you Curriculum Vitae (fig 3.3).
Lesson 4

ARIA Saved Submissions in CRIMSON

You will notice CRIMSON has been added to the ARIA system toolbar. Click on the “CRIMSON” link in the navigation menu to view saved protocols in the CRIMSON module of ARIA. Note: this is not for studies saved in the IRB module of ARIA but for studies saved in the CRIMSON module (fig 3.1).

Fig. 4.1
Lesson 5
ARIA New Submissions

1. For any **new submissions** involving human subjects requiring Institutional Review Board review you must click on the **NEW PROTOCOL** link in the navigation menu (fig 5.1). This involves Full IRB review, Expedited, or Exempt studies.

![Fig. 5.1](image)

2. The following screen will appear

![Fig 5.2](image)

3. Select the study type based on your category of research either Behavioral or Biomedical (fig 5.3).

![Fig. 5.3](image)
4. Select your position while conducting the research protocol from the following list (fig 5.4):

![Fig 5.4]

5. Click on the magnifying glass icon to lookup primary contact information (fig 5.5).

   Note: The primary contact will receive all IRB correspondences.

![Click here to lookup Contact Information. Fig. 5.5](image)

6. This screen will allow you to enter primary contact information in one of the following three fields. Once the first name, middle initial or last name is entered, then click the **Find** button (fig 5.6).

![ARIA - Microsoft Internet Explorer](image)
7. This information is auto-generated from the ARIA profile. Click the **Use this Information** button to update the Primary Contact Information fields (fig 5.7).

![ARIA - Microsoft Internet Explorer window](image)

**Fig. 5.6**

<table>
<thead>
<tr>
<th>ID #:</th>
<th>11:11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Person in PI’s Office:</td>
<td>John Doe</td>
</tr>
<tr>
<td>Address:</td>
<td>4301 W. Markham</td>
</tr>
<tr>
<td>Mailslot:</td>
<td>718-3</td>
</tr>
<tr>
<td>City:</td>
<td>Little Rock</td>
</tr>
<tr>
<td>State:</td>
<td>AR</td>
</tr>
<tr>
<td>Zip:</td>
<td>72205</td>
</tr>
<tr>
<td>Work:</td>
<td>123-4567</td>
</tr>
<tr>
<td>Pager:</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
<tr>
<td>E-Mail:</td>
<td><a href="mailto:spinkscynthiad@uams.edu">spinkscynthiad@uams.edu</a></td>
</tr>
</tbody>
</table>

*If any on this information is inaccurate please have the contact listed log into ARIA and edit their profile.*

**Fig 5.7**
8. Answer the following two questions regarding the location where the research will be conducted (fig. 4.8.1). The second question implies the use of any UAMS office space including telephones, computers, fax machines, or copiers.

(Fig 5.8.1)

- Option 1
  If you answer “Yes” to the first question and “No” to the second question and click [Continue], you will automatically proceed to the IRB submission form to complete and submit for review.

- Option 2
  If you answer “No” to the first question and “Yes” to the second question and click [Continue], you will automatically proceed to the Redirection to Clinical Research Module screen (fig 4.8.2).

(Fig. 5.8.2)

- Option 3
  If you answer “Yes” to the first question and “Yes” to the second question and click [Continue], you will automatically proceed to the Redirection to Clinical Research Module screen (fig 5.8.2).
9. Click [Continue] to be redirected to the Clinical Research Information Management System On Line (CRIMSON) (fig 5.9).

10. A new research study is created and an IRB number has been assigned to the study. This IRB number will remain with the study through out its entirety (fig 5.10).

   - New research study is created. IRB Number for this study is 80783. Please answer the following questions to proceed.

(Fig 5.10)

An IRB number has been created in the CRIMSON module and in the IRB module of ARIA. This makes it possible for you to work in both modules under that one IRB number. (Note: you can not submit to the IRB for review until your research study has been approved in CRIMSON).
11. Answer the following billing questions (fig 5.11).

![Table of Billing Questions]

If you answer yes to any of questions 1-11 and click on Next you will be redirected to the Study Details screen of CRIMSON to enter study information, funding source(s) information, upload documents, develop a detailed budget and submit for approvals by the PI (fig 4.11).

If you answer no to all of the above questions and click on Next you will not be required to build a budget and will be redirected to the Study Details screen of CRIMSON to enter study information, funding source(s) information, upload documents and submit for approvals by the PI (fig 5.11).
Lesson 6

Completion of Study Details Screen

![Study Details Screen](image)

**Fig. 6.1**
Completion of Study Information Section

1. Protocol Title – enter the title of the study as listed on the protocol. This title may be provided by the pharmaceutical company for industry sponsored studies or by the investigator for investigator initiated studies or by the cooperative group for cooperative studies. *This is a required field. Note: This section has copy and paste functions.

2. Brief Title - a title where key identifiers are entered. When the full study title is not yet known or maybe entered if the study has a shorter working title in addition to the full protocol title.

3. Study College/Division – the college or division under which the research study is being conducted. (Example: College of Medicine)

4. Department – the department under which the research study is being Conducted (Example: Medicine)

5. Sub-Department – a sub-part of the department (Example: Cardiology)

Completion of PI (Principal Investigator) Information Section

Principal Investigator - person who is ultimately responsible for the conduct of the clinical research study.

1. Select Other Investigators to include all of the sub-investigators on the study (fig 6.2). These individuals will only be able to view to study.
2. Select **I am the PI** if you are the Principal Investigator.

3. Select **Pick/Change PI** to pick or change the PI (fig 6.3).
4. Type in the Last Name and First Name of the individual to pick or change to the PI (fig. 6.4).

![Fig. 6.4](image)

5. Click on Select to enter the PI.

**Completion of Primary Contact Information Section**

1. Select Other Study Contacts to include all of the sub-investigators on the study (fig 6.5). These individuals will only be able to view the study.

![Fig. 6.5](image)

2. Select I am the SC if you are the primary contact.

3. Select Pick/Change SC to pick or change the Primary Contact (fig. 6.6).
4. Type in the Last Name and First Name of the individual to pick or change to the PI (fig. 6.7).

5. Click on Select to enter the PI.
Completion of Locations Where Research will be Conducted Section
(Check all that apply).

1. UAMS facility – University of Arkansas for Medical Sciences
2. AHEC – Area Health Education Centers
3. CAVHS – Central Arkansas Veterans Health System (John L. McClellan)
4. CAVHS NLR - Central Arkansas Veterans Healthcare System (North Little Rock)
5. ACH – Arkansas Children’s Hospital
6. ACHRI - Arkansas Children’s Hospital Research Institute
7. AR DOH – Arkansas Department of Health
8. DHHS – Department of Health and Human Services
9. Other (List other Locations)

Completion of Study Category Section (Check all that Apply)

1. Select a Study Category. *This is a required field.

2. If **Industry Sponsored** is the selected you will complete the following fields:

   - Select **Phase of Study** *This is a required field.
   - Select **Contacted By** from the provided drop down box - Who contacted you about the clinical research study?
   - Select a **Contact Method** from the provided drop down box – How were notified about the clinical research study?
   - Enter **Sponsor Assigned Protocol ID** – Number assigned to the protocol by the sponsor (Example: GSK XYZ001)
3. If **Cooperative Group** is the selected Study Category, you will complete the following fields:

- Enter **Cooperative Group**
- Enter **Cooperative Group ID**
- Select **Phase of Study** *This is a required field.*

4. If **Investigator Initiated** is the selected, you will complete the following fields:

- Select **Primary Funding Source** *This is a required field.*
  - Industry Supported
  - Federal Grant
  - Non-Federal Grant
  - Dept Funds
  - Foundation Funds
  - No Funds
- Select **Phase of Study** *This is a required field.*

If **Student Research** is the selected, you will complete the following fields:

- Select **Phase of Study** *This is a required field.*
- Enter **Faculty Advisor** *This is a required field.*

**Completion of Study Type Section (Check all that apply) (fig. 6.8)**

```
Study Type (Check all that apply):
  ☐ Questionnaire or Survey       ☐ Interview       ☐ Observation       ☐ Video or Audio Taping
  ☐ Instruction/curriculum       ☐ Use of Focus Groups       ☐ Intervention       ☐ Archival Data
  ☐ Record or Chart Review       ☐ Inpatient       ☐ Outpatient       ☐ Long Term Care Facility
  ☐ Community Based

Other: ________________________________________________
```

Fig. 6.8
Completion of Regulatory Information Section

1. Test Article (Check all that apply)
   Click on the □ then select one of the options.

   Select One
   □ N/A
   □ Biologic
   □ Device – Category A
   □ Device – Category B
   □ Dietary Supplement
   □ Drug
   □ Human Tissue

   • 1. Drug: Any chemical compound (oral, IV, topical, drops or injectable) intended for use in the diagnosis, treatment, cure or prevention of a disease administered to humans.
   • 2. Device: An instrument, apparatus, implement, machine, implant, in vitro diagnostics, including any components, parts or accessories, which is intended for the use in diagnosis, treatment, cure and prevention of a disease. (Examples: crutches, pacemakers, arterial grafts, orthopedic implants, etc).

   • 1. Significant Risk (SR) Devices (Category A): Innovative devices for which absolute risk of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type is safe and effective). [www.cms.gov](http://www.cms.gov)
   • 2. Non-Significant Risk (NSR) Devices (Category B): Non-experimental and/or investigational devices where underlying questions of safety and effectiveness of that device type have been resolved. [www.cms.gov](http://www.cms.gov)
3. **Biologic**: A virus, vaccine, toxin, anti-toxin, blood product, and therapeutic serum intended for the prevention, treatment, cure or injury in humans. [www.fda.gov](http://www.fda.gov)

4. **Human Tissue**: Transplantation, transfer or infusion of human cells or tissue into a human. [www.fda.gov](http://www.fda.gov)

5. **Dietary Supplement**: A product that contains a dietary ingredient taken by mouth intended to supplement the diet. [www.fda.gov](http://www.fda.gov)

2. **Manufacturing**

   Note: Cellular products, drugs, devices, placebo or drug compounding are manufactured at UAMS.

   Click on the ▼ then select one of the options.

   ![Select One]

   Select One

   N/A
   
   Cellular products, drugs, or devices
   
   Placebo or drug compounding

3. **PRMC Review** (Protocol Review Management Committee)

   This committee reviews all cancer research studies.

   Does this study require PRMC review? Select □ Yes □ No

4. **Study Monitor**

   **Option 1**

   Does this study require monitoring? □ Yes □ No

   Is UAMS the Study Monitor? □ Yes □ No

   If YES, is an external group monitoring the study? □ Yes □ No

   If YES, enter External Monitor: *

   ![External Monitor]
Option 2

Does this study require monitoring?  ☐ Yes ☐ No

Is UAMS the Study Monitor?  ☐ Yes ☐ No

If NO, then enter Study Monitor:  

Option 3

Does this study require monitoring?  ☐ Yes ☐ No

Is UAMS the Study Monitor?  ☐ Yes ☐ No

If YES, is an external group monitoring the study?  ☐ Yes ☐ No

If UAMS is the study sponsor for any external location(s), list location(s) and PI(s).

Location  PI  Add a Location

Type in the Location(s) then select  Add a Location

Option 4

Does this study require monitoring?  ☐ Yes ☐ No

5. Registration with Clinical Trials.gov

Does this study require registration with clinicaltrials.gov?  ☐ Yes ☐ No

Has the study been registered?  ☐ Yes ☐ No

Industry Sponsored Clinical Research Studies the following will be provided by the Sponsor for entry.

Registration Date

Registration Number
Investigator Initiated Clinical Research Studies

Registration Date

Registration Number

1. Contact Lindsey Avery at 501-686-5190 for assistance at the Research Support Center.

6. Completion of Miscellaneous Section *This is a required field.

   **Disease Site:**
   1. *Select One*

   Click on the then select one of the options.

   **Bacterial and Fungal Diseases**

   Click on the then select one of the options.

   **Disease Subsite:**
   2. *Select One*

   The selection of the Disease Site and Subsite with auto-populate the box to the right of the screen (fig. 6.9).

   **Bacterial and Fungal Diseases - Anthrax**

   Fig. 6.9

   Select Remove to delete any selection.

   Note: You may select any many disease sites and sub-sites as needed.

   **Study Classification:**
   3. *Select One*

   N/A
   Bioterrorism
   Cancer-related
   Cancer-specific
   Geriatric-related
   Geriatric-specific
   Translational Research
1. Cancer Related: If the specific aim of the research study is not the treatment of cancer but the subjects enroll in the research study have cancer. (Example: treatment of cancer patients with nausea cause by chemotherapy)

2. Cancer Specific: If any of your research subjects are participating in an oncology research study.

3. Bioterrorism: Any research being conducted on prevention, awareness, preparedness, response or recovery related to acts of bioterrorism.

www.fda.gov

4. Geriatric Related: The research study is not specifically designed to study the Geriatric population but includes Geriatric subjects.

5. Geriatric Specific: Research studies specifically designed to study diseases of the Geriatric population.

6. Translational Research: Scientific discoveries from basic research translated into practical application in humans.

4. UARK #

The UARK # is a tracking number for the cancer studies being conducted at the Myeloma Institute for Research and Therapy.

UARK #: 

7. Completion of Summary Section*This is a required field.
Note: This section has copy and paste functions.

Protocol Lay Summary (150 words max.):

A brief description or synopsis of the research protocol.

Study Comments

Study Comments:

Free text about the clinical research study.
8. Completion of Update Notes Section

Update Notes:

Free text used by Research Personnel to keep notes about a clinical research study. You must select the save button before you leave ARIA. Once you logout and log back into ARIA these update notes will only appear within the log screen.

9. Completion of Clinical Research Organization/Site Management Organization Section (if applicable)

Click on the then select one of the options.
Select Add as CRO if Clinical Research Organization
Select Add as SMO if Site Management Organization

Select Add Contact (fig 6.10).
Fig 6.10

Select **Add Contact**

**Saving of Study Details Screen Section**

Click on **CANCEL** to cancel the entire page.

Click on **SAVE** to save the page. Note: if there are any errors on the screen a error section will appear at the top of the screen.

Click on **CONTINUE** to save the study details screen but to continue to the next screen. Note: if there are any errors on the screen a section will appear at the top of the screen listing what needs to be corrected.
Lesson 7

Completion of Funding Source Page

1. Question 1 Completion Criteria

If any external funding agency is providing funds for your research study (i.e., grant, private organization, or pharmaceutical company).

Click on the □ then select one of the options.

<table>
<thead>
<tr>
<th>Funding Agency Name</th>
<th>Project Title</th>
<th>Full/Partial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allamed Laboratories, Inc.</td>
<td>Edit</td>
<td>In Full</td>
</tr>
</tbody>
</table>

Select □ **In Full** if the Sponsor is providing compensation for the entire research study.

Select □ **In Part** if the Sponsor is providing compensation for part of the research study.

Select **Add** .

Select **Edit** to add a title for a research study being funded by a specific Industry Sponsor or Grant agency.
Select Add Contact (fig 7.1).

**Fig. 7.1**

Select Add Contact.

Clinical Research Organization/Site Management Organization

Click Show CRO/SMO.

Select: Select One

Click on the then select one of the options.

Select Add as CRO if Clinical Research Organization

Select Add as SMO if Site Management Organization
Select Add Contact (fig 7.2).

Fig. 7.2

2. Question 2 Completion Criteria

If a grant has been previously submitted and awarded. A 5 digit Proposal Registration Number (PRN) will have been assigned to the research study by the Office of Research Sponsored Programs (ORSP) and provided in an Email.

Select  if the Project is providing compensation for the entire research study.

Select  if the Project is providing compensation for part of the research study.

Select Add .
3. Question 3 Completion Criteria

If the funding/support is provided by your department for any charges/fees.

<table>
<thead>
<tr>
<th>Fund</th>
<th>Cost Center</th>
<th>Full/Part</th>
<th>In Full</th>
<th>In Part</th>
<th>Add</th>
</tr>
</thead>
</table>

Enter a 3 digit fund number
Enter a 7 digit Cost Center number.
Select ☐ Full if the Fund is providing compensation for the entire research study.

Select ☐ Part if the Fund is providing compensation for part of the research study.

Select ☐ Add.

Select Question 4 if funding has not been obtained for the research study.

Select ☐ Check if funding has not been obtained.

Select the Department: that is providing the funds.

Enter the 3 digit fund number: .

Enter the 7 digit cost center number: .

4. Question 4 Completion Criteria

A research study conducted by an individual to fulfill the requirements for a master’s thesis, doctoral dissertation or other research requirement to complete a medical program.

Place a check ☑ Student Research - Funding is Not Required.
5. **Question 5 Completion Criteria**

Vendor supplied items (e.g. study drug(s), device or test article). Do not enter Case Report Form (CRF) binders, Lab kits etc.

Vendor Name: [ ]

Type in the [ ]

Supplied Material: [ ]

Select [ ] **Add**. **Note:** enter 1 item per line.

<table>
<thead>
<tr>
<th>Vendor Name</th>
<th>Supplied Materials</th>
<th>Plan to Bill?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Company X</td>
<td>Drug 123</td>
<td>NO</td>
</tr>
</tbody>
</table>

Do you plan to bill for drug/device? [ ] **YES** [ ] **NO**

Do you plan to bill for drug/device? [ ] **YES** [ ] **NO**.

If [ ] **YES** is selected you will need to contact Carole Hamon 501-526-7437 or Lyndsey Avery 501-686-5190 for assistance at the Research Support Center to obtained a waiver from the FDA to bill for the drug or device.

6. **Update Notes**

Update Notes: [ ]

Free text used by Research Personnel to keep notes about a clinical research study. You must select the save button before you leave ARIA. Once you logout and log back into ARIA these update notes will only appear within the log screen.
7. Funding Source Information Screen Completion

Click on CANCEL to cancel the entire page.

Click on SAVE to save the page. Note: if there are any errors on the screen a error section will appear at the top of the screen.

Click on CONTINUE to save the study details screen but to continue to the next screen. Note: if there are any errors on the screen a section will appear at the top of the screen listing what needs to be corrected.
Lesson 8

Budget Parameters Screens

Note: The study details screen must be completed before you can generate a budget matrix.

1. If you answer NO to all 11 of the billing questions you are not required to generate a budget. You will see the following screen (fig 8.1).

Click on the link to view your responses to the 11 billing questions.

Click on the link to change any of the responses to the 11 billing questions.

If you are not required to generate a Budget and click on the link the total budget dollar amounts will be 0.
2. If you answer YES to any of the 11 billing questions on the Billing Question form you are required to generate a budget. You will see the following screen (fig. 8.2)

![Fig 8.2](image)

Click on the link **Show Billing Question form** to view your responses to the 11 billing questions.

Click on the link **Edit Billing Questions** to change any of the responses to the 11 billing questions.

Once you generate a Budget and click on the link **Print Budget Cover Page** the total budget dollar amounts will be displayed.

3. Click on the link **Generate New Budget Matrix** to create a new budget matrix through a series of questions.

Select one of the three budget template types (fig 8.3).

![Fig. 8.3](image)
1. **Basic**: Budget template to develop a standard research study budget format.

2. **Oncology**: Budget template specifically designed for oncology studies with arms and cycles.

3. **Custom**: Budget template that allows customization to meet specific research study needs.

Select **Next >>** to go to the next set of budget parameters questions.
Lesson 9

Copy from a Budget Template

Click **Select One** from the list of saved Budget Templates.

Click **Create** to generate the Budget Template.

Click **Cancel** to close.
Lesson 10

Click \texttt{Select One} from the list of saved Budget Templates.

Click \texttt{Delete} to generate the Budget Template.

Click \texttt{Cancel} to close.
Lesson 11

Budget Parameters for a Basic Template

1. **Choose budget template type:** Basic

   Click **Next >>**.

2. The Facilities and Administration (F & A) field for Industry Sponsored and Industry Supported studies will automatically populate to 25%. When conducting other research studies, the Facilities and Administration (F & A) field should be changed to 0% (fig 11.1).

   Fig 11.1

3. Select the Department (Faculty Group Practice) where the research will be conducted from the drop down box (fig 11.2).

   Fig 11.2
4. **Automatically fill in names (Periods, visits, etc.)?**

   - Yes
   - No

   If the selection is “No” the text fields are free text.

   This selection will allow you to automatically name the period name (e.g. Pre-Screening, Screening, Pre-Treatment, Pre-Study, Treatment, Study Drug, Follow-up, or End of Treatment) and period description (e.g. name of study drug(s), weeks, days, months or hours).

   **Automatically fill in names (Periods, visits, etc.)?**

   - Yes
   - No

   This selection will auto-populate the period name but allows free text for the Period Description as follows: weeks, days, months or hours.

5. Click **Next >>** to continue or **<< Back** to return to the previous screen.

6. Enter the number of subjects for the research study (fig 11.3).

   **# of Subjects (for Budgeting / Contract):**

   ![Fig 11.3](image)

   **<< Back** **Next >>**

7. Click **<< Back** to return to the previous screen or **Next >>** to continue.

8. Complete the following fields (fig 11.4):

   **Automatically fill in names (Periods, visits, etc.)?**

   - Yes
   - No

   If the selection is “No” the text fields are free text from previous screen.
**Fig 11.4**

**Period Name**: name of the specific research study period (e.g. Pre-Screening, Screening, Pre-Treatment, Pre-Study, Treatment, Study Drug, Follow-up, or End of Treatment).

**Period Description**: weeks, days, months, years or hours

9. Complete the following fields (fig 11.5):

   This selection will auto-populate the period name but allows free text for the Period Description as follows: weeks, days, months or hours from the previous screen.

<table>
<thead>
<tr>
<th>Period Name:</th>
<th>Study Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Period Description:</td>
<td></td>
</tr>
<tr>
<td># of Visits:</td>
<td></td>
</tr>
<tr>
<td># of Subjects (for Budgeting / Contract):</td>
<td></td>
</tr>
</tbody>
</table>

   ![Fig 11.5](image)

   **Fig 11.5**

10 Click **# of visits**: number of study visits per study protocol.

   ![Next >>](image) to continue or ![<< Back](image) to return to the previous screen.
11. Click on **Create Budget** to continue or **<< Back** to return to the previous screen.

Budget is ready to be generated. Click **Create Budget** button below to create the budget. Keep in mind that any previously entered budget information will be **DELETED**.
Lesson 12

Budget Parameters for an Oncology Template

Choose budget template type: Oncology

Click Next >>.

1. Enter the number of arms (fig 12.1).

<table>
<thead>
<tr>
<th>Budget Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of arms, if applicable:</td>
</tr>
<tr>
<td>Are there cycles?</td>
</tr>
<tr>
<td>Facilities and Admin (F &amp; A):</td>
</tr>
<tr>
<td>Dept (Faculty Group Practice):</td>
</tr>
<tr>
<td>Automatically fill in names (Periods, visits, etc.)?</td>
</tr>
</tbody>
</table>

   Fig. 12.1

2. Are there any cycles? Yes or No

3. The Facilities and Administration (F & A) field for Industry Sponsored and Industry Supported studies will automatically populate to 25%. When conducting other research studies, the Facilities and Administration (F & A) field should be changed to 0% (fig 12.2).

   | Facilities and Admin (F & A): |
   | 25 % |

   Fig 12.2

4. Select the Department (Faculty Group Practice) where the research will be conducted (fig 12.3).
5. If the selection is “No” the text fields are free text.

This selection will allow you to automatically name the period name (e.g. Pre-Screening, Screening, Pre-Treatment, Pre-Study, Treatment, Study Drug, Follow-up, or End of Treatment) and period description (e.g. name of study drug(s), weeks, days, months or hours).

6. This selection will auto-populate the period name but allows free text for the Period Description as follows: weeks, days, months or hours

7. Click Next >> to continue or << Back to return to the previous screen.

8. Click Next >> to continue or << Back to return to the previous screen.
Option 1

Oncology study includes arms and but NO cycles

Complete the following fields (fig.12.4):

<table>
<thead>
<tr>
<th>Arm</th>
<th>Budget Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm 1</td>
<td>Arm Name: [ ]</td>
</tr>
<tr>
<td>Arm 2</td>
<td>Arm Name: [ ]</td>
</tr>
</tbody>
</table>

**Fig. 12.4**

**Arm Name:** name of the specific research study period (Chemo 1, Chemo 2)

**Arm Description:** weeks, days, months, years or hours

Click << Back to continue or Next >> to return to the previous screen.
Complete the following fields on each of the arms (Screening, Treatment, Follow-up sections) (fig. 12.5):

<table>
<thead>
<tr>
<th>Chemo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Period Name:</td>
</tr>
<tr>
<td>Period Description:</td>
</tr>
<tr>
<td># of Visits:</td>
</tr>
<tr>
<td># of Subjects (for Budgeting/Contract):</td>
</tr>
<tr>
<td>Period Name:</td>
</tr>
<tr>
<td>Period Description:</td>
</tr>
<tr>
<td># of Visits:</td>
</tr>
<tr>
<td># of Subjects (for Budgeting/Contract):</td>
</tr>
<tr>
<td>Period Name:</td>
</tr>
<tr>
<td>Period Description:</td>
</tr>
<tr>
<td># of Visits:</td>
</tr>
<tr>
<td># of Subjects (for Budgeting/Contract):</td>
</tr>
</tbody>
</table>

(Fig. 12.5)

**Period Name:** name of the specific research study period (e.g. Pre-Screening, Screening, Pre-Treatment, Pre-Study, Treatment, Study Drug, Follow-up, or End of Treatment).

**Period Description:** weeks, days, months, years or hours

Click **# of visits:** number of study visits per study protocol.

Click **Next>>** to continue or **<< Back** to return to the previous screen.

7. Click on **Create Budget** to continue or **<< Back** to return to the previous screen.
Option 2

Research study includes arms and cycles.

1. Complete the following fields (fig. 12.6):

<table>
<thead>
<tr>
<th>Arm 1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm Name:</td>
<td></td>
</tr>
<tr>
<td>Arm Description:</td>
<td></td>
</tr>
<tr>
<td># of Cycles:</td>
<td>3</td>
</tr>
<tr>
<td># of Subjects (for Budgeting / Contract):</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Arm 2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm Name:</td>
<td></td>
</tr>
<tr>
<td>Arm Description:</td>
<td></td>
</tr>
<tr>
<td># of Cycles:</td>
<td>3</td>
</tr>
<tr>
<td># of Subjects (for Budgeting / Contract):</td>
<td></td>
</tr>
</tbody>
</table>

**Arm Name**: name of the specific research study period (Chemo 1, Chemo 2)

**Arm Description**: weeks, days, months, years or hours

2. Click **# of cycles**: number of study visits per study protocol.

3. Click **# of visits**: number of study visits per study protocol.
4. Complete Cycle Name and Description

<table>
<thead>
<tr>
<th>Cycle Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle Description:</td>
<td></td>
</tr>
<tr>
<td># of Visits:</td>
<td>1</td>
</tr>
<tr>
<td># of Subjects (for Budgeting / Contract):</td>
<td>1</td>
</tr>
</tbody>
</table>

**Cycle Name:** name of the specific research study period (Chemo 1, Chemo 2)

**Cycle Description:** weeks, days, months, years or hours

5. Click **Next >>** to continue or **<< Back** to return to the previous screen.

6. Click on **Create Budget** to continue or **<< Back** to return to the previous screen.

Budget is ready to be generated. Click Create Budget button below to create the budget. Keep in mind that any previously entered budget information will be **DELETED**.
Lesson 13

Budget Parameters for an Custom Template

Choose budget template type: Custom

Click Next >>.

1. Enter the number of arms (fig 13.1).

<table>
<thead>
<tr>
<th>Budget Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of arms, if applicable:</td>
</tr>
<tr>
<td>Are there cycles?</td>
</tr>
<tr>
<td>Facilities and Admin (F &amp; A):</td>
</tr>
<tr>
<td>Dept (Faculty Group Practice):</td>
</tr>
<tr>
<td>Automatically fill in names (Periods, visits, etc.)?</td>
</tr>
</tbody>
</table>

Fig. 13.1

2. Are there any cycles? No

3. The Facilities and Administration (F & A) field for Industry Sponsored and Industry Supported studies will automatically populate to 25%. When conducting other research studies, the Facilities and Administration (F & A) field should be changed to 0% (fig 13.2).

| Facilities and Admin (F & A): | 25 % |
| Dept (Faculty Group Practice): | Select One |
| Automatically fill in names (Periods, visits, etc.)? | Yes ☑ | No |

Fig. 13.2
4. Select the Department (Faculty Group Practice) where the research will be conducted (fig 13.2).

![Budget Parameters Table]

5. If the selection is “No” the text fields are free text.

   This selection will allow you to automatically name the period name (e.g. Pre-Screening, Screening, Pre-Treatment, Pre-Study, Treatment, Study Drug, Follow-up, or End of Treatment) and period description (e.g. name of study drug(s), weeks, days, months or hours).

6. This selection will auto-populate the period name but allows free text for the Period Description as follows: weeks, days, months or hours.

7. Enter
8. Click **Next >>** to continue or **<< Back** to return to the previous screen.

Complete the following fields (fig 13.3):

<table>
<thead>
<tr>
<th>Budget Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Arm 1</strong></td>
</tr>
<tr>
<td>Arm Name:</td>
</tr>
<tr>
<td>Arm Description:</td>
</tr>
<tr>
<td># of Subjects (for Budgeting / Contract):</td>
</tr>
<tr>
<td><strong>Arm 2</strong></td>
</tr>
<tr>
<td>Arm Name:</td>
</tr>
<tr>
<td>Arm Description:</td>
</tr>
<tr>
<td># of Subjects (for Budgeting / Contract):</td>
</tr>
</tbody>
</table>

**Fig. 13.3**

**Arm Name**: name of the specific research study period (Drug 1, Drug 2)

**Arm Description**: weeks, days, months, years or hours

Click **<< Back** to continue or **Next >>** to return to the previous screen.
Complete the following fields on each of the arms (Screening, Treatment, Follow-up sections) (fig. 13.4):

| Period Name: |  |  |
| Period Description: |  |  |
| # of Visits: |  |  |
| # of Subjects (for Budgeting / Contract): | 1 |

| Period Name: |  |  |
| Period Description: |  |  |
| # of Visits: |  |  |
| # of Subjects (for Budgeting / Contract): | 1 |

| Period Name: |  |  |
| Period Description: |  |  |
| # of Visits: |  |  |
| # of Subjects (for Budgeting / Contract): | 1 |

(Fig. 13.4)

**Period Name**: name of the specific research study period (e.g. Pre-Screening, Screening, Pre-Treatment, Pre-Study, Treatment, Study Drug, Follow-up, or End of Treatment).

**Period Description**: weeks, days, months, years or hours

Click **# of visits**: number of study visits per study protocol.

Click **Next >>** to continue or **<< Back** to return to the previous screen.

7. Click on **Create Budget** to continue or **<< Back** to return to the previous screen.
Budget is ready to be generated. Click Create Budget button below to create the budget. Keep in mind that any previously entered budget information will be **DELETED**.

[<< Back  Create Budget]
Chapter 14

Completion of Budget Details Screen

This section includes Budget Information, Study Initiation Expenses (Non-Refundable), Per Subject Budget, Budget Totals, Study Expenses (Invoiced per Occurrence).

Budget Information

All of the fields in this section auto-populate from the study details page except Budget Manager, Primary and Secondary Campus Facility.

1. Select Budget Manager (fig 14.1).

The budget manager is the individual (Principal Investigator, Study Coordinator, Research Nurse, Research Assistant, Budget Manager, or Business Manager) who is responsible for preparing the detailed budget.
2. Type in the last name or last name and first name of the individual responsible for the budget development (fig. 14.2).

3. Click on Select (fig. 1.43). This will auto-populate the Budget Manager Field.

4. Primary Location – the primary campus location utilized for conducting the majority of your research study.

   Select one from the drop down category.

   Primary Campus Facility: Select One

5. Secondary Location(s) – any campus locations that may be utilized to conduct any research procedures outside the primary location. (E.g.: If Radiology is utilized for a chest x-ray, the secondary location would be University Hospital. If Ophthalmology is utilized for an eye exam, the secondary location would be Jones Eye Institute.

   Secondary Campus Facility: Select One

   Select one from the drop down category.
Select **Add Secondary Location**.

Click **Save**.

### 2. Study Initiation Expenses (Non-refundable)

The Non-refundable or Upfront costs include expenses that the study site and staff incur whether or not the research study is ever initiated or enrolls a subject (fig. 14.4).

<table>
<thead>
<tr>
<th>Description</th>
<th>Notes</th>
<th>Amount</th>
<th>F &amp; A</th>
<th>Total Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Review Fee: New Submission</td>
<td></td>
<td>0</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Setup Fee - Base Fee</td>
<td></td>
<td>0</td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>Administrative Expenses</td>
<td></td>
<td>0</td>
<td>Yes</td>
<td>0</td>
</tr>
<tr>
<td>Personnel Expense</td>
<td></td>
<td>0</td>
<td>Yes</td>
<td>0</td>
</tr>
<tr>
<td><strong>Study Initiation Expenses Total:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

![Fig. 14.4](image)

1. **IRB Review Fee: New Submission** - a fee that is assessed for the IRB to review a new research study submission (fig. 14.5).

![Fig. 14.5](image)

Note: If Other (must upload supporting document) is selected upload the award letter for a grant or the front cover page of your grant proposal.

2. **Base Fee Pharmacy Setup Fee - Base Fee**

Place a check **Pharmacy Setup Fee - Base Fee** to select Pharmacy Setup Fee - Base Fee - a fee that is assessed for the review of the research study protocol, pharmacy capability to participate, research pharmacist time, storage and dispensing of study drug, and staff education.

Click **Details**
## Study Initiation, Management and Closeout

<table>
<thead>
<tr>
<th>Basic Fee</th>
<th>$1,000.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerated storage (ADD $250.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Randomization, binding, or placebo control (ADD $250.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Schedule II drugs (ADD $250.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Storage of used bottles or vials (ADD $100.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Multiple drugs (ADD $400.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>IVR System (ADD $250.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Other: Mail drug shipments to other sites (ADD $500.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Other: Site initiation visit/travel expenses (ADD $500.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Other: Supplies (ADD $500.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Other: Drug Purchases (ADD $500.00)</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

**Total:** $1,000.00

### Dispensing Fees (Per Treatment)

<table>
<thead>
<tr>
<th>Basic Dispensing Fee</th>
<th>$0.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral or topical dose (ADD $10.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Oral/oral drug requiring special preparation (administration, packaging, etc.) (ADD $10.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Parenteral IM, SC, etc. drug (ADD $200.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Parenteral IV drug requiring intravenous administration (ADD $200.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Parenteral drug with complex or time consuming administration (ADD $200.00)</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

**Total:** $0.00

### Other Charges (Annual charges for the pharmacy/budget)

<table>
<thead>
<tr>
<th>Other Charges</th>
<th>$0.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Maintenance fee (ADD $200.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Study mentor visits to pharmacy (est. 1 visit/year) (ADD $100.00)</td>
<td>$0.00</td>
</tr>
<tr>
<td>Pharmacy Document Storage (ADD $500.00)</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

**Total:** $0.00

**INSTRUCTIONS:**

Click the link to download the Outpatient Investigational Drug Storage Information Form. When completed, upload the form in the Documents section as type Outpatient Investigational Drug Storage Information Form. After the form has been uploaded, click the 'Request pharmacy waiver' button under Pharmacy Setup Details: Outpatient Investigational Drug Responsibility Form.

The basic set up fee is $1000. The basic dispensing fee is $15 per subject. Increased fees have been charged so that more complex studies will be reimbursed. Check the boxes in the first (left) column that apply to the proposed study. The total pharmacy fees will be calculated and displayed in the budget.

If any study requires a special procedure not listed above, contact Mike Parr (Telephone: 886-6220) or Jennifer Roberts (Telephone: 886-6220) for a price quote.

Upload a copy of the study protocol and the Investigator's brochure for UW-M School of Pharmacy review in UW-M Documents. If the UW-M School of Pharmacy has questions or any issues, they will be contacted for review. If the Investigator's brochure is not available, be sure to communicate this to the Pharmacy.

The UW-M School of Pharmacy will review the estimated price for accuracy. If the UW-M School of Pharmacy accepts the proposed charges, the Investigator will be notified within 2 business days and informed that the protocol has been accepted. If there is any discrepancy between the fees estimated by the Investigator and the UW-M School of Pharmacy, the Investigator will be notified by telephone, email, or in person within 2 business days after receipt of the protocol and proposed budget.

**There are some cases where there are multiple study drugs to dispense at each treatment point. For example, we want to dispense a single drug at each study visit and would want dispensing fee for each drug based on the combination dispensing as I suggest above.**

<table>
<thead>
<tr>
<th>UW-M Pharmacy Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mike Parr</td>
</tr>
<tr>
<td>Jennifer Roberts</td>
</tr>
</tbody>
</table>
Note: The Research Protocol and Investigator’s Brochure must be uploaded in Documents before you submit the pharmacy budget for approval.

Click on at the bottom of the Pharmacy Budget. The Research Pharmacist will complete the budget based on specifications of the research study and upload the approved pharmacy budget in the Non Refundable section of the budget.

Click on and for the Research Pharmacist to review and Approve or Disapprove a completed Pharmacy budget by the research study staff. Note: The Research Pharmacy would prefer if you do not develop a pharmacy budget and submit for their approval.

Click on for the Research Pharmacist to review and grant a waiver for the fee that is assessed for the review of the research study protocol, pharmacy capability to participate, research pharmacist time, storage and dispensing of study drug, and staff education for specific research studies.

Click on this link for the Principle Investigator and study staff to store and dispense the study drug (fig. 14.7).

Click on .
Complete the following form.

**Outpatient Investigational Drug Storage Information Form**
&

**Acknowledgement of Responsibility Sheet**
(Complete for each Study Drug Supplied by the Study)

Company Sponsor: _________________________________

Study Drug Location: _______________________________

Person Responsible for Study Drug: ___________________

Responsible Individual’s Phone Number: ________________

Responsible Individual’s Deeper Number: ________________

**Acknowledgement of Responsibility**

I ____________________ acknowledge that I will comply with the following requirements for investigational drug storage and the dispensing of investigational agents to outpatients.

1. All patients will have a signed informed consent before entry into the study.

2. All study drugs will be stored under lock and key.

3. My designee or I will accurately maintain dispensing records and monthly audits will be performed.

4. I will allow the Department of Pharmacy or the Office of Research Compliance to audit drug supply and dispensing records upon their request.

5. I understand that Arkansas law requires that a physician must dispense the medication to the patient.

6. I understand that the medication dispensed to the patient will be labeled with the following information.

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Date</th>
<th>Name of Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Study Number</td>
<td>Instructions for Patient</td>
<td></td>
</tr>
<tr>
<td>Name of a Study Contact</td>
<td>24 Hours Phone Number</td>
<td></td>
</tr>
</tbody>
</table>

___________________________  ______________________
Investigator Signature        Date

Fig. 14.7
Click on **Yes** to save your changes to a selected file (fig. 14.8).

Next convert the save document to a PDF and upload into the Documents section of CRIMSON.

Click on **Request pharmacy waiver** to submit to the Research Pharmacist. The waive status of the study will be uploaded in the Non Refundable section of the budget.

3. **Place a check to select Administrative Expenses.**

   ![Administrative Expenses](https://crms.uoms.edu/templates/Outpatient%20Investigational%20Drug%20Responsibility%20Form.doc)

   **Fig. 14.8**

Administrative Expenses - Document preparation for the sponsor (e.g. FDA 1572 form), study personnel CV’s, Financial Disclosure forms, W-9 form, ARIA submission forms, budget development and negotiation) or any other forms required by the sponsor. This field could be utilized for study supplies (e.g. copier, copier paper, fax, telephone lines and computers).

   ![Administrative Expenses Table](https://crms.uoms.edu/templates/Outpatient%20Investigational%20Drug%20Responsibility%20Form.doc)

   **Table:** Administrative Expenses

<table>
<thead>
<tr>
<th>Expense</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   Click **Details**.

   Complete the following expense rows with an amount.

   Click **Add Row** for each additional administrative expense to be added.

   Click **Save**.
4. Place a check to select Personnel Expenses. Personnel Expense - Investigator/Coordinator time to review protocol and assess ability to participate in the research study, subject recruitment plans, staff orientation, Pre-study and site initiation visit. This could include the time and effort for the Principle Investigator, Study Coordinator, Research Nurse or Research Assistant.

Click [Details].

Complete the following expense rows with an amount.

Click [Add Row] for each additional administrative expense to be added.

Click [Save].
Per Subject Section of the Budget

- **Add Misc.** – this selection allows you to add procedures, test, or activities performed strictly for the research protocol and is not considered conventional care or requires a CPT code.

- **Add by Procedure** – this selection allows you to add a procedure that requires a CPT code for any charges assessed by other departments.

- **Add by Visit** – this selection will allow you to add a procedure to a specific visit.

- **Add Outside Procedure** – this selection will allow you to add any outside procedures (example: Convance Labs). List all of the labs that are being sent to an outside lab. Note: This section has copy and paste functions.

---

**Generate Budget Documents** – budget documents are generated in the documents section for printing options

---

- **Study Details**

- **Budget**

- **Approval**

---

- the amount of money the study sponsor is offering to pay for a service, laboratory assessment, or other procedure required by the study.

---

- the amount of money that UAMS charges to the research account for a service, laboratory assessment, or procedure required by the research study (NOTE: DO NOT SEND A COPY WITH THE COST SECTION TO THE STUDY SPONSOR).
of money the study sponsor will be billed for a service, laboratory assessment, or procedure required by the research study. The price should be the same or more than the cost of the service. If your cost for a service, laboratory assessment, or procedure is less than the sponsor is offering to pay, you should strongly consider re-negotiation with the study sponsor.

Of money that you have left after paying the cost for a service, laboratory assessment or procedure (i.e. the difference between the price and the cost).

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Sponsor</th>
<th>Cost</th>
<th>Price</th>
<th>Residual</th>
</tr>
</thead>
<tbody>
<tr>
<td>LABORATORY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete echoecho echo</td>
<td>$40.00</td>
<td>$90.00</td>
<td>$34.00</td>
<td></td>
</tr>
<tr>
<td>Ultrasound, ultrasound</td>
<td>$15.00</td>
<td>$10.00</td>
<td>$24.00</td>
<td></td>
</tr>
<tr>
<td>Cavage</td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
<td></td>
</tr>
<tr>
<td>RADIOLGY/DIAGNOSTIC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X-ray exam of spine (H $54.50)</td>
<td>$150.00</td>
<td>$77.50</td>
<td>$150.00</td>
<td>$72.50</td>
</tr>
<tr>
<td>DRUGS/DRUGS CODE</td>
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<td></td>
<td></td>
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<tr>
<td>50-09 190 mg</td>
<td>$27.00</td>
<td>$50.00</td>
<td>$27.00</td>
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<tr>
<td>CHEMOTHERAPY</td>
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<td></td>
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<tr>
<td>Chemol, KInfusion, Tetrac</td>
<td>$30.00</td>
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<td>$30.00</td>
<td>$0.00</td>
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<tr>
<td>MISC</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Other</td>
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<td>$0.00</td>
<td>$50.00</td>
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</table>

Study Period

<table>
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<tr>
<th>Week</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td></td>
<td></td>
<td>R</td>
<td></td>
<td>R</td>
<td>$120.00</td>
</tr>
<tr>
<td>C</td>
<td></td>
<td></td>
<td></td>
<td>I</td>
<td>R</td>
<td>$45.00</td>
</tr>
<tr>
<td>I</td>
<td></td>
<td></td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>$750.00</td>
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<tr>
<td>R</td>
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<td></td>
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<td>R</td>
<td>R</td>
<td>$1,129.74</td>
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<tr>
<td>R</td>
<td></td>
<td></td>
<td>R</td>
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<td>R</td>
<td>$519.59</td>
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<tr>
<td>R</td>
<td></td>
<td></td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>$259.00</td>
</tr>
</tbody>
</table>

Per Subject Direct Total: $3,211.24
Facilities and Admin (1%) (5%): $802.81
Per Subject Total: $4,014.05
# of Subjects: 10
Final Total: $40,140.59

Research Support Center
May 27, 2008
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### Budget Total

This section includes the study initiation expenses total (non-refundable costs), the procedure total (per subject costs) and the total for the entire budget excluding invoiceables and conventional care costs.

<table>
<thead>
<tr>
<th>Budget Total:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Initiation Expenses Total:</td>
<td>0</td>
</tr>
<tr>
<td>Procedure Total:</td>
<td>0</td>
</tr>
<tr>
<td>Budget Total:</td>
<td>0</td>
</tr>
</tbody>
</table>

Study Initiation Expenses Total: total budget amount for the Study Initiation Expense section of the budget

Procedure Total: total budget amount for the Procedure or per subject section of the budget

Budget Total: total amount for the entire budget including the Study Initiation Expenses and Procedure Total. (This does not include the Study Expenses Invoiced per Occurrence.)
Study Expenses – Invoiced per Occurrence

IRB Review Fees- Continuing Review – Select the appropriate research category for the correct IRB fee

Protocol Amendments (Staff Time)
Monitoring Visits (Staff Time)
Screen Failures- per contract
Incomplete Subjects- pr contract
Research Document Storage-Pharmaceutical companies usually require a Principle Investigator to hold all of the study files for a period of 15 to 20 years.
Study Close-Out Fees- a fee that is access for the time it takes the study staff to close out a study with the pharmaceutical company and the IRB.
Regulatory Processing (Staff Time)
Safety Reports –Simple (Staff Time)
Safety Reports- Complex (Staff Time)
Annual Charges for the pharmacy budget-
Pharmacy Study Monitor Visits – per research pharmacy
Pharmacy Study Storage - per research pharmacy
Other- free text invoiceable
Lesson 15

Save Budget Matrix as a Template

1. A budget matrix that has been created may be saved as a budget template for future studies. (Note: Based on the fee schedule for different types of study types an Industry Sponsored template must be used for an Industry Sponsored study and an Investigator Initiated template must be used for an Investigator Initiated study).

   Click **Save Budget Matrix as a Template**.

   Create an identifying name for the budget Matrix

   Click **Save**.

2. Instead of creating a new budget matrix a copy can be made from a Budget Template.

   Click **Copy from a Budget Template**.

   Select the saved budget matrix from the Budget Template List.

   Click **Create**

3. A budget template may be deleted.

   Click **Delete a Budget Template**.

   Select the budget template from the list.

   Click **Delete**.
Lesson 16

Generating Budget Documents

Note: It is not necessary to Generate a Budget Document each time the budget matrix is amended. Only Generate a Budget Document to upload in the Documents section of CRIMSON for reference or the print a copy.

Select to copy the budget in the Documents section.

Select which is located at the bottom of the per subject budget matrix.
LESSON 17

Upload Documents

Click on the Documents tab at the top of the screen.

This will re-direct you to the screen to upload your protocol.

1. Browse for your file that contains your documents.
2. Type: Select protocol, consent, etc. from the list.
3. Title: You may rename the uploaded document for your recognition.
4. You can upload Word or Excel documents.

   *Note: Documents must be in PDF format for submission to the reviewing Committees.

5. Select.

   Upload
LESSON 18

Upload a Revision to a Document

1. Browse for your file that contains your documents.
2. Type: Select protocol, consent, etc. from the list.
3. Select the revision tab located in the study documents section of the original document.

4. Select tab in the Upload Document Form section

5. The Revision of the document will be uploaded in the Study Documents section.
Lesson 19

Approval Process for Studies Without a Budget

The PI will login to ARIA and perform the following steps:

1. Click on the CRIMSON button on the Navigation bar.

2. Click on the IRB# of the appropriate research study from the Principle Investigator’s research queue

3. Select the Approval tab at the top of the page.

4. Scroll to the bottom of the page and submit to (Project Team Leader) PTL at the Research Support Center.

5. The PI and the Primary Contact will receive an email upon approval of your study in CRIMSON.

6. Once you receive the approval email this will allow you to complete and submit your IRB submission for review and approval via the IRB module.

The approval screen will allow you to track the approval process for your study. You may click on the Approval Log on the toolbar to view any comments made about your study during the approval process.
Lesson 20

Approval Process for Studies With a Budget

The PI will login to ARIA and perform the following steps:

1. Click on the CRIMSON button on the Navigation bar.

2. Click on the IRB# of the appropriate research study from the Principle Investigator’s research queue.

3. Select the Approval tab at the top of the page.

4. Scroll to the bottom of the page and submit to Budget Review (fig 20.1).

Fig. 20.1
Lesson 21
Complete CRIMSON and Update to IRB for Review

Note: the PI will only be required to sign off once during the approval process. This sign off will occur after all other required approvals have been granted.

The PI will login to ARIA and perform the following steps:

1. Click on the CRIMSON button on the Navigation bar.

2. Click on the IRB# of the appropriate research study from the Principle Investigator’s research queue

3. Select the Approval tab at the top of the page.

4. Scroll to the bottom of the page and select Complete CRIMSON (fig 21.1).

<table>
<thead>
<tr>
<th>Reviews</th>
<th>Approvals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P.I</strong></td>
<td><strong>Status</strong></td>
</tr>
<tr>
<td>UMIR Clinical Services</td>
<td>Approved May 29 2008 1:46AM</td>
</tr>
<tr>
<td>Budget Review Details</td>
<td>Approved May 29 2008 1:08PM</td>
</tr>
<tr>
<td>Compliance Details</td>
<td>In Review May 29 2008 1:46AM</td>
</tr>
<tr>
<td>INDIEE Details</td>
<td>Approved May 29 2008 1:46AM</td>
</tr>
<tr>
<td>GMP/QP Details</td>
<td>Approved May 29 2008 1:46AM</td>
</tr>
<tr>
<td>Monitoring Plan</td>
<td>NA</td>
</tr>
<tr>
<td>Pharmacy (UMIR) Details</td>
<td>Approved May 29 2008 1:46AM</td>
</tr>
<tr>
<td>CMS</td>
<td>NA</td>
</tr>
<tr>
<td>IRMC</td>
<td>NA</td>
</tr>
<tr>
<td>CRIO/CTSA Review</td>
<td>NA</td>
</tr>
<tr>
<td>VASafety</td>
<td>NA</td>
</tr>
<tr>
<td>Bio-Safety</td>
<td>NA</td>
</tr>
<tr>
<td>Radiation Safety</td>
<td>NA</td>
</tr>
<tr>
<td>Conflict of Interest (COI)</td>
<td>NA</td>
</tr>
<tr>
<td>Contracts</td>
<td>NA</td>
</tr>
</tbody>
</table>

Fig. 21.1
Please wait until you are routed to the ARIA IRB site and the IRB submission form appears on your screen (fig. 20.2).

1. PI is notified that Approvals Complete
2. PI log into ARIA CRIMSON, navigate to Approvals screen, click Complete CRIMSON button
3. Message displays on screen to not log out until IRB Protocol New Submission displays.
4. Control is transferred to ARIA, IRB Protocol New Submission screen with data transferred.

*If timed out:*
1. Status on CRIMSON reflects CRIMSON Complete. Status on ARIA Protocols reflects Pending CCR.
2. Navigate to the Research queue in CRIMSON. Message displays: “The following studies did not transfer successfully to ARIA Protocols: and a list of the IRB # that failed.”
3. Click the IRB number to navigate to the Approval screen for the study that failed.
4. Note that the status of the study has reverted to “Approvals Complete” and the Status of the Approvals is “Submission failed (Please resubmit)”

5. The “Complete CRIMSON” button is Active
6. Click “Complete CRIMSON” and wait till the ARIA IRB Protocol New Submission form displays.
7. If process still does not complete, notify RSC for assistance.

NOTE: The change in status will not be seen until you leave the study and return. Jiang is working on a batch job that will run at regular intervals during the day to notify the PI / PTL via email when a study failed to upload to ARIA Protocols.
Lesson 22

Clinical Research List

This area displays a summary of each of your clinical research studies in ARIA.

Information includes a Number ▼ (Clinical Research Number or CRN), Protocol or Brief Title, Study Category, Principal Investigator, Disease Site and Status of your protocol(s).

IRB Number - a unique number automatically generated by ARIA to identify your clinical research study protocol(s).

Number ▼ display all of the clinical research studies in a descending order.

Number ▲ display all of the clinical research studies in an ascending order.
**Title (Protocol)** - the title of the study as listed on the protocol. This title may be provided by the pharmaceutical company for industry sponsored studies or by the investigator for investigator initiated studies or by the cooperative group for cooperative studies.

**Study Category** -

- **Industry Sponsored** - a clinical trial that is funded and monitored by a drug, biological or device manufacturing company. [www.fda.gov](http://www.fda.gov)

- **Cooperative Coop** - a clinical trial conducted by a collective group of researchers, institutions and physicians throughout the United States and/or other countries to investigate new methods for treatment of a disease. Industry, NIH or other entities may be the sponsor of this study. [www.fda.gov](http://www.fda.gov)

- **Investigator Initiated** - a clinical trial developed by an independent individual or group of individuals. These trials are not funded or reviewed by an outside agency. The Investigator may obtain an investigational drug and/or some funding support from an outside agency or industry. The investigator assumes responsibilities normally inherit with sponsorship. [www.fda.gov](http://www.fda.gov)

- **Student Research** -

**Study Category ▲** - Display all of the study categories in ascending order (A-Z).

**Principal Investigator** - the person who is ultimately responsible for the conduct of the Clinical Research Study.

**Principal Investigator ▲** - Displays Principal Investigators in ascending order (A-Z).

**Disease Site** - primary site of a disease or condition. Example: Heart and Blood Vessel Diseases or Eye Diseases

**Status** - Status of your protocol

- **Saved** – the clinical research study information has been saved.
● In Route – if the study is transferred or forwarded to another Principle Investigator, department members or department. The clinical research study will be in route until it is reviewed.

● Review – If the clinical research study is in review you are interested in doing this study and would like to review the study protocol.

● Accepted – after reviewing the study protocol you decide to accept the clinical research study.

● Rejected - after reviewing the study protocol you decide to reject the clinical research study.

Status ▲ Display your clinical research study status in ascending order (A-Z).

Lesson 23
Locating a Specific Protocol

1. Click on the IRB # listed in the Number ▼ column. Example: IRB123.

2. Jump to IRB #.

   Jump to CRN #:  [Input Box]  Go  To use the Jump to IRB # command, type in the IRB # and click on Go to display a specific research study protocol.

3. Click on the Study details tab. Note: The active tab will be bold. (Fig. 23.1)
4. Click on the corresponding tabs Study Information, Funding Sources, Documents, Log to review the completed screens. (Note: The active option will be highlighted).

5. Click on the Budget tab to locate a specific budget. The active tab will be **bold**. (Fig. 23.2)

6. Click on the corresponding tabs to review Budget Information, upload or review documents or review log entries. (Note: The active option will be highlighted).
Chapter 24

Search Functions

The search command is located at the upper left corner of the clinical research list. (Fig. 24.1)

Fig. 24.1

1. Click [Search] to open the Search Form. (Fig. 24.2)
2. Enter information in one search box or multiple search boxes and click on [SEARCH] at the top or bottom of the search form.

3. **Keyword Search**
   1. Type in a word as a specific locator.
   2. Click on [SEARCH] at the top or bottom of the search form.

4. **Study Title** Search Parameters
   1. Type in the study title
   2. Click on [SEARCH] at the top or bottom of the search form.

5. **IRB #** Search Parameters.
   1. Type in the IRB Submission number.

6. **Sponsor Assigned Protocol ID** Search Parameters.
   1. Type in the Sponsor Assigned Protocol ID
   2. Click on [SEARCH] at the top or bottom of the search form.

7. **UARK #** Search Parameters
   1. Type in the UARK #.
   2. Click on [SEARCH] at the top or bottom of the search form.

8. **Cooperative Group ID** Search Parameters
   1. Type in the Cooperative Group ID
   2. Click on [SEARCH] at the top or bottom of the search form.

9. **Study Category** Search Parameters
   1. Select one of the categories in the list
   2. Click on [SEARCH] at the top or bottom of the search form.

10. **Study Status** Search Parameters
    1. Select one of the categories in the list
    2. Click on [SEARCH] at the top or bottom of the search form.

11. **Disease Site** Search Parameters
    1. Select the primary disease or condition from the list.
    2. Select the **Disease Subsite** from the list.
    3. Click on [SEARCH] at the top or bottom of the search form.
12. **Principal Investigator or Study Contact** search parameters

   Step 1 - Select the pick from list command.

   Step 2 - Type in the Last Name of the person to select from a list (fig. 24.3).

   ![Clinical Trials System - UAMS - Microsoft Internet Explorer](image)

   **Fig. 24.3**

   Step 3 - Click on Select.

   Step 4 – Click on Close.

   5. If selection is not correct highlight the Department in the Search box and select **Remove Selection**.

   6. Then repeat Steps 1, 2, 3, 4

   7. Click on **SEARCH** at the top or bottom of the search form.
13. **Department** Search Parameters

Step 1- Select Division from drop down box
Step 2- Select Department from drop down box
Step 3- **Add Selected**

4. If selection is not correct highlight the Department in the Search box and select **Remove Selection**.

5. Then repeat steps 1, 2, 3

6. 4- Click on **SEARCH** at the top or bottom of this form.

14. **Date** Search Parameters.

1. Click on calendar icon.  

2. Select a date from the drop down box.

3. Select a year.

4. Click on a day (highlighted in red) to populate the Date (mm/dd/yyyy) (Fig. 24.4)

**Fig. 24.4**

**Date(mm/dd/yyyy):**

From:  
To:  

**SEARCH**
5. Click on [SEARCH] at the top or bottom of this form.

15. **Overdue period** Search Parameters.
   1. Select how many days a research study is overdue.
   2. Click on [SEARCH] at the top or bottom of this form.

16. **Sort Order** Search Parameters.
   1. Select the order you would like to sort your search parameters. You can sort each category either in an ascending or descending order.

**Reset**

1. Click on [Reset] to clear the search form.

**Search Parameters Information Screen**

This screen provides the search parameters entered on the search form and provides the clinical research study or a list of clinical research studies that contain the information in your search profile. (Fig. 24.5).

1. Click **Save** to retain any of the search parameters.
2. Click **Modify** to change any of the search parameters on the Search Form
3. Click **Clear** to return to the Home page of ARIA

![Fig. 24.5](image_url)
Chapter 25

Customize View of Clinical Research List Screen

1. The appearance of the Clinical Research List can be customize to your preferences. (Fig 25.1).

2. Click **SEARCH**.

3. Click on **Customize View** at the bottom of the search form.

4. Select the preferences for the Clinical Research List.

5. Select **RESET**.

5. Click on **SEARCH**.

6. Click on **Cancel** to return to the Search Form.

![Customize view](image)
Chapter 26

Screen Preferences for Budget Matrix

1. Select Use Scrolling: for the budget matrix to scroll up and down.

2. Scrolling Settings: Use scrolling if there are more than 2 visits and show 50 visits on screen.

3. Use scrolling features if more than a certain number of visits.

4. Show a set number of visits on the budget matrix screen.

5. Show 100 rows on each arm screen. How many rows will show on each arm?

6. Use Colors on the budget matrix.

7. Click Update.
Chapter 27

Edit and View Mode Functions

1. If View is highlighted changes may be made to all of the screens in CRIMSON.

2. If Edit is highlighted change may not be made to any of the screens in CRIMSON.

The PI, Primary Contact and Budget Manager will all have edit rights and will all receive emails when approvals are granted or more information is requested. Any one of the three can make changes and re-submit.
Chapter 28

Approval Status in CRIMSON

Click the Approval tab.

The approval information screen indicates the reviewing committee, review status, date completed and status (In Review, Temporarily Approved, Disapprove, Submitted for Approval).
System Log –

A detailed record of research study throughout the entire CRIMSON process.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action By</th>
<th>Entered By</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jun 4 2008 2:33PM</td>
<td>Notified</td>
<td></td>
<td>Comments: Based on the action of the Coverage Review Manager the following users were notified: Barbara K. Adams</td>
</tr>
<tr>
<td>Jun 4 2008 2:26PM</td>
<td>Notified</td>
<td></td>
<td>Comments: Based on the action of the Budget Review Manager the following users were notified: Cynthia Sprinkles</td>
</tr>
<tr>
<td>Jun 4 2008 10:36AM</td>
<td>Notified</td>
<td></td>
<td>Comments: Based on the action of the PTL the following users were notified: Thomas O. Wells, Julie K. Washburn, Cynthia Sprinkles, Jiang Bi, Sharon D. Waller, Callie H. Douglas, Jane Hiltz, Hervetina Kouikisoglou, Saraha Padma, Mona. Horton Blevins</td>
</tr>
</tbody>
</table>

Approval Log –

A detailed record of the reviews for selected research protocols including the review body, decision, date, and action performed by and notes.

<table>
<thead>
<tr>
<th>Reviewer Name BODY</th>
<th>DECISION</th>
<th>DATE</th>
<th>ACTION PERFORMED BY</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage Review</td>
<td>Reviewer assigned</td>
<td>Jun 4 2008 2:33PM</td>
<td>Reviewer Name</td>
<td>Manager assigned to review this study.</td>
</tr>
<tr>
<td>Budget Review</td>
<td>Reviewer assigned</td>
<td>Jun 4 2008 2:26PM</td>
<td>Reviewer Name</td>
<td>Manager assigned to review this study.</td>
</tr>
<tr>
<td>Coverage Review</td>
<td>In Review</td>
<td>Jun 4 2008 10:36AM</td>
<td>Reviewer Name</td>
<td>PTL submitted</td>
</tr>
<tr>
<td>Budget Review</td>
<td>In Review</td>
<td>Jun 4 2008 10:36AM</td>
<td>Reviewer Name</td>
<td>PTL submitted</td>
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<tr>
<td>PTL</td>
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<td>Jun 4 2008 10:36AM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTL</td>
<td>In Review</td>
<td>Jun 4 2008 10:19AM</td>
<td>Reviewer Name</td>
<td>Performing body PI:</td>
</tr>
<tr>
<td>PI</td>
<td>Submitted for Approval(s)</td>
<td>Jun 4 2008 10:19AM</td>
<td>PI</td>
<td></td>
</tr>
<tr>
<td>Pharmacy (UAMS)</td>
<td>Approved</td>
<td>May 28 2008 11:07AM</td>
<td>Pharmacist</td>
<td>PI has completed an outpatient Drug Responsibility form and will be responsible for drug accountability for this study. Pharmacy approves study. Pharmacy charges have been waived.</td>
</tr>
</tbody>
</table>