

# IRB and Greater than Minimal Risk Research

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Research Compliance Officer

# Objectives

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- What is high risk research?
- What does it mean for IRB review?
- How do I need to modify study design in:
  - Recruitment
  - Consent
  - Data collection and storage
- Planning for timeline

# Minimal Risk?

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- This threshold can be one of the most fluid pieces of Federal Regulations
- "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (from 45 CFR 46.102(i)).

# Minimal Risk vs. High risk (greater than minimal)

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It's just a survey  
so that is  
minimal risk  
right?



# Criteria for High Risk Study

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- Research activities that present **greater than minimal risk** to human subjects
- Triggers
  - Any disclosure of illegal activities, sexual attitudes, genetics, religious beliefs, mental health that could place participants at risk of criminal or civil liability, be damaging to the participants financial standing, employability, insurability, reputation, or be stigmatizing
    - Depression and mental health disorders
    - Sexual abuse
    - Violent crimes or other criminal behavior
    - Opinions about employer



# Criteria for High Risk Study

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- Research activities that present **greater than minimal risk** to human subjects
- Triggers
  - Coercion (e.g. student/teacher)
  - Deception or incomplete disclosure
  - Population involves persons with cognitive disabilities or inability to provide informed consent
  - Pregnant women
  - Medically invasive, (e.g., blood draws, clinical trial)
- ***Full Review- Goal: 6 to 8 weeks (involves review of entire committee)***



# Examples of Titles high risk research

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- Experiences among Muslim youth post 9/11
- Siblings with Autism and Impacts on the Family Dynamics
- Assessment of community nutrition program on rates of substance abuse
- Abstinence Education Programs in Middle schools
- Adolescent Family Life Demonstration Project
- Retrospective study of youth sexual development through early identification with gay culture

# High risk research



# Examples of Benefits as Provided for High Risk Social Behavioral Research

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- Impact policy change and reform current programs available to children in the community
- Will provide evidence of program success and allow for future funding in this community
- Results and presentations may help others through the “coming out” process\*
- Potential benefits for other girls include that the results of the research study can be used by the agencies to secure funding so that ALL girls can receive the enhanced services, if they are deemed to improve outcomes. \*\*
- The study report will be particularly important for the Administration for Children's Services in identifying unique needs for pregnant teens in foster care and how certain programs can address those needs for this special population.\*\*
- Not including the benefits or providing inadequate benefits will make the IRB reviewer send your study back to you for
  - ≠ Never been done before; novel concept
  - ≠ Thesis committee supported study

• \* courtesy of Dr. Forenza \*\* courtesy of Dr. Lieberman

# IRB application

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- Plan time to meet with the IRB if this is your first greater than minimal risk research
- What in the application does a reviewer look at to decide if the study is greater than minimal risk?

i. Approximately how long will each session be?

**7. Does your research involve recruiting any of the following persons/groups?**

- a. Persons who are under the age of 18 years
- b. Persons who are pregnant
- c. Human fetuses/newborns
- d. SONA - MSU's Student Participant Pool
- e. Persons who are cognitively disabled or impaired
- f. Persons who are veterans
- g. Persons who are elderly or aged
- h. Persons who are terminally ill
- i. Persons who have diminished capacity to give informed consent
- j. Persons who do not speak English
- k. Persons who are under the authority of the research team:  
*For example, students, staff, patients, clients*
- l. Persons who are institutionalized:  
*For example, prisoners, persons in hospices, persons in hospitals, nursing homes, rehabilitation centers, homeless shelters, holding centers for immigrants*

<input type="radio"/> Yes	<input type="radio"/> No
<input type="radio"/> Yes	<input type="radio"/> No
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<input type="radio"/> Yes	<input type="radio"/> No
<input type="radio"/> Yes	<input type="radio"/> No
<input type="radio"/> Yes	<input type="radio"/> No

**8. What are the characteristics of the individuals you will recruit to participate in this study?**

- a. What is the total number of participants you expect to enroll - include anticipated breakdown by gender (*please note this is not binding*)?

Please fill out the following form. You can save data typed into this form. Highlight Existing Field

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**9. Does your research involve any of the following ?**

- a. Deception, incomplete disclosure, and/or restrictions that the research team does not disclose the true nature of the research to the participants  Yes  No
- b. Administration of drugs  Yes  No
- c. Covert observation  Yes  No
- d. Induction of mental and/or physical stress  Yes  No
- e. Materials/issues commonly regarded as socially unacceptable  Yes  No
- f. Information regarding sexual attitudes, preferences, or practices  Yes  No
- g. Information regarding the use of alcohol, drugs, or other addictive products  Yes  No
- h. Information pertaining to illegal conduct  Yes  No
- i. Genetic Information  Yes  No
- j. Information recorded in a patient's medical record  Yes  No
- k. Information in a student's educational record  Yes  No
- l. Information pertaining to a person's psychological health or well-being  Yes  No
- m. Procedures that may be regarded as an invasion of privacy  Yes  No
- n. Information that if released, could reasonably damage an individual's financial standing, employability, or reputation within the community  Yes  No

**10. For every item that you checked "yes" in question 9 above, provide justification. Describe the precautions that will be used to minimize the risks.**



# Tips to minimize risks with data

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- De-identify data once it is collected
  - Transcribe in a timely fashion
- Plan for data security
- Collect the minimum set of identifiers needed; what do you really need?
  - DOB
  - Street address
  - Audio/voice

How is IRB review different for  
high risk research?

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# Review at Full Board

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- PI must submit by deadlines for meetings
- One reviewer is assigned to review and then presents to committee at a meeting
- All committee members review materials
- Vote is taken to
  - Approve “as is”;
  - Approve with changes;
  - Table until next meeting [ too many significant changes or study is not clear].



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## Review Schedule

### Meeting Schedule for 2015

IRB applications are reviewed on a rolling basis as received. Only studies that include more than minimal risk to participants will fall into a **full review category**. The schedule below applies to studies that require full review by the entire Institutional Review Board at their monthly meeting.

#### *Deadline for Submission for Full Review*

- **November 14, 2014**
- December 26, 2014
- **January 16, 2015**
- February 27, 2015
- **March 13, 2015**
- April 17, 2015
- **May 15, 2015**

#### *Meeting Date for Full Review*

- **December 17, 2014**
- January 21, 2015
- **February 18, 2015**
- March 25, 2015
- **April 15, 2015**
- May 20, 2015
- **June 17, 2015**

Study design implications for greater  
than minimal risk research

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# The substance abuse and mental health study

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- Recruitment
  - Privacy in recruitment; snowball recruitment may not be ideal
  - Flyer with contact information in the lobby may be appropriate
- Consent
  - Capacity to consent may need to be considered
  - Consent must ensure participants confidentiality
- Data
  - The data will be stored on a partitioned, password protected sub-directory on a password protected work stations, stored in a locked office on the campus of Montclair State University. Any working files, output generated from these data, and drafts of related presentations/articles will also be kept in the same manner as described above without any participant identifiers



# Consent language

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- During this interview, we will ask you some questions about your age, who you live with, whether you are married or single, if you use drugs, if you have HIV and if you have any other medical problems. We will note down your answer to these questions. Your answers could be risky outside of this research because it could get you arrested, or you could lose your job, or your reputation. But, we will make every effort to make sure that your information is kept private. We will conduct the interview in a private room at \_\_\_\_\_. We will never share your personal information with anyone outside of the research. If any of the questions make you uncomfortable, with your permission, we will refer you to your counselor or case manager who can assist you. \*courtesy of Dr. Meena Mahadevan

to this form.

i. Approximately how long will each session be?

**7. Does your research involve recruiting any of the following persons/groups?**

- a. Persons who are under the age of 18 years
- b. Persons who are pregnant
- c. Human fetuses/newborns
- d. SONA - MSU's Student Participant Pool
- e. Persons who are cognitively disabled or impaired
- f. Persons who are veterans
- g. Persons who are elderly or aged
- h. Persons who are terminally ill
- i. Persons who have diminished capacity to give informed consent
- j. Persons who do not speak English
- k. Persons who are under the authority of the research team:  
*For example, students, staff, patients, clients*
- l. Persons who are institutionalized:  
*For example, prisoners, persons in hospices, persons in hospitals, nursing homes, rehabilitation centers, homeless shelters, holding centers for immigrants*

<input type="radio"/> Yes	<input checked="" type="radio"/> No
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<input type="radio"/> Yes	<input checked="" type="radio"/> No
<input type="radio"/> Yes	<input checked="" type="radio"/> No

Translated documents may be necessary (wait until your English documents are approved)

**8. What are the characteristics of the individuals you will recruit to participate in this study?**

a. What is the total number of participants you expect to enroll - include an anticipated breakdown by gender (please note this is not binding)?

Females  Males  Total

b. Persons who are:

- i. 0-7 years (parental and oral child assent as appropriate are needed)
- ii. 8-17 years (parental and written child assent as appropriate are needed)
- iii. 18 years and older (consent is needed)

<input type="radio"/> Yes	<input checked="" type="radio"/> No
<input type="radio"/> Yes	<input checked="" type="radio"/> No
<input checked="" type="radio"/> Yes	<input type="radio"/> No

c. Will participants be screened to include or exclude on:

- i. gender
- ii. ethnicity
- iii. race

<input type="radio"/> Yes	<input checked="" type="radio"/> No
<input type="radio"/> Yes	<input checked="" type="radio"/> No
<input type="radio"/> Yes	<input checked="" type="radio"/> No

d. Describe the characteristics of your participant group.

The group of individuals will be recruited from those seeking ongoing counseling services at the substance abuse center for adults in the community. They range in age from 18-55.

e. Will you use screening tools to select your participants?

<input type="radio"/> Yes	<input type="radio"/> No
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f. Are the materials you are planning to use copyrighted?

<input type="radio"/> Yes	<input type="radio"/> No
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into this form.

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9. Does your research involve any of the following ?

- a. Deception, incomplete disclosure, and/or restrictions that the research team does not disclose the true nature of the research to the participants
- b. Administration of drugs
- c. Covert observation
- d. Induction of mental and/or physical stress
- e. Materials/issues commonly regarded as socially unacceptable
- f. Information regarding sexual attitudes, preferences, or practices
- g. Information regarding the use of alcohol, drugs, or other addictive products
- h. Information pertaining to illegal conduct
- i. Genetic Information
- j. Information recorded in a patient's medical record
- k. Information in a student's educational record
- l. Information pertaining to a person's psychological health or well-being
- m. Procedures that may be regarded as an invasion of privacy
- n. Information that if released, could reasonably damage an individual's financial standing, employability, or reputation within the community

<input type="radio"/> Yes	<input checked="" type="radio"/> No
<input type="radio"/> Yes	<input checked="" type="radio"/> No
<input type="radio"/> Yes	<input checked="" type="radio"/> No
<input checked="" type="radio"/> Yes	<input type="radio"/> No
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<input checked="" type="radio"/> Yes	<input type="radio"/> No
<input type="radio"/> Yes	<input checked="" type="radio"/> No
<input checked="" type="radio"/> Yes	<input type="radio"/> No

10. For every item that you checked "yes" in question 9 above, provide justification. Describe the precautions that will be used to minimize the risks.

Item Letter:

Precautions you will take to protect participants:

Click here to add more rows

Click here to remove rows

d.

Should the individual participant feel mental distress from the interview they will be informed that they can stop the interview at any time. The PI is trained in working with this group and has served as a mental health counselor for three years. The counseling center has also agree that they will provide Each participant with ongoing counseling as part of their care.

# If your study MAY cause mental or physical distress

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- Study questions that include mental health status or violent attacks should refer to
  - Counseling and Psychological Services (CAPS) for student participants
  - Other counseling services for general public or other groups
- Study questions that include health and well-being should refer to:
  - University Health Center for MSU student participants
  - Health Care Provider for general public or other groups

# The inner city violence study (data collected online/mobile devices)

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- Recruitment
  - Emails are identifiable and IP address might be as well
- Consent and Internet Data collection
  - Data will be collected using the Internet; no guarantees can be made regarding the interception of data sent via the Internet by any third party (i.e. your employer). Confidentiality will be maintained to the degree permitted by the technology used.
- Data
  - De-identified during entire process vs. linking code for Longitudinal research

VIOLENCE  
PREVENTION

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

I. Persons who are institutionalized:

*For example, prisoners, persons in hospices, persons in hospitals, nursing homes, rehabilitation centers, homeless shelters, holding centers for immigrants*

Yes  No

8. What are the characteristics of the individuals you will recruit to participate in this study?

a. What is the total number of participants you expect to enroll - include an anticipated breakdown by gender (please note this is not binding)?

Females  Males  Total

b. Persons who are:

i. 0-7 years (parental and oral child assent as appropriate are needed)

Yes  No

ii. 8-17 years (parental and written child assent as appropriate are needed)

Yes  No

iii. 18 years and older (consent is needed)

Yes  No

c. Will participants be screened to include or exclude on:

i. gender

Yes  No

ii. ethnicity

Yes  No

iii. race

Yes  No

d. Describe the characteristics of your participant group.

Adult men will be recruited into this study by posting an ad on a local organization (Town group) webpage.

e. Will you use screening tools to select your participants?

Yes  No

f. Are the materials you are planning to use copyrighted?

Yes  No

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

**9. Does your research involve any of the following ?**

a. Deception, incomplete disclosure, and/or restrictions that the research team does not disclose the true nature of the research to the participants	<input type="radio"/> Yes <input checked="" type="radio"/> No
b. Administration of drugs	<input type="radio"/> Yes <input checked="" type="radio"/> No
c. Covert observation	<input type="radio"/> Yes <input checked="" type="radio"/> No
d. Induction of mental and/or physical stress	<input type="radio"/> Yes <input checked="" type="radio"/> No
e. Materials/issues commonly regarded as socially unacceptable	<input type="radio"/> Yes <input checked="" type="radio"/> No
f. Information regarding sexual attitudes, preferences, or practices	<input type="radio"/> Yes <input checked="" type="radio"/> No
g. Information regarding the use of alcohol, drugs, or other addictive products	<input type="radio"/> Yes <input checked="" type="radio"/> No
h. Information pertaining to illegal conduct	<input checked="" type="radio"/> Yes <input type="radio"/> No
i. Genetic Information	<input type="radio"/> Yes <input checked="" type="radio"/> No
j. Information recorded in a patient's medical record	<input type="radio"/> Yes <input checked="" type="radio"/> No
k. Information in a student's educational record	<input type="radio"/> Yes <input checked="" type="radio"/> No
l. Information pertaining to a person's psychological health or well-being	<input type="radio"/> Yes <input checked="" type="radio"/> No
m. Procedures that may be regarded as an invasion of privacy	<input type="radio"/> Yes <input checked="" type="radio"/> No
n. Information that if released, could reasonably damage an individual's financial standing, employability, or reputation within the community	<input checked="" type="radio"/> Yes <input type="radio"/> No

**10. For every item that you checked "yes" in question 9 above, provide justification. Describe the precautions that will be used to minimize the risks.**

<i>Item Letter:</i>	<i>Precautions you will take to protect participants:</i>
<div style="border: 1px solid gray; padding: 2px; display: inline-block;">Click here to add more rows</div> <div style="border: 1px solid gray; padding: 2px; display: inline-block; margin-left: 100px;">Click here to remove rows</div>	
h.	The questions in the survey instrument will be asking individuals about engaging in physical fights and use of weapons. No identifiers will be collected during the survey that will be linked to the participants. There are no open ended questions in the instrument that could potentially identify and individual.
n.	While the survey will collect an individuals experience using weapons there is no reasonable way for the researcher or others to link the identity of an individual respondent. Careful attention has been paid to the <u>online</u> survey tool to ensure that IP address and email will not be maintained from the participant. Furthermore, the link to the raffle will be set up in a completely separate survey that does not involve any date or time stamps that could potentially link the participant to the survey responses.

**11. Where do you propose to carry out your research?**

# The “coming out” study \*

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- Recruitment
  - Participants are to be recruited via gay-affirming organizations such as Garden State Equality, Prideworks, and True Colors. The PI-- through his professional network-- will contact representatives at these agencies asking them to distribute the recruitment flyer to interested members. It is then up to interested participants to contact the PI.
- Consent
  - Full disclosure that the information and video testimonial will be shared by the PI and streamed publicly
- Data
- \*courtesy of Dr. Forenza

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## 9. Does your research involve any of the following ?

- |   |                                      |                                     |
|---|--------------------------------------|-------------------------------------|
| a. Deception, incomplete disclosure, and/or restrictions that the research team does not disclose the true nature of the research to the participants | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| b. Administration of drugs  | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| c. Covert observation   | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| d. Induction of mental and/or physical stress   | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| e. Materials/issues commonly regarded as socially unacceptable  | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| f. Information regarding sexual attitudes, preferences, or practices  | <input checked="" type="radio"/> Yes | <input type="radio"/> No            |
| g. Information regarding the use of alcohol, drugs, or other addictive products   | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| h. Information pertaining to illegal conduct  | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| i. Genetic Information  | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| j. Information recorded in a patient's medical record   | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| k. Information in a student's educational record  | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| l. Information pertaining to a person's psychological health or well-being  | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| m. Procedures that may be regarded as an invasion of privacy  | <input type="radio"/> Yes            | <input checked="" type="radio"/> No |
| n. Information that if released, could reasonably damage an individual's financial standing, employability, or reputation within the community        | <input checked="" type="radio"/> Yes | <input type="radio"/> No            |

10. For every item that you checked "yes" in question 9 above, provide justification. Describe the precautions that will be used to minimize the risks.

Item Letter:

Precautions you will take to protect participants:



f.

1. This sample shall be comprised of "out and PROUD" adult, gay men
2. Sexual orientation is not regarded as taboo by this out and proud sample; it is willfully embraced and discussed
3. Beyond orientation as sampling criterion, there shall be no questions about explicit sexual practices, etc.
4. The study is strengths-based and seeks to elicit protective factors in one's coming out process

n.

1. A closeted individual may, in fact, be fearful of his perceived status being effected by participation
2. The main sampling criterion is that gay men in this study be out and proud in all areas of life
3. Out and proud gay men live all realms of life as "gay;" it is an active part of their identity

10. For every item that you checked "yes" in question 9 above, provide justification. Describe the precautions that will be used to minimize the risks.

*Item Letter:*

*Precautions you will take to protect participants:*

Click here to add more rows

Click here to remove rows

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n.

1. A closeted individual may, in fact, be fearful of his perceived status being effected by participation
2. The main sampling criterion is that gay men in this study be out and proud in all areas of life
3. Out and proud gay men live all realms of life as "gay;" it is an active part of their identity
4. Because of the nature of this purposeful sample, there is no risk to one's perceived status
5. Potentials risks of this study are indicated via the following mediums: (a) recruitment form, (b) informed consent,

# The sensitive topic with teens study

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- Recruitment
  - Will there be autonomy and time to decide if they want to continue
  - Make sure compensation is not causing undue coercion
- Consent process
  - Parent/guardian consent
- Data
  - De-identify to the extent possible and have a data security plan if you are using a linking code



While you are in this study, you may feel upset about something we ask you. If something that you talk about makes you feel upset, we will give you the name of someone who can help you. You may be worried that something you say will not be kept private. We use a code number for each person in the study. We never use your name. The interviewer will never give any personal information about you to anyone. The only time the interviewer would tell anyone about you, is if you or your baby were in danger. That means things like child abuse or sexual abuse. When we talk about the study, we will ONLY talk about the entire group of girls and babies in this study. No one, except your social worker or the person who gives you the services will know that you are in the study. \* courtesy of Dr.

Lisa Lieberman

# Psychology Deception Study

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- Recruitment
  - Recruitment material must come as close as possible to explaining elements of study without impacting the deception piece
- **Consent**
  - Must consent and the “re-consent” or debrief with option to withdraw data
  - Use template for de-brief online
- Data
  - Confidentiality of data

# Planning Tips

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- Check IRB Full Meeting Schedule and submission deadlines
- Make appointment to meet with IRB Coordinator or IRB Chair if this is your first high risk study submission
- Site Approval – For high risk studies, this may take more time than expected – you can approach sites for approval, before submitting your IRB application, remember to use the Site Approval Template
- Identifiers –
  - Make sure you have reduced the number of identifiers you are collecting. Can you collect age instead of DOB? Do you need city and state for participants or just the state they reside?
  - If you are using a pre-developed survey instrument – go through every question, are you looking for all this data, can you omit certain questions at a higher risk?

# Contact Us

- IRB Coordinator: Amy Krenzer
  - [reviewboard@mail.montclair.edu](mailto:reviewboard@mail.montclair.edu)
  - Ext. 7583
- IRB Program Assistant: Mylka Biascochea
  - [biascocheam@mail.montclair.edu](mailto:biascocheam@mail.montclair.edu)
  - Ext. 3021
- Research Compliance Officer: Hila Berger
  - [bergerh@mail.montclair.edu](mailto:bergerh@mail.montclair.edu)
  - Ext. 7781
- IRB Chair: Dr. Katrina Bulkley
  - Ext. 5189
- IRB Office: College Hall 248

