



Institutional Review Board (IRB) Application Manual

June 2007

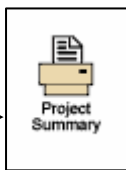
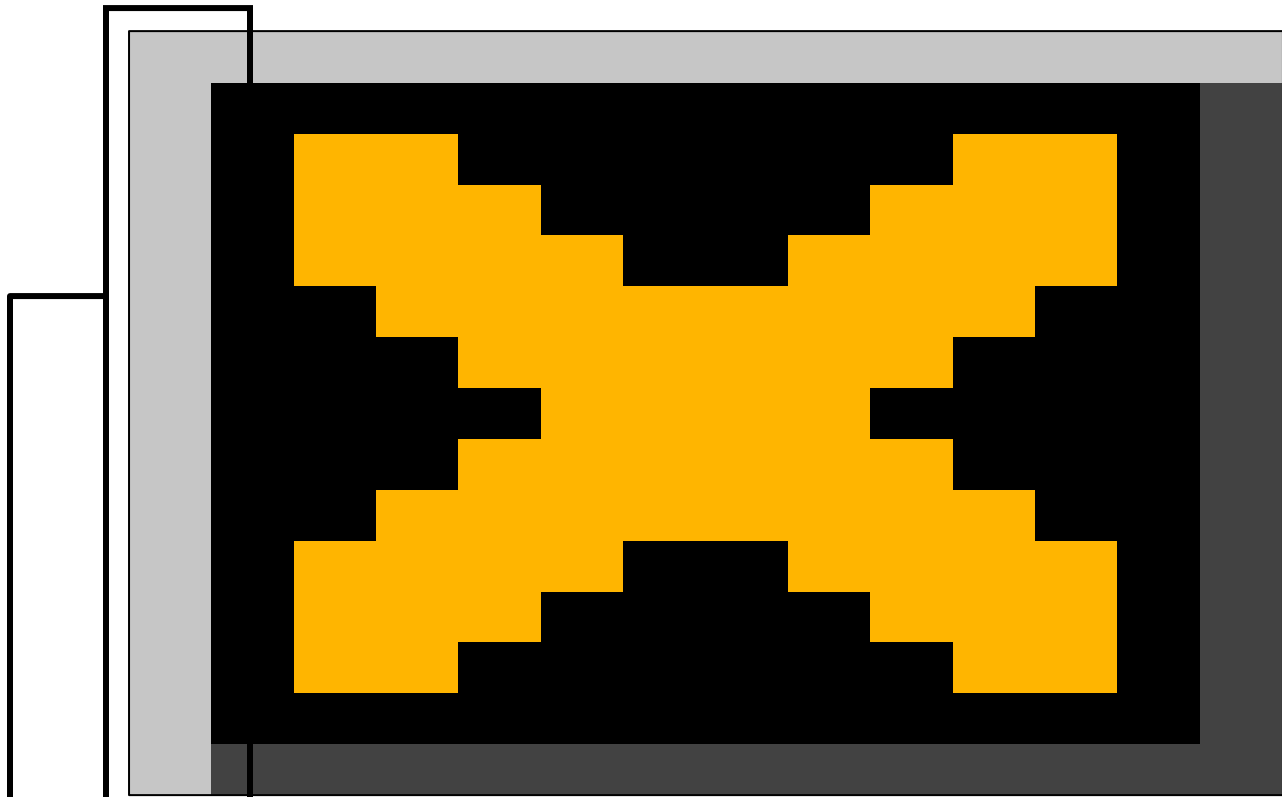
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IRB Application Instructions

Once logged into the Research Channel and the Routing Form has been completed with choosing “Clinical Trials” or “Human Subjects Involved (IRB)”, the IRB application will appear as a new folder under Proposal Activity. Choose the IRB folder to begin entering information into the application.

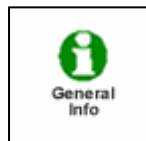
NOTE: Once the IRB Application is submitted to the IRB Committee changes are not allowed. Carefully review your application to prevent submission of inaccurate information.



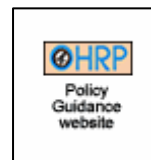
The project summary can be reviewed and printed from this icon.



The IRB Meeting Schedule can be reviewed and printed from this icon.



General Submission information.



This Icon links directly to the OHRP website for Policy Guidance information.



This Icon links directly to a blank IRB Worksheet

Tab 1: General

Institutional Review Board

LU number **104304** Status **NEW**

Title **Humoral Mechanisms of MGUS Neuropathy in Veterans**

Principal Investigator **Stubbs, Evan**

Benefits/Risks	Recruitment ✓	Consent ✓	Importance ✓	Competing ✓	Review/Submit
Participants	Study Design	Treatments	Financial	Alternatives ✓	
General ✓	Co-Investigators ✓	Diseases/Objectives ✓	Procedures ✓	Drugs ✓	Devices ✓

Full Title: Humoral Mechanisms of MGUS Neuropathy in Veterans

Department **Neurology**

Division

Contact

Contact Ext.

Email

Protocol Source

Company Sponsor: Loyola University Medical

Cooperative Group Group: -- Select --- Other:

In-House

Contents			
Grant Application	<input type="radio"/> Y <input type="radio"/> N	Questionnaires, Inventories	<input type="radio"/> Y <input type="radio"/> N
Retrospective	<input type="radio"/> Y <input type="radio"/> N	Discarded Material	<input type="radio"/> Y <input type="radio"/> N
Epidemiological Surveys	<input type="radio"/> Y <input type="radio"/> N	Repository Material	<input type="radio"/> Y <input type="radio"/> N
Investigational Drug(s)	<input type="radio"/> Y <input type="radio"/> N	Commercial Drug(s)	<input type="radio"/> Y <input type="radio"/> N
Investigational Device(s)	<input type="radio"/> Y <input type="radio"/> N	Commercial Device(s)	<input type="radio"/> Y <input type="radio"/> N

Save Changes

This information is directly linked to the Routing Form.

Protocol Source:

Sponsor: Name can be typed directly into the text box.

Protocol Source

Company Sponsor: Biogen

Cooperative Group Group: -- Select --- Other:

In-House

Cooperative Group: Select an option from the drop down box or type

Protocol Source

Company Sponsor: Biogen

Cooperative Group Group: -- Select --- Other:

In-House

- GOG
- POG
- RTOG
- SWOG
- COG

Protocol Source

Company Sponsor:

Cooperative Group Group: -- Select --- Other:

In-House

In-House: Click the radio button to select.

Contents: Click Y (Yes) or N (No) for the following questions.

Contents			
Grant Application	<input type="radio"/> Y <input type="radio"/> N	Questionnaires, Inventories	<input type="radio"/> Y <input type="radio"/> N
Retrospective	<input type="radio"/> Y <input type="radio"/> N	Discarded Material	<input type="radio"/> Y <input type="radio"/> N
Epidemiological Surveys	<input type="radio"/> Y <input type="radio"/> N	Repository Material	<input type="radio"/> Y <input type="radio"/> N
Investigational Drug(s)	<input type="radio"/> Y <input type="radio"/> N	Commercial Drug(s)	<input type="radio"/> Y <input type="radio"/> N
Investigational Device(s)	<input type="radio"/> Y <input type="radio"/> N	Commercial Device(s)	<input type="radio"/> Y <input type="radio"/> N

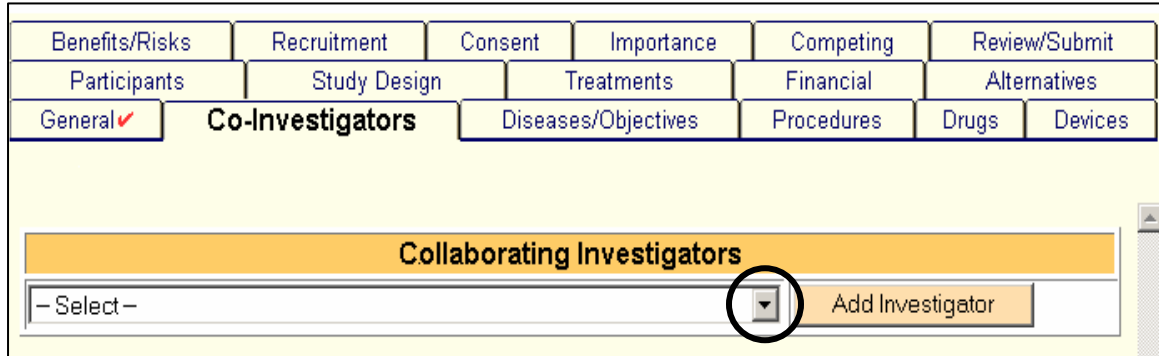
1. Grant Application: Is this a grant application?
2. Retrospective: Is this retrospective?
3. Epidemiological Surveys: Are there any epidemiological surveys involved in this study?
4. Investigational Drug(s): Are investigational drugs being used in this study?
5. Investigational Device(s): Are investigational devices being used in this study?
6. Questionnaires, Inventories: Are there any questions for the patient to answer? (ex. Quality of life questionnaires)
7. Discarded Material: Is there any tissue or bodily fluid in excess of what is needed for diagnosis going to be used?
8. Repository Material: Will tissue or body fluids be stored for future research (Note: a tissue banking protocol and/or operations manual must be provided).
9. Commercial Drug(s): Are there any commercial drugs being used for this study?
10. Commercial Device(s): Are there any commercial devices being used for this study?

When this page is completely filled out hit the **Save Changes** icon to save all inputted information.

Save Changes

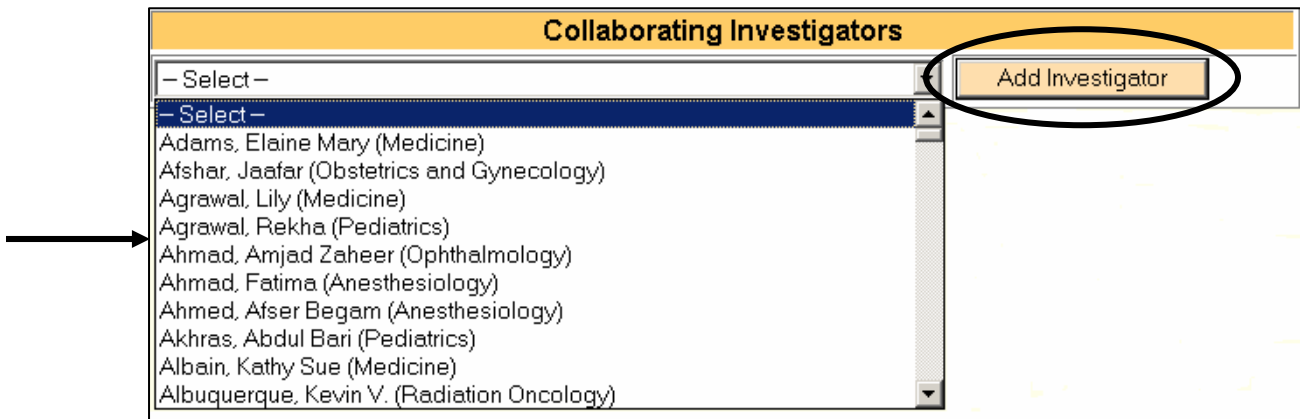
Tab 2: Co-Investigators

1. Co-Investigators can only be Loyola Principle Investigators. If there is a Co-Investigator from another institution, he/she should not be included on this IRB form.



The screenshot shows the IRB form interface with the 'Co-Investigators' tab selected. The 'Collaborating Investigators' dropdown menu is highlighted with a circle, and the 'Add Investigator' button is visible.

2. Add Co-Investigator: Choose the arrow to view the list.
3. Select your investigator's name and click **Add Investigator**.



The screenshot shows the 'Collaborating Investigators' dropdown menu expanded, displaying a list of investigators. The 'Add Investigator' button is circled, and an arrow points to the list of investigators.

Collaborating Investigators
- Select -
- Select -
Adams, Elaine Mary (Medicine)
Afshar, Jaafar (Obstetrics and Gynecology)
Agrawal, Lily (Medicine)
Agrawal, Rekha (Pediatrics)
Ahmad, Amjad Zaheer (Ophthalmology)
Ahmad, Fatima (Anesthesiology)
Ahmed, Afser Begam (Anesthesiology)
Akhras, Abdul Bari (Pediatrics)
Albain, Kathy Sue (Medicine)
Albuquerque, Kevin V. (Radiation Oncology)

Tab 3: Diseases/Objectives

Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit	
Participants	Study Design	Treatments	Financial	Alternatives		
General ✓	Co-Investigators	Diseases/Objectives		Procedures	Drugs	Devices

Disease Studied

none specified

Objective


undefined

1. Add as many diseases necessary but try to keep the terms general (ex. Colon Cancer) and click **Add Disease**.

Disease Studied


none specified

Colon Cancer


2. To delete a disease, click .


Disease Studied


Colon Cancer

 (Delete)

3. Objective: Enter the objective portion of the protocol into this section. Enter the same objectives from the protocol. You may add many objectives. To add an objective simply type the information into the text box and click **Add Objective**.

Objective	
Prevention of Colon Cancer	Save Changes 
	Add Objective

- a. To change an existing objective, edit in the text box and click **Save Changes**.
- b. To delete an objective, click .

Objective	
Prevention of Colon Cancer	Save Changes 
	Add Objective

Tab 4: Procedures

1. Add as many procedures that are needed.
2. Choose a procedure from the drop down list and click Add Procedure.

Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit
Participants	Study Design	Treatments	Financial	Alternatives	
General ✓	Co-Investigators	Diseases/Objectives ✓	Procedures	Drugs	Devices

Procedure(s) used

- Select -	Add Procedure
- Select -	
Abdominal surgery	
ADMT	
Acupuncture	
Adenoidectomy	
AICD	
AICD implant	
AICD implantation	
AICD insertion	
Anesthesia	
Anesthetic	

3. To delete a procedure, click ✕.

Procedure used


Abdominal surgery	✕ (Delete)
- Select -	Add Procedure

Tab 5: Drugs

Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit
Participants	Study Design	Treatments	Financial	Alternatives	
General ✓	Co-Investigators	Diseases/Objectives ✓	Procedures ✓	Drugs	Devices

Commercial Drugs		
Name	New Use?	
<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="button" value="Add Commercial Drug"/>

Investigational Drugs		
Name	Use	
<input type="text"/>	<input type="text"/>	<input type="button" value="Add Investigational Drug"/>

1. **Commercial Drugs:** Enter the name and if it a new use. (Note: A new use would be considered an unlabeled use for the drug.)
2. **Investigational Drugs:** Enter the name and use for the drug.
3. To Save the Information entered click (Add Commercial Drug and Add Investigational Drug)
4. To Delete a Commercial or Investigational Drug: click .

Commercial Drugs		
Name	New Use?	
atenolol	No	<input type="button" value="X (Delete)"/>
<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="button" value="Add Commercial Drug"/>

Investigational Drugs		
Name	Use	
investigational drug	investigational use	<input type="button" value="Update X"/>
<input type="text"/>	<input type="text"/>	<input type="button" value="Add Investigational Drug"/>

5. To Change the contents of the Investigation Drugs: Change the text and then click UPDATE.

Investigational Drugs		
Name	Use	
Invest. Drug	Investigational Drug	<input type="button" value="Update X"/>
<input type="text"/>	<input type="text"/>	<input type="button" value="Add Investigational Drug"/>

Tab 6: Devices

1. Enter in the name of the device, choose type and enter the purpose.
Check if there has been a 510K filed and then click **Add Device**.

Institutional Review Board

LU number **104304** Status **NEW**

Title **Title should include**
Principal Investigator **Micetich, Kenneth**

Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit
Participants	Study Design	Treatments	Financial	Alternatives	
General ✓	Co-Investigators	Diseases/Objectives ✓	Procedures ✓	Drugs ✓	Devices

Device(s)				
Name	Type	Purpose	510K filed	
<input type="text"/>	<input type="radio"/> Commercial <input type="radio"/> Investigational	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	Add Device

2. To delete a device, click **X**.

Device				
Name	Type	Purpose	510K filed	
Heart Pump	Commercial		Yes	X (Delete)
<input type="text"/>	<input type="radio"/> Commercial <input type="radio"/> Investigational	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	Add Device

Tab 7: Participants

Institutional Review Board

LU number **104308** Status **NEW**
 Title **Title should include any unique identifiers, version dates, protocol dates, ammentdments, IDB, SAE/version date of conse ...**
 Principal Investigator **Wolozin, Benjamin**

General <input checked="" type="checkbox"/>	Co-Investigators	Diseases/Objectives	Procedures	Drugs	Devices
Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit
Participants	Study Design	Treatments	Financial	Alternatives	

<div style="background-color: #ffcc00; padding: 2px; text-align: center;">Criteria</div> <p># of Participants <input style="width: 100px;" type="text"/></p> <table style="width: 100%; border: 1px solid #ccc;"> <tr> <td style="width: 30%;">Normal Volunteer</td> <td style="width: 20%;"> <input type="radio"/> No <input type="radio"/> Yes </td> <td style="width: 50%;">Source <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Sex</td> <td> <input type="radio"/> Both <input type="radio"/> Female <input type="radio"/> Male </td> <td> Age <input type="checkbox"/> <18 <input type="checkbox"/> 18+ Min: <input style="width: 30px;" type="text"/> Max: <input style="width: 30px;" type="text"/> </td> </tr> </table> <p>Expected Duration of Patient(s) in Project</p> <table style="width: 100%;"> <tr> <td># Days <input style="width: 40px;" type="text"/></td> <td>or</td> <td># Weeks <input style="width: 40px;" type="text"/></td> <td>or</td> <td>Lifetime <input type="checkbox"/></td> </tr> </table>	Normal Volunteer	<input type="radio"/> No <input type="radio"/> Yes	Source <input style="width: 100%;" type="text"/>	Sex	<input type="radio"/> Both <input type="radio"/> Female <input type="radio"/> Male	Age <input type="checkbox"/> <18 <input type="checkbox"/> 18+ Min: <input style="width: 30px;" type="text"/> Max: <input style="width: 30px;" type="text"/>	# Days <input style="width: 40px;" type="text"/>	or	# Weeks <input style="width: 40px;" type="text"/>	or	Lifetime <input type="checkbox"/>	<div style="background-color: #ffcc00; padding: 2px; text-align: center;">Special Populations</div> <table style="width: 100%; border: 1px solid #ccc;"> <tr><td>Fetus</td><td><input type="checkbox"/></td></tr> <tr><td>Impaired Levels of Consciousness</td><td><input type="checkbox"/></td></tr> <tr><td>Incompetent</td><td><input type="checkbox"/></td></tr> <tr><td>Mentally Challenged</td><td><input type="checkbox"/></td></tr> <tr><td>Minors</td><td><input type="checkbox"/></td></tr> <tr><td>Neonates</td><td><input type="checkbox"/></td></tr> <tr><td>Nursing Women</td><td><input type="checkbox"/></td></tr> <tr><td>Physically Handicapped</td><td><input type="checkbox"/></td></tr> <tr><td>Pregnant Women</td><td><input type="checkbox"/></td></tr> <tr><td>Prisoners</td><td><input type="checkbox"/></td></tr> <tr><td>Women on Birth Control</td><td><input type="checkbox"/></td></tr> </table>	Fetus	<input type="checkbox"/>	Impaired Levels of Consciousness	<input type="checkbox"/>	Incompetent	<input type="checkbox"/>	Mentally Challenged	<input type="checkbox"/>	Minors	<input type="checkbox"/>	Neonates	<input type="checkbox"/>	Nursing Women	<input type="checkbox"/>	Physically Handicapped	<input type="checkbox"/>	Pregnant Women	<input type="checkbox"/>	Prisoners	<input type="checkbox"/>	Women on Birth Control	<input type="checkbox"/>
Normal Volunteer	<input type="radio"/> No <input type="radio"/> Yes	Source <input style="width: 100%;" type="text"/>																																
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Neonates	<input type="checkbox"/>																																	
Nursing Women	<input type="checkbox"/>																																	
Physically Handicapped	<input type="checkbox"/>																																	
Pregnant Women	<input type="checkbox"/>																																	
Prisoners	<input type="checkbox"/>																																	
Women on Birth Control	<input type="checkbox"/>																																	

Choose all that will be allowed to participate in the study.

Total participants for the complete study listed in the protocol.

Source of Normal volunteers

The duration starts at the begin date of collections to the final visit date

Criteria

of Participants

Normal Volunteer	<input type="radio"/> No <input type="radio"/> Yes	Source <input style="width: 100%;" type="text"/>
Sex	<input type="radio"/> Both <input type="radio"/> Female <input type="radio"/> Male	Age <input type="checkbox"/> <18 <input type="checkbox"/> 18+ Min: <input style="width: 30px;" type="text"/> Max: <input style="width: 30px;" type="text"/>

Expected Duration of Patient(s) in Project

# Days <input style="width: 40px;" type="text"/>	or	# Weeks <input style="width: 40px;" type="text"/>	or	Lifetime <input type="checkbox"/>
--	----	---	----	-----------------------------------

Tab 8: Study Design

Institutional Review Board					
LU number 104308			Status NEW		
Title Title should include any unique identifiers, version dates, protocol dates, amendments, IDB, SAE/version date of conse ...					
Principal Investigator Wolozin, Benjamin					
General <input checked="" type="checkbox"/>	Co-Investigators	Diseases/Objectives	Procedures	Drugs	Devices
Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit
Participants	Study Design	Treatments	Financial	Alternatives	
Design Includes:		<input type="checkbox"/> Justification of Participant Number			
		<input type="checkbox"/> Interim Analysis			
		<input type="checkbox"/> Data & Safety Monitor Board			
Techniques:		<input type="checkbox"/> Placebo	<input type="checkbox"/> Randomized		
		<input type="checkbox"/> Open Label	<input type="checkbox"/> Open Label Extension		
		<input type="checkbox"/> Single Blind	<input type="checkbox"/> Double Blind		
		<input type="checkbox"/> Blinded Extension			
Phases:		<input type="checkbox"/> Phase 1 (Dose Finding)	<input type="checkbox"/> Phase 2 (Activity)		
		<input type="checkbox"/> Phase 3 (Comparison)	<input type="checkbox"/> Phase 4 (Post Marketing)		
Patient Types:		<input type="checkbox"/> Inpatient			
		<input type="checkbox"/> Outpatient			
Sites:		<input type="checkbox"/> Ambulatory Surgery (ASC)			
		<input type="checkbox"/> Bone Marrow Transplant			
<input type="button" value="Save"/>					

Choose all that apply and click **Save**

1. Design Includes: Be sure that these three options are in the protocol before checking.

Tab 9: Treatments

Institutional Review Board					
LU number 104304			Status NEW		
Title Title should include					
Principal Investigator Micetich, Kenneth					
General ✓	Co-Investigators	Diseases/Objectives ✓	Procedures ✓	Drugs ✓	Devices ✓
Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit
Participants	Study Design	Treatments		Financial	Alternatives
Treatment(s)					
Description		Duration (wks.)			
<input type="text"/>		<input type="text" value="0"/>		<input type="button" value="Add Treatment"/>	

1. The intent of the Treatment section is to sketch out major experimental procedures. (ex. Drug treatment/biopsy/chart review/invitro/drugs etc.)
2. A Placebo is also considered a treatment.
3. Duration: If the duration is not clearly defined leave at 0 or put in the number of weeks that leads up to the evaluation. (How long will you be reporting on patient?)

Tab 10: Financial

Institutional Review Board					
LU number 104304			Status NEW		
Title Title should include					
Principal Investigator Micetich, Kenneth					
General ✓	Co-Investigators	Diseases/Objectives ✓	Procedures ✓	Drugs ✓	Devices ✓
Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit
Participants	Study Design	Treatments	Financial	Alternatives	
Compensation					
Participants Compensated?		<input type="radio"/> No <input type="radio"/> Yes			
		Amount (\$) <input type="text" value="0"/>			
Compensation Schedule		<input type="text" value="- Select -"/>			
Financial Responsibility					
1) Who is paying for charges? <input type="text"/>					
2) What protocol events will not be charged to the patient? <input type="text"/>					
3) Will hospitalization be required? If Yes, check here. <input type="checkbox"/>					
4) Will hospital stay be increased by participation? If Yes, enter # of days: <input type="text" value="0"/>					
5) Will any tests be performed which are not considered standard tests in diagnosis/treatment of patient? If Yes, list: <input type="text"/>					
6) Who is responsible for the cost of care for a research-related injury? <input type="text"/>					
<input type="button" value="Save"/>					

- Select -

- Select -

Annual

Semi-Annual

Monthly

Weekly

Per Visit

Quarterly

1. **Compensation:** How are the patients being compensated? (ex. Gift certificate – estimate the value)
 - a. Choose compensation schedule
2. **Financial Responsibility:** List if patient is paying for charges, or if drugs are free of cost to the participant, is the grant paying for anything.
3. Click **SAVE** before moving to the next tab.

Tab 11: Alternatives

Institutional Review Board

LU number **104304** Status **NEW**

Title **Title should include**

Principal Investigator **Micetich, Kenneth**

General ✓	Co-Investigators	Diseases/Objectives ✓	Procedures ✓	Drugs ✓	Devices ✓
Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit
Participants	Study Design	Treatments	Financial	Alternatives	

Alternatives to Participation

none described

Add Alternative

1. Some examples of Alternatives to participation:
 - a. Therapeutic research: What can the patient use to treat their disease?
 - b. Different drugs
 - c. Palliative care
2. Click Add Alternative

Alternative to Participation

use of different drugs to treat illness

Update X (Delete)

Add Alternative

3. To Change the contents of the Alternatives: Change the text and then click UPDATE.
4. To Delete an Alternative click X.

Tab 12: Benefits/Risks

Institutional Review Board

LU number **104304** Status **NEW**

Title **Title should include**

Principal Investigator **Micetich, Kenneth**

General ✓	Co-Investigators	Diseases/Objectives ✓	Procedures ✓	Drugs ✓	Devices ✓
Participants	Study Design	Treatments	Financial	Alternatives ✓	
Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit

Benefits	
Check applicable	Description
<input type="checkbox"/>	Future patients may benefit.
<input type="checkbox"/>	Company may benefit financially.
<input type="checkbox"/>	Loyola may benefit financially.
<input type="checkbox"/>	Participant may benefit.
<input type="checkbox"/>	Other: (describe below)
	<input type="text"/>

Check all that apply

Risks	
Check applicable	Description
<input type="checkbox"/>	Treatment may not be effective
<input type="checkbox"/>	Known, unknown risk of study, medication or procedure
<input type="checkbox"/>	Assigned treatment less effective/ creates greater problems than other unassigned treatments.
<input type="checkbox"/>	Other: (describe below)
	<input type="text"/>

Check all that apply

Save

1. Other risks: unpredictable or unique risks that can occur.

Tab 13: Recruitment

Institutional Review Board					
LU number 104304			Status NEW		
Title Title should include					
Principal Investigator Micetich, Kenneth					
General ✓	Co-Investigators	Diseases/Objectives ✓	Procedures ✓	Drugs ✓	Devices ✓
Participants	Study Design	Treatments	Financial	Alternatives ✓	
Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit

Recruitment Methods	
- Select -	Add Method

Recruitment Methods	
Brochure/Pamphlet	X (Delete)
- Select -	Add Method

- Select -
- Select -
Brochure/Pamphlet
General Solicitation
Newspaper/Magazine
Physician Solicitation
Radio
Website

Choose an option and click **Add Method**

To delete a method, click **X**.

Discovery	
1) How will potential participants be identified?	<input type="text"/>
2) How will potential participants learn about the study?	<input type="text"/>
Save	

Tab 14: Consent

1. Fill out all of the questions and click **Save**.

Institutional Review Board

LU number **104304** Status **NEW**

Title **Title should include**

Principal Investigator **Micetich, Kenneth**

General ✓	Co-Investigators	Diseases/Objectives ✓	Procedures ✓	Drugs ✓	Devices ✓
Participants	Study Design	Treatments	Financial	Alternatives ✓	
Benefits/Risks	Recruitment	Consent	Importance	Competing	Review/Submit

Procurement of Consent

1) Who will obtain consent?

2) Where will consent be obtained?

3) When will consent be obtained?

Save

Tab 15: Importance

1. Provide a brief statement of the projects importance (ex. new therapies for rectal cancer). Click **Save** when completed.

The screenshot shows the IRB system interface. At the top, a dark blue header contains the text "Institutional Review Board". Below this, the LU number is 104304 and the status is NEW. The title is "Title should include" and the principal investigator is "Micetich, Kenneth". A navigation menu contains several tabs: General (checked), Co-Investigators, Diseases/Objectives (checked), Procedures (checked), Drugs (checked), Devices (checked), Participants, Study Design, Treatments, Financial, Alternatives (checked), Benefits/Risks, Recruitment, Consent, **Importance** (highlighted), Competing, and Review/Submit. Below the menu is a large text area titled "Statement of Project's Importance" with a scroll bar. At the bottom center, a "Save" button is circled in black.

Tab 16: Competing

1. Are there any competing trials in your area at Loyola?
2. If yes, give the name of the trial, in what manner do they compete and how will the patients be informed of the competing trials.
3. Click **Save** when done.

Institutional Review Board							
LU number 104304				Status NEW			
Title Title should include							
Principal Investigator Micetich, Kenneth							
General ✓	Co-Investigators	Diseases/Objectives ✓	Procedures ✓	Drugs ✓	Devices ✓		
Participants	Study Design	Treatments	Financial	Alternatives ✓			
Benefits/Risks	Recruitment	Consent	Importance	Competing		Review/Submit	
Are there Competing Clinical Trials?		<input type="radio"/> Yes <input checked="" type="radio"/> No					
If Yes, answer the following:							
Name of Competing Trials		<input type="text"/>					
How do they compete?		<input type="text"/>					
How will patients be informed of competing trials?		<input type="text"/>					
<input type="button" value="Save"/>							

Tab 17: Info Security

The goal for the Information Security tab is to have all patient identifiable research data collected and stored in a secured location.

Institutional Review Board

LU number **107356** Status **NEW**

Title

Principal Investigator **Fareed, Jawed**

General ✓	Co-Investigators ✓	Diseases/Objectives	Procedures	Drugs	Devices
Participants	Study Design	Treatments	Financial	Alternatives	Competing
Benefits/Risks	Recruitment	Consent	Importance	Info. Security	Review/Submit

Information Security Agreement

Federal regulations and institutional policy require that all persons collecting or managing protected or confidential information exercise prudent security measures to assure that information is not accessed or available to unauthorized individuals. The Principal Investigator (PI) is responsible to ensure that all supporting personnel understand and comply with all information system policies.

[View Policies](#)

I have reviewed and accept the information security policies.

Additional Information Security Questions

Will patient-identifiable information be collected and stored electronically?

No Yes

NOTE: One approved information storage option is saving your data on a secure fileserver. There is a research server available for this purpose. If you are in need of a secure fileserver/share, contact Joe Korral (jkorral@lumc.edu or x67904) or check here and provide the names of everyone needing access: .

1. Once the policies have been viewed and read click in the box to indicate that you have reviewed and accepted the information security policies.
2. Answer **no or yes** to the additional security questions regarding patient identifiable information (Patient-identifiable information refers to ALL Protected Health Information as defined by the Healthcare Insurance Portability and Accountability Act of 1996)
 - a. If you answer **NO** to the storing of patient identifiable information the next step is to click on the **SAVE** button.

- b. If you answer **YES** that patient identifiable information will be collected and stored electronically, more questions will appear.
- c. Select the appropriate box where the information will be stored and hit the save button.

Additional Information Security Questions

Will patient-identifiable information be collected and stored electronically?
 No Yes

Where will the collected study information be stored?

- Sponsor-provided website
- Sponsor-provided laptop
- Institutionally-provided fileserver
- Institutionally-provided laptop
- Institutionally-provided desktop

NOTE: One approved information storage option is saving your data on a secure fileserver. There is a research server available for this purpose. If you are in need of a secure fileserver/share, contact Joe Koral (jkoral@lumc.edu or x67904) or check here and provide the names of everyone needing access:

- d. An email is automatically sent to the security team for review. If the security team approves where you are storing the patient-identifiable data you will be able to submit the IRB application.
- e. If you are not approved, the PI and contact person will receive an email stating what needs to be changed. The most common change is that the patient-identifiable information needs to be stored on an Institutionally-provided file server. If this is the case then:
- f. Select Intuitionally-provided fileserver and then type in Requested.

Additional Information Security Questions

Will patient-identifiable information be collected and stored electronically?
 No Yes

Where will the collected study information be stored?

- Sponsor-provided website
- Sponsor-provided laptop
- Institutionally-provided fileserver
- Institutionally-provided laptop
- Institutionally-provided desktop

- i. Click on the box in the NOTE section and type in the full names of the people needing access to this LU number and data and select Save. This will automatically send an email to Joe Koral (jkoral@lumc.edu x67904).

NOTE: One approved information storage option is saving your data on a secure fileserver. There is a research server available for this purpose. If you are in need of a secure fileserver/share, contact Joe Koral (jkoral@lumc.edu or x67904) or check here and provide the names of everyone needing access:

- ii. A shared server to store this information will be created. The security team will send an email back to the PI and the contact person listed on the IRB with the name of the file server.
- iii. The PI or contact person will need to return to the Info. Security tab in the IRB application and change the check mark to Institutionally-provided fileserver and enter in the file server name provided to you in the email.

Additional Information Security Questions

Will patient-identifiable information be collected and stored electronically?
 No Yes

Where will the collected study information be stored?


- Sponsor-provided website
- Sponsor-provided laptop
- Institutionally-provided fileserver
- Institutionally-provided laptop
- Institutionally-provided desktop

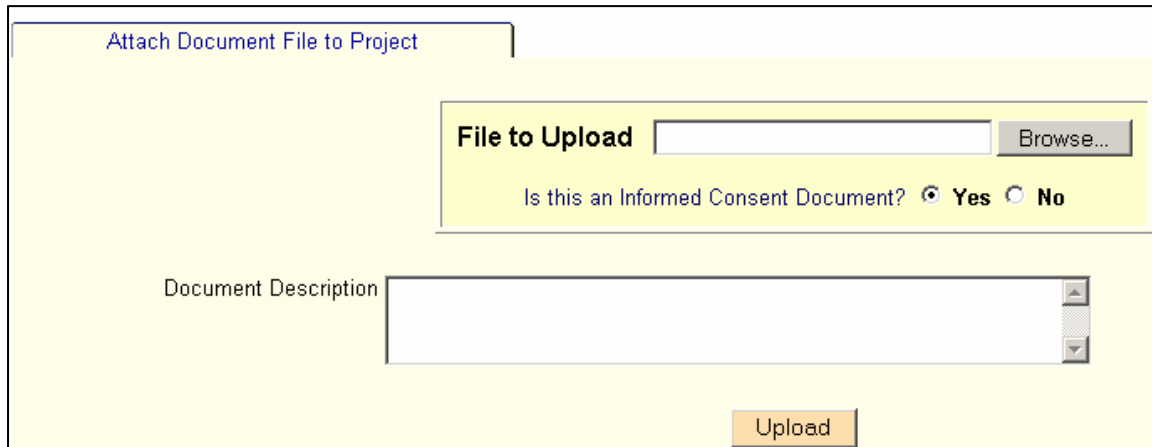
Enter Server/Share name

NOTE: One approved information storage option is saving your data on a secure fileserver. There is a research server available for this purpose. If you are in need of a secure fileserver/share, contact Joe Korral (jkorral@lumc.edu or x67904) or check here and provide the names of everyone needing access: .

- iv. Once this is changed and the Save button is clicked, an email is sent to notify the security team of the change for an approval of the tab.
 - v. Once the approval has been obtained, the IRB can be submitted.
3. Access to the file server is created first by PI and then by LU number.

Uploading documents

3. By clicking:  This form will load into a new browser window.
4. (Note: The following file-types/formats are supported: MS Word document, Spreadsheet (MS Excel Format), PDF (Adobe Acrobat Format), or HTML (.htm, .html).)



Attach Document File to Project

File to Upload Browse...

Is this an Informed Consent Document? Yes No

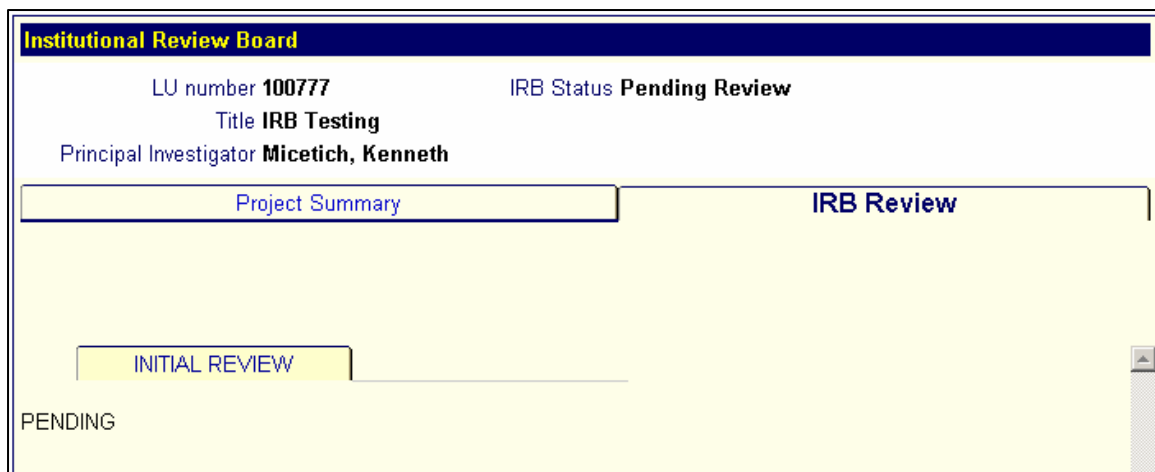
Document Description

Upload

5. Choose Submit for IRB Review.
Remember: Once the submit is enabled, there is no possible way to edit this proposal. It automatically goes to the IRB Committee.



6. This is what your screen will look like once your IRB has been submitted.



Institutional Review Board

LU number **100777** IRB Status **Pending Review**

Title **IRB Testing**

Principal Investigator **Micetich, Kenneth**

Project Summary | IRB Review

INITIAL REVIEW

PENDING

IRB Full Approval


Project Summary

1. All consent documents will be located on the web.
2. The ability to print out and view the consent document is available.
3. The most current approved consent documents will be is "RED".
4. You have the ability to save these documents to your hard drive or floppy disk. By doing this you will be able to go in and modify your documents and upload the new information.
5. To view the attached documents (event) click on the link and a new browser window will open with that document presented.






The screenshot shows a web interface for IRB management. At the top, there are navigation tabs: "New Adverse Event", "Temporary Closure", "Closure/Termination", "Project Summary", "IRB Review", and "New Amendment". The "Project Summary" tab is active. Below the tabs, the "Full Title" field is empty. The "Department" is "Medicine" and the "Division" is "Hematology/Oncology". A section titled "Attached Documents (event)" contains a list of links. Two links are circled in black: "adverse attach changed (Adverse Event 1)" and "* ICD: 05/12/2003". Other links include "adverse 2 (Adverse Event 1)", "amend 6 -revised icd (Amendment 6) ICD: 01/01/1900", "New ICD - 5/8/2003 (Amendment 6)", "100155.051203 (Amendment 10)", "100155.051203 (Amendment 1)", "100155.050703 (Amendment 7)", and "100155.050703 (Amendment 8) ICD: 05/07/2003". A box on the right side of the list is labeled "Current Approved Consent Document".

IRB Review

1. When your IRB has been approved these are the new options that will appear.
2. The screen will open up to the IRB Review screen.
3. Here the approval letter can be viewed and printed by clicking the Approval Letter Icon.

Institutional Review Board		
LU number	IRB Status Full Approval	
Title		
Principal Investigator Micetich, Kenneth	IRB #	
New Adverse Event	Temporary Closure	Closure/Termination
Project Summary	IRB Review	New Amendment
INITIAL REVIEW		
Meeting Date	05/21/2003	
Review Action	Full Approval	
Conflict of Interest	None.	
Issues concerning the Project	1. None.	
Approval Date	04/16/2003	
Review Frequency	Annual	
Conditions of Approval		

4. Further down the page there is a tab for Other Reviews which lists anything submitted after the IRB application has been submitted (i.e. Amendments or Adverse Reactions).
5. To View and Print the Approval Letter, click on the icon.

OTHER REVIEWS					
Type	Submitted	Description	Reviewed	Action	
Amendment	04/29/2003	The consent document has been updated to reflect HIPAA.	04/29/2003	Full Approval	
Amendment	04/30/2003	Company amendment # 2 dated 5/16/2003 increases the dose of oxaliplatin.	04/30/2003	Full Approval	
Amendment	04/30/2003	This is a test Amendment (#3) to check processing and emailing functions.	04/30/2003	Full Approval	
Amendment	04/30/2003	Company amendment # 3 dated 4/30/2003 indicates that patients with red hair cannot participate in the project.	04/30/2003	Full Approval	
Amendment	04/30/2003	Company amendment # 7 dated 3/30/2003 indicates that patients with colon cancer can now participate.	04/30/2003	Full Approval	

Submitting a New Amendment

1. Choose the New Amendment Tab.
2. Upload all related attachments before completing/submitting this part of the form. Click the Upload Document icon.
3. If this is the first time that the portal is being used, a recent copy of the consent document must be submitted.

You have the ability to browse your computer to find the appropriate file.

Use the calendar to

SUN	MON	TUE	WED	THU	FRI	SAT
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Note: The following file-types/formats are supported: MS Word document, Spreadsheet (MS Excel Format), PDF (Adobe Acrobat Format), or HTML (.htm, .html).

There is the ability to upload as many documents as needed.

NOTE: Amendments that are judged to place the patient at increased risk or are judged to be substantive in nature will be reviewed by the full Board. Amendments, revisions, or changes to the protocol that are minor will be reviewed using the expedited review mechanism.

New Adverse Event

1. Upload all related attachments BEFORE completing/submitting this form.
2. Describe what the Adverse Event was.
3. Will the past or current participants be informed of the event?
4. Were there changes to the ICD? If the answer is yes, enter in the version date by using the calendar at the right.
5. Click on **Submit for IRB Review** when screen is completed.

The screenshot shows a web-based form titled "New Adverse Event". At the top, there are three tabs: "Project Summary", "IRB Review", and "New Amendment". Below these, there are three sub-tabs: "New Adverse Event" (which is selected), "Temporary Closure", and "Closure/Termination".

In the top right corner, there is an "Upload Document" button with a document icon. Below it, a note reads: "(Upload ALL related Attachments BEFORE completing/submitting this form.)".

The main content area is titled "Adverse Protocol Event (#2)". It contains a "Description" label next to a large text input field. Below the input field, there are two rows of radio button options:

- Row 1: "Past or Current Participants to be Informed?" with radio buttons for "No" and "Yes".
- Row 2: "Changes to ICD?" with radio buttons for "No" and "Yes". To the right of the "Yes" option is a text box labeled "(If Yes, enter Version Date" followed by a calendar icon and a closing parenthesis.)

At the bottom center of the form is a large orange button labeled "Submit for IRB Review".

At the very bottom of the page, there is a note: "NOTE: The full Board reviews all Adverse Protocol Events."


Note: Report protocol violations as adverse events; report changes to the investigational drug brochures as adverse events.

Temporary Closure

Project Summary	IRB Review	New Amendment
New Adverse Event	Temporary Closure	Closure/Termination

Temporary Closure Request

Reason for Closure	
--------------------	--

Date of Temporary Closure	<input type="text"/>	
---------------------------	----------------------	---


NOTE: A Temporarily-Closed Project cannot be Re-opened without review by the full Board.

Use this report when the study is temporarily closed for analysis. Use the reopen screen to request a reopening of the study. Note that any study that underwent full board review and then temporarily closes, requires full board to reopen. Provide detailed statements of the closing and reopening and any actions/modifications to the protocol. Provide a revised consent document if applicable.

Project Closure Request

Project Summary	IRB Review	New Amendment
New Adverse Event	Temporary Closure	Closure/Termination

Project Closure Request

Closure Date	<input type="text" value="05/15/2003"/> 
Type of Closure Requested	<input type="radio"/> Closed to Enrollment <small>(Closed to New Patient accrual but Participants continue to be followed on the Protocol. Annual Review and Adverse Protocol Reaction Reports are still required.)</small>
	<input type="radio"/> Termination <small>(Closed to New Patient accrual and Participants are no longer followed on the Protocol. Annual Review and Adverse Protocol Reaction Reports are no longer required.)</small>

Total Number of Participants enrolled:	<input type="text"/>
Number of Male Participants:	<input type="text"/>
Number of Female Participants:	<input type="text"/>
Number of Adverse Protocol Reactions:	<input type="text" value="1"/>
Number of Participants who were enrolled but later found to be Protocol-ineligible:	<input type="text"/>
Have the results of this research been accepted for publication?	<input checked="" type="radio"/> No <input type="radio"/> Yes
If Yes, provide journal citation (if available):	
<input type="text"/>	

Describe your experience with this Protocol:
(include comment on the value of the research to the participant, society, Loyola and/or the sponsoring company)

If no patients were enrolled in this Study, indicate the reasons for no accrual:

Why is the Research Project being closed at this time?

Annual Reviews (open and closed studies)

1. Will be sent to you electronically
2. Require response
3. Follow directions in e-mail about required attachments.
4. Answer questions about protocol online
5. Submit
6. Board will review and you will be notified of action. If approved for another time period, you will receive updated consent document electronically.

The consent document will contain a new re-review date on page 1:

This project will be re-reviewed on or before

The footer will be changed:

Document ID#: LU NUMBERarx.date of review

Version Date: Date of review

Continuing/Annual Review Questions

Responses submitted by: lwrona on 03/29/2004

LU# 14474.0		Review# 1	
1. Has the project been closed to new participant accrual with no participants being followed on the study?	<input type="radio"/>	No	<input type="radio"/> Yes
2. Has the project been closed to new participant accrual but with existing participants still being followed on the study?	<input type="radio"/>	No	<input checked="" type="radio"/> Yes
If Yes, indicate the number of participants:		53	
3. Have any and all Adverse Protocol Reactions (occurring at Loyola or elsewhere) since the last review of research activity been reported to the IRB?	<input type="radio"/>	No	<input checked="" type="radio"/> Yes
If No, explain:		<input type="text"/>	
4. Have any and all protocol amendments/revisions and/or changes to the consent document since the last review of research activity been submitted to the IRB?	<input type="radio"/>	No	<input checked="" type="radio"/> Yes
If No, explain:		<input type="text"/>	
5. Have you received any participant complaints concerning the protocol and/or the informed consent document since the last review of research activity?	<input type="radio"/>	No	<input checked="" type="radio"/> Yes
If Yes, explain:		<input type="text"/>	
6. Have any participants experienced a financial problem or a billing problem as a result of participation in this study since the last review of research activity?	<input type="radio"/>	No	<input checked="" type="radio"/> Yes
If Yes, explain:		<input type="text"/>	
7. Have you judged that any Loyola participant has been injured as a result of participating in this research since the last review of research activity?	<input type="radio"/>	No	<input checked="" type="radio"/> Yes
If Yes, explain:		<input type="text"/>	
8. In considering your experience with the research project since the last review of research activity, are there any changes you feel should be made to the protocol and/or the consent document?	<input type="radio"/>	No	<input checked="" type="radio"/> Yes

If Yes, explain:

9. In considering the advances made in Medical Science and/or the result of any interim analyses performed and/or your experience with the efficacy and the side effects of the research project since the last review of research activity, is there any new information available that should be reported to the participants? (ANY NEW INFORMATION THAT WOULD AFFECT THE WILLINGNESS OF THE PATIENT TO REMAIN IN THE RESEARCH PROJECT MUST BE REPORTED TO THE PATIENT.)

No Yes

If Yes, explain and indicate the proposed action:
(Also, address the issue of whether the project remains viable.)

10. Has any participant elected to withdraw from the research project? No Yes

If Yes, indicate the number of participants who have withdrawn and the reasons:

11. Have you elected to withdraw a participant from this research project? No Yes

If Yes, indicate the number of participants whom you have withdrawn and the reasons:

Project Census

Enter the total number of Participants enrolled since the last review of research activity:


Enter the number of MALE Participants enrolled since the last review:

Enter the number of FEMALE participants enrolled since the last review:

Enter the total number of Participants enrolled since the project began:

If there has been no protocol accrual since the last review of research activity or no protocol accrual since the project began, indicate the reasons and why you feel the project should remain active:


n/a

Save Changes 


New Attachments



Active ICD* Re-name

[final protocol](#) (03/29/2004) 



[14474.0.050603](#) (03/29/2004) 



Save Changes

[Close window](#)

LOYOLA UNIVERSITY MEDICAL CENTER
MAYWOOD, ILLINOIS
DEPARTMENT OF MEDICINE

INFORMED CONSENT

Patient's Name: _____

Patient Medical Record: _____

Protocol: LU107103: (GOG-0204) A Randomized Phase III Study of Paclitaxel Plus Cisplatin Versus Vinorelbine Plus Cisplatin Versus Gemcitabine Plus Cisplatin Versus Topotecan Plus Cisplatin in Stage IVB, Recurrent or Persistent Carcinoma of the Cervix

The project will undergo re-review on or before 01/21/2005.

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a clinical trial (research project). It is important that you read and understand the following principles that apply to all individuals who agree to participate in a clinical trial:

1. clinical trials include only patients who choose to take part; taking part in the research is entirely voluntary;
2. we do not know if you will personally benefit from taking part in the research, but the knowledge obtained may help others;
3. you may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled;
4. if during your participation in the research project, new information becomes available (such as better therapies or side effects of the study medications) which would affect your being in the research project, your doctor will discuss this new information with you and will help you make a decision about your continuing in the research project.

The purpose of the research and how it is to be done as well as your role will be described below. Also described are the risks, inconveniences, discomforts and other important information that you will need to make a decision about whether or not you wish to participate. Please take your time to make your decision. You are urged to discuss the research with family and friends, and direct any questions you may have with the staff members who explain it to you.

Document ID #:

Version Date: