How to Submit to the UMC IRB

1.	Navigating the IRB Websitepg. 2	2
	a. From the Intranetpg. 2	2
	b. From the Internetpg. 2	2
	c. The UMC HRPP Webpagepg. 3	3
	d. Forms and Templatespg. 4	1
	e. Requesting an Accountpg. 4	1
2.	IRB Requirementspg. 6	5
	a. Curriculum Vitae – CVpg. 6))
	b. Collaborative Institutional Training Initiative (CITI Program)pg. 7	,
	c. Conflict of Interest Disclosurepg. 8	;
3.	Sample Retrospective Chart Review Protocolpg. 9	>
4.	Sample Application and Initial Submission Packetpg. 1	7
5.	Where to find assistance/helppg. 2	25

1. Navigating the UMC IRB Website

a. From the Intranet - <u>https://umcintranet/</u>

To If you are on the UMC intranet, from the home page: Hover over => Departments

From the dropdown Select => Human Research Protection Program



This will take you to the HRPP Website 1.c.

1. Navigating the UMC IRB Website

b. From the Internet - https://www.umcsn.com/

To If you are on the internet, from the home page: Hover over => Employees & Physicians

From the dropdown Select => Research & Education



This will take you to the HRPP Website 1.c.

1. Navigating the UMC IRB Website

c. The Human Research Protection Program Webpage

From the menu on the left, under Research & Education Select => Institutional Review Board



This will take you to the UMC IRB Webpage

From the UMC IRB Webpage, from the menu on the left, Select => Forms and Templates

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This will take you to the Forms and Templates Webpage

1. Navigating the UMC IRB Website d. Forms and Templates

On the Forms and Templates page you will find multiple resources, but specifically:

- 1. Chart Review Protocol Template
- 2. Retrospective Chart Review Application Sample
- 3. Data Collection Tools

Go to #4 of this guide for the contents of each of the above

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		HIPAA Document					
		PHI Identifiers					
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1. Navigating the UMC IRB Website

e. Requesting an Account

From the UMC IRB Webpage, from the menu on the left, Select => eIRB Login

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From the eIRB Login screen Select => Request new account



Complete the request form and submit (please complete as much information on this request as possible)

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2. IRB Requirements

IRB Policies and Procedures Manual – Section 30. INVESTIGATOR RESPONSIBILITIES

Principal Investigators

At UMC, the following may serve as the Principal Investigator on a research project involving human subjects:

- physician staff members,
- registered nurses holding a Master's degree or higher, employed full time by UMC
- pharmacists holding a Doctoral degree in Pharmacy (PharmD), on staff or employed full time by UMC
- Physician Assistant's (PA's) and Advanced Practice Nurses (APN's) on staff or employed full time at UMC may conduct research as a Principal Investigator within the realm of their clinical specialty and research abilities as long as they possess the qualifications as stated in the IRB Policy & Procedure manual.

All Principal Investigators must meet the following qualifications in order to conduct research involving human subjects:

- have an active license in Nevada.
- be an active staff member in good standing at UMC.
- be familiar with the medical literature related to the drug/device/procedure/disease stated to be studied.
- be familiar with the protocol guiding the drug/device/procedure to be studied.
- have knowledge of known clinical and/or pharmacological potential of the investigational drug, device or procedure under study.
- have previous documented research experience as described in the IRB Policy & Procedure Manual and complete the CITI Course.

Resident/Student Investigators

Residents and/or students may not serve as Principal Investigators. They must have a staff physician sponsor who fulfills the principal investigator eligibility criteria and who will serve as Principal Investigator on the study. Any investigator whose status is considered to be "in training" (i.e. students and medical residents) may not serve as a Principal Investigator but may serve as a co-investigator.

2. IRB Requirements

a. Curriculum Vitae – CV

The UMC IRB requires a signed current copy of each members CV. This can be emailed to <u>umcirb@umcsn.com</u>

2. IRB Requirements

b. Collaborative Institutional Training Initiative (CITI) Completion Certificate

The UMC IRB requires a valid CITI Completion Certificate for Biomedical Research – Basic Course.

Instructions:

The University Medical Center Institutional Review Board has partnered with the Collaborative Institutional Training Initiative (CITI) Web-based Training Program to offer a course in Human Subjects Research Education. The UMC IRB requires that any Investigator, Resident, Research Administrator, Clinical Research Administrator, or other personnel listed on the protocol to complete this course in order to be able to participate in the research.

Please follow the instructions below:

- Log on to <u>http://www.citiprogram.org</u> to register for CITI online training.
- Once there, they simply click on "Create an Account Register"
- From "Select Your Organizational Affiliation" select "University Medical Center of Southern Nevada"
- Next proceed to enter your Name & Email Address
- Complete the remaining registration questions
- Select "Basic Human Subjects Biomedical & Social & Behavioral Focus"
 - Select the Biomedical Research Group

You only need to complete the following course in the curriculum which has been assigned to you:

1. Biomedical Research – Basic Course

2. Good Clinical Practice (GCP) – not required by UMC IRB, only if required by study sponsor

- After going through the registration process you should be ready and setup as a CITI Learner.
- Click on "Not Started Enter" to start your course
- Complete "The Integrity Assurance Statement" before beginning the course.
- Complete all the modules

Once you have completed all the modules you will be prompted to print out a copy of your certification for your own records. To ensure that you have registered with the appropriate institution and have completed all the required modules, please email <u>Robert.Bimbi@umcsn.com</u> after you have completed the course. If you have any questions, please feel free to contact me.

2. IRB Requirements

d. Conflict of Interest Disclosure

The UMC IRB requires a current and completed Conflict of Interest Disclosure.

Conflict of Interest Disclosure Form

Once completed and signed this can be emailed to <u>umcirb@umcsn.com</u>

5. Where to find assistance/help

IRB Contacts

Ronald Roemer	ronald.roemer@umcsn.com	702 207-8345
Robert Bimbi	robert.bimbi@umcsn.com	702 383-7302
Jennifer Robinson	jennifer.robinson@umcsn.com	702 383-7842
Robert Panganiban	robert.panganiban@umcsn.com	702 383-7336

Physical Location

Research Institute – South Building First Floor (in the heart failure clinic)