

Guidance in  
*PROTOCOL SUBMISSION*  
to Barry University IRB

April 14, 2020

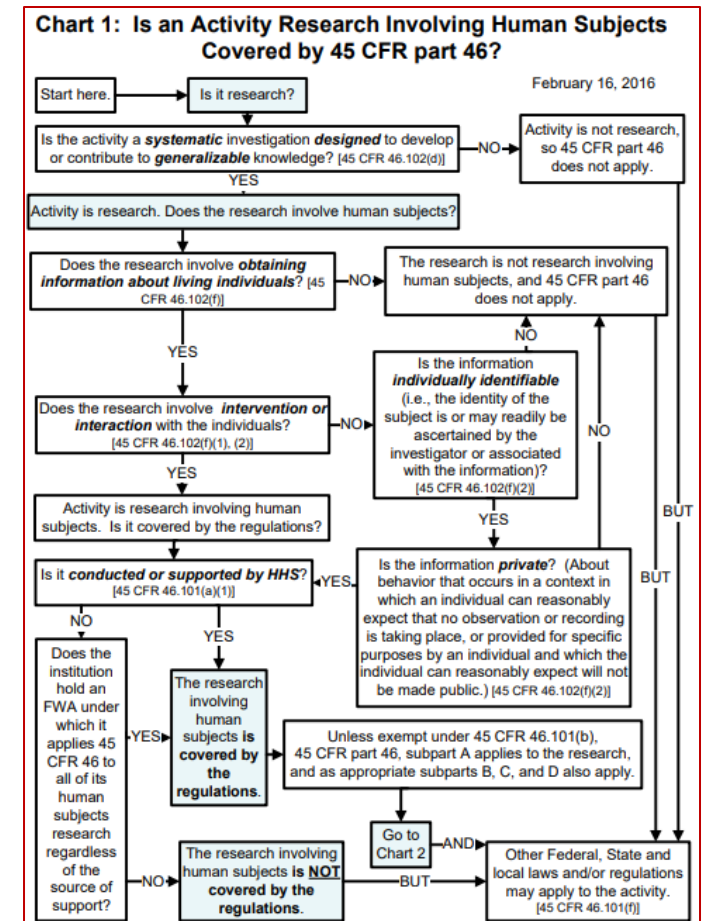
# Objectives of THIS guidance: *Barry's IRB*

- Overview of Barry University IRB process
- Protocol forms and procedures
  - Full board, Exempt, Expedited
- Review process and possible outcomes
- Protocol form examples and boilerplate language
- Reporting requirements and forms
- Additional issues

*See posted [IRBGuidance CITI](#) and [IRBGuidance IRBNet](#).*

# Not covered in this presentation (see Resources)

- History of research ethics and federal creation of IRBs in the U.S.
- Barry policy on Classroom and Student Research (see IRB website)
- OHRP Decision Charts (11 charts)
  - What constitutes research with human subjects?
  - Can the study be exempt or expedited?
  - Can consent or documentation of consent be waived?



# Meetings and deadlines for submission

- Barry's IRB meets 10 times each year
  - No meeting is held in July or December
- Meetings are *generally* third Wednesday
  - 1 PM to 4 PM
  - Check <https://www.barry.edu/irb/> for meeting location
- Full board review: Submissions must be received by noon on first Friday of each month in which there is a meeting.
- Exempt and expedited protocols are accepted at any time.
  - Note: If the reviewer determines that a protocol submitted for exempt/ expedited review must go to full board, the protocol will be reviewed at the next meeting only provided that the protocol was received by the deadline.

# Submission types

- Full board review: It is recommended that you attend the meeting *either in person or remotely* (schedule a remote connection with the IRB point of contact, Anoush McNamee at 305-899-3020 or amcnamee@barry.edu)
- Exempt review
  - Exemption categories were revised during 2019.
  - If judged exempt, receive decision/feedback via IRBNet (email notice)
  - If not judged exempt, will be reviewed at the next meeting of the full board
  - ***New procedure: Protocols determined to be exempt will have no expiration date and require no annual report.***
- Expedited review
  - Can be requested for time sensitive projects (e.g., class projects)
  - Can be requested for exempt or non-exempt studies.

***\*All submission types use the same form.\****

***Download the form from IRBNet.org***

***Forms & Templates***

**Barry University  
Institutional Review Board  
Protocol Form**  
*Full Board / Exempt / Expedited  
Adopted January 2020*

**Shaded Areas for IRB Use Only**

Primary Reviewer:	
Protocol #	

Title of Project	
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<b>Researchers Complete All Unshaded Sections.</b> If an item is not applicable, leave it blank. For guidance, see <i>IRBGuidance Protocol Process</i> , which is available on IRBNet > Forms and Templates.	N/A	YES	NO
<b>Are you requesting <i>expedited</i> review?</b> <i>If so, provide justification for the request.</i>  Yes <input type="checkbox"/> No <input type="checkbox"/>			
<b>Principal Investigator (PI) Provide:</b> <ul style="list-style-type: none"> <li>• Name</li> <li>• Campus address for Faculty</li> <li>• Home address for Students</li> <li>• Telephone</li> <li>• Barry email</li> </ul>			
<b>Faculty Sponsor</b> (for student projects only)			
<b>School/Department/Unit</b>			

Barry University  
 Institutional Review Board  
 Protocol Form  
 Full Board / Exempt / Expedited  
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**Shaded Areas for IRB Use Only**

Primary Reviewer:	
Protocol #	

Title of Project	
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<b>Researchers Complete All Unshaded Sections.</b> If an item is not applicable, leave it blank. For guidance, see IRB Guidance Protocol Process, which is available on IRBNet > Forms and Templates.	N/A	YES	NO
<b>Are you requesting expedited review?</b> If so, provide justification for the request. Yes <input type="checkbox"/> No <input type="checkbox"/>			
<b>Principal Investigator (PI) Provide:</b> <ul style="list-style-type: none"> <li>• Name</li> <li>• Campus address for Faculty</li> <li>• Home address for Students</li> <li>• Telephone</li> <li>• Barry email</li> </ul>			
<b>Faculty Sponsor</b> (for student projects only)			
<b>School/Department/Unit</b>			

*Researchers & reviewers complete the same form.*

If revisions are required, researchers receive official "Revision Letter" along with original submitted protocol with reviewer requests for revision in the relevant section.

## Research with Human Subjects Protocol Review

### REQUIRED REVISIONS TO BE VERIFIED BY CHAIR

Date:	xxx
Protocol Number:	xxx
Study Title:	xxx
Principal Investigator:	xxx
Faculty Sponsor:	xxx
Number of revisions required:	xxx
Attachment:	Reviewer Worksheet with Feedback

Revision  
letter notes  
number of  
required  
revisions  
and...

Dear Researcher:

Your protocol has been reviewed and will be approved pending receipt and approval of required revisions to your protocol. The revisions are numbered and described (**red font**) on your protocol form (attached to this email and/or uploaded to IRBNet). Data collection may commence only when you have obtained an approval letter.

Dear Researcher:

Your protocol has been reviewed and will be approved pending receipt and approval of required revisions to your protocol. The revisions are numbered and described (**red font**) on your protocol form (uploaded to IRBNet). Data collection may commence only when you have obtained an approval letter.

Submit 2 copies of the revised protocol and any ancillary revised documents.

- Highlighted copy
  - Submit
    - One copy of the protocol that includes the following:
      - Reviewer's comments
      - *Highlighted and numbered* changes in response to the comments.
    - Revised *ancillary documents* with revisions *highlighted* and *numbered* to correspond to the requested revision.
  - Do *not* include all tracked changes, simply highlight the revisions that your reviewer requested.
- Clean copy
  - Submit a second copy of the protocol that is a "clean" copy (remove reviewer's comments, numbers, and highlights). *Do not remove any reviewer markings from the shaded areas.*
  - Also, submit each revised ancillary document as a clean copy (no highlights or numbers).

**IMPORTANT: Re-submit your revised protocol as a New Package in your original Project. Download the *IRBGuidance - IRBNet*--from the IRBNet library for guidance in how to add a new Package to an existing Project. The package must be signed by the PI. For student research, it must also be signed by the faculty sponsor.**

If you have questions or need any additional assistance from the IRB, please contact the IRB point of contact, Ms. Anoush McNamee (305-899-3020 or amcnamee@barry.edu).

Instructions  
for  
resubmission

3

If requesting **EXEMPT** review, mark “yes”, indicate category, and explain.

<p><b>Does your study meet one of the categories for Exempt status?</b>  <i>If yes, check “Yes” below, mark the appropriate category, and explain below.</i></p>	<p><b>2019 Exempt Categories</b>  <i>(see OHRP guidelines for full description of exempt criteria)</i></p>		
<p>Exempt YES <input type="checkbox"/>          Exempt NO <input type="checkbox"/></p>	1. Educational research (applicable to minors)		
	2. Educational tests, surveys, interviews, observation of public behavior (limited application to minors)		
	3. Benign behavioral interventions ( <u>not</u> applicable to minors)		
	4. Secondary research for which consent is not required (applicable to minors)		
	5. Federally supported research and demonstration projects (applicable to minors)		
	6. Taste and food quality studies (applicable to minors)		
	7. Storage or maintenance of biospecimens for potential secondary research (applicable to minors)		
	8. Secondary research for which broad consent is required (applicable to minors)		
<p>If yes, explain specifically which conditions are satisfied under the exemption category to qualify the study as exempt.</p>			

# Examples of appropriate exemption rationale...

*This study fits the criteria for a category 2 exemption because it is an anonymous survey of adults.*

*OR*

*This study fits the criteria for a category 2 exemption because it involves interviews of adults, no identifying information will be recorded during the study, and the focus of the study poses no risk to participants.*

*OR*

*This action research study fits the criteria for a category 1 exemption because it is a study of normal educational practices in the teacher/researcher's own classroom.*

If requesting **EXPEDITED** review  
mark the appropriate item & justify your request.

<p>Are you requesting <i>expedited</i> review? If so, provide justification for the request.</p> <p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p>	
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# IRB Exempt Category Revisions

New Federal Guidelines  
Effective January 21, 2019

# IRB Exempt Category Revisions- Summary

- Two new categories were added
  - Previous guidelines had six Exempt categories
  - Revised guidelines now have eight Exempt categories
    - New Categories 7 & 8 Address Issues of Storage/Maintenance of Data/Specimens and Secondary use of Data/Specimens (Broad Consent) which are not currently applicable to Barry's IRB and will not be covered in this presentation
- All but one category was revised
  - Revisions to Categories 1-3 Primarily Apply to the Current Work of Barry's IRB
  - Exempt Category 6: Food acceptance studies – Unchanged
- Two new processes were introduced with the new categories:
  - Limited IRB review (Similar to Barry's Current Exempt Review Process)
  - Broad consent (Not Currently Applicable to Barry's IRB)

# IRB Exempt Category Revisions: Category 1 Educational Research-

## Same Category Name and Number: Minor Revisions

- **Pre 2018 Definition:**

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
  - (i) research on regular and special education instructional strategies, or
  - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- **Revision maintains much of the same text but adds the condition that the research should not adversely impact students' opportunity to learn required educational content or the assessment of educators.**

- **New Definition:**

- (1) Research, conducted in established or commonly accepted educational settings, *that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction*. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

# IRB Exempt Category Revisions:

## Category 2 Surveys/Educational Tests, Interviews or Observations of Public Behavior -

### Same Category Name and Number: Revisions Clarify Applicable Research

- **Pre 2018 Definition:**

- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- Revisions clarify that this category only applies to the types of interactions specified.
- Broadens the applicable research to include visual and audio recordings.
- Adds educational advancement as a risk of any disclosures of the participants' responses outside of the research.
- Major revision allows for the inclusion of identifiable AND sensitive surveys/interviews as approved by an IRB limited review.

- **New Definition:**

- (2) Research that *only includes interactions* involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
  - (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
  - (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, *educational advancement*, or reputation; or
  - (iii) *The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).*

# IRB Exempt Category Revisions:

## Category 3- Benign Behavioral Interventions

### NEW Text As Previous Category 3 Text Was Eliminated

- Former Category 3 was eliminated and replaced.
- Category is for “benign behavioral interventions” involving adults participants only.
- Benign behavioral interventions are defined as “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing” (HHS 2017)
- Examples:
  - having subjects play an online game
  - having subjects solve puzzles under various noise conditions
  - having subjects decide how to allocate a nominal amount of received cash between themselves and someone else
- Exemption is permitted if the data are recorded in such a way that the identity of the subjects cannot be readily ascertained either directly or indirectly or if the subjects’ identities can be ascertained, a disclosure of the responses outside the research setting would not reasonably place the subjects at risk of harm.
- If the subjects’ identities can readily be ascertained and if a disclosure of subjects’ responses has potential to harm subjects, the exemption is permitted if the IRB conducts a *limited review* and determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- If a study involves deception, it is not eligible under this category unless participants are told during the recruitment/consent process that there is an element of deception in the study and they agree to participate.

- **Definition:**

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

# IRB Exempt Category Revisions: Category 4 Secondary Research for Which Consent is not Required - Same Category Number: Category Rewritten

- **Pre 2018 Definition:**

- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- Category completely rewritten now allowing for both existing as well prospective data collection.
- Allows for private identifiable data or biospecimens.
- Also covers when data is regulated under HIPAA and when the research is conducted by or on behalf of a federally funded department or agency.

- **New Definition:**

- (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
  - (i) The identifiable private information or identifiable biospecimens are publicly available;
  - (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
  - (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
  - (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

# IRB Exempt Category Revisions:

## Category 5 Research and Demonstration Projects-

### Same Category Name and Number: Minor Revisions

- **Pre 2018 Definition:**
  - (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
    - (i) Public benefit or service programs;
    - (ii) procedures for obtaining benefits or services under those programs;
    - (iii) possible changes in or alternatives to those programs or procedures; or
    - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
  - **Revisions primarily clarify research conducted/funded by the federal government and/or its agencies.**
- **New Definition:**
  - (5) Research and demonstration projects that are conducted or supported by a *Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and* that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. *Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.*
    - (i) *Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.*
    - (ii) [Reserved]

# Exemption category 6 (unchanged)

- **Category 6:** Taste and food quality evaluation and consumer acceptance studies,
  - (i) if wholesome foods without additives are consumed or
  - (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.  
(Applicable to minors)

*Taste and food quality studies*

# New exemptions

- New Categories 7 & 8 Address Issues of Storage/Maintenance of Data/Specimens and Secondary use of Data/Specimens (Broad Consent) which are not currently applicable to Barry's IRB.

# Submission components: You must submit...

- Protocol form
- Consent document(s)
  - Consent form—includes signature lines for PI and participant
  - “Cover letter”—exactly the same consent information with no signatures
    - Adds additional privacy protection. Must be no risk study
- Participants under age 18: Require parental consent and child assent forms
- Ethics training certificates: All researcher(s) and faculty sponsor (if applicable)
- Recruitment documents: Flyer, recruitment email, recruitment script
- Instruments, e.g.:
  - Survey questions
  - Guiding interview/focus group questions

*It is no longer necessary to submit thesis/dissertation.*

# Submission process

- Access and follow Barry's *most recent* guidance for Using IRBNet, which is posted with ***Forms and Templates*** on <https://www.irbnet.org/>


IRBGuidance IRBNET

# Review process

- IRB Contact checks all submissions
  - Assigns complete submissions to a reviewer
  - Returns incomplete submissions to researchers with guidance
- Reviewer
  - Receives notice from IRBNet that a project is waiting for review
  - Reviews within 7 days, adding feedback directly to the protocol form
  - Makes a recommendation to the IRBChair/Co-Chair
  - Submits to the IRBChair/Co-Chair on IRBNet
- IRBChair/Co-Chair
  - Reviews feedback and recommendation
  - Drafts Approval Letter, Approval Exempt Letter, or Revision Letter
  - Posts letter and feedback to researcher on IRBNet
- Possible outcomes...

# Possible outcomes

Reviewer's Recommendation	
Approve as submitted	→ Approval Letter
Approved with required revisions verified by Chair	→ Revision Letter
Approve Exempt	→ Approval Letter
Approve Exempt with required revisions verified by Chair	→ Revision Letter
Defer—Work with reviewer on revision	→ Defer/Revision Letter
Defer—Resubmit for Full Board Review at a future scheduled meeting of the Board	
Disapprove	→ Discussion with IRB Chair about the potential for revisions that would be required for future success—Per federal guidelines, a project can be disapproved only at a full board meeting.



Deferral Letter

# Required components of submissions

1. Title of the project must be identical everyplace that it appears in any documents (e.g., protocol form, consent, flyer).
2. Provide information for all members of the research team.

# CITI certificates: Research ethics training evidence

- Two CITI courses are required
  1. Basic course (either Social/Behavioral Research OR Biomedical)
  2. Responsible Conduct of Research (either Social/Behavioral Research OR Biomedical)
- CITI certificates are required for
  - Each member of the research team
  - The faculty sponsor (for student research)
- Submitting CITI certificates
  - See *Guidance IRBNet* for instructions on uploading certificates to USER PROFILE and LINKING to project.

# Protocol questions & boilerplate language

*Note that this is not required language, but examples of language that are similar to the language that the IRB reviewers will be looking for.*

*You must edit the language to be specific to your study. For example, if you are not using focus groups or audio recordings, you must remove reference to those items.*

*Using boilerplate language does not guarantee approval as is, but should put you in the general vicinity of what the reviewer is looking for.*

# Maximum number of participants

- *This means the “total number of participants with whom you will interact after they have agreed to participate following informed consent.”*
- *That is, if a participant drops out, you still have to count them as a participant. Consequently, you want to overestimate the number of your participants with whom you may interact, to account for attrition or bad data.*
- *The IRB doesn't care how many participants that you have as long as you don't interact with even one more than you have listed here.*
- *Add description here, as necessary, to help reviewers understand (e.g., a maximum of 4 interview participants, 20 focus group participants, and 100 survey participants).*
- *Be consistent across all sections of your protocol.*

**Abstract** (200 words or less)

*The abstract should include short descriptions of the purpose of the study, participants, design, methods, and implications of the findings.*

*A good abstract should include one short sentence each about:*

- *Problem addressed by the study or the purpose of the study*
- *Participants*
- *Instruments*
- *Procedure: What will your participants be asked to do?*
- *Implications*

*This question asks only about how you will recruit your participants.*

- *Describe your target population*
- *How will you approach potential participants to invite them to participate?*
  - *Email (If so, include email script as an appendix.)*
  - *Telephone (If so, include script of your conversation as an appendix.)*
  - *Gatekeeper (If so, who will be the gatekeeper and what will be their role?)*
  - *Hard copy flyer (If so, how will you disseminate the flyer? Include flyer as an appendix.)*
  - *Electronic flyer (If so, how will you disseminate the electronic flyer? Include as appendix.)*
- *Recruitment language should be inviting, directed to the participant, and should provide only an overview of the study from the perspective of what the participant will be asked to do. (Do not include informed consent details in your recruitment materials.)*

## **Recruitment Procedures**

*Describe the selection of participants, methods of recruitment, and recruitment materials that will be used (e.g., email, letter, or Flyer). Upload each as a separate document to IRBNet.*

## **Methods**

*Describe procedures to which participants will be subjected. If deceptive techniques will be used, describe and justify the deception and describe debriefing procedures.*

*This section should include everything that is part of your methodology, with particular emphasis on the activities of the participants and how researchers will interact with them.*

- Add any additional participant description not address in recruitment section.*
- Instruments that you will use (tests, surveys, questionnaires, guiding questions)*
- Interventions (what, where, how, how long, whom?)*
- Data gathering procedures*
  - Surveys/questionnaires/tests (how and where will you administer?)*
  - Interviews/focus groups (how and where will you conduct these activities?)*
- Include the total time commitment that is being requested from participants. Time commitment should be consistent across all documents.*

- You must include a benefits statement in the protocol and also on your informed consent document.

- *Boilerplate language options (edit as necessary)*

- *Protocol (writing to the reviewers)*

- *There are no direct benefits to participants.*

- *There are no direct benefits to participants. However, the research will inform our understanding...*

- *Consent document (writing to potential participants)*

- *There are no direct benefits to you for participating in the study.*

- *Although there may be no direct benefit to you, the research will help us learn more about ...*

### **Benefits statement**

*Describe benefits to the individual participant and/or society. Note that incentives or compensation paid to participants are not considered benefits to participating in your study.*

<b>Risk statement</b> <i>Describe physical, psychological, and/or social risks to the participant and precautions that will be taken to minimize them.</i>					
<b>Indicate level of risk</b>	<table border="1"> <tr> <td data-bbox="733 325 802 382"></td> <td data-bbox="802 325 1888 382">Minimal risk</td> </tr> <tr> <td data-bbox="733 382 802 445"></td> <td data-bbox="802 382 1888 445">More than minimal risk</td> </tr> </table>		Minimal risk		More than minimal risk
	Minimal risk				
	More than minimal risk				

*Check box*

*Describe risk.*

## *Boilerplate language option (edit as necessary)*

- *No/Minimal risk*
  - *There are no known risks to participating in this study.*
  - *Risks to participating in this study are no greater than those encountered in everyday life.*
- *Risk: In studies with risk, you must describe the risks and address what you will do should there be a negative outcome, such as providing referral information regarding available services.*
  - *Risks to participating in this study include... Should you feel the need for support following your participation in this study, please call xxx hotline number at ...*

## Anonymity/Confidentiality

Describe methods to be used to ensure the confidentiality of data obtained. Note that Barry University requires that data be kept securely for at least five years following completion of the study. You may keep study data indefinitely.

## **Boilerplate language option (edit as necessary)**

*All study data (i.e., observation, interview, focus group, implementation, and outcome data) will be kept confidential. No participant, site, or institution names will be used in reports of the findings. Participants' names (including consent forms) will be stored separately from the data. Audio recordings will be captured and stored digitally on password protected devices, and transcribed by researchers. In the event that external transcription is sought, non-researcher transcriptionists will sign confidentiality agreements. Electronic data (including transcripts) will be stored on password protected computers. Hard copy data will be locked in a researcher's office. All data will be kept indefinitely, for at least five years following completion of the study. If it becomes necessary to destroy the data at a later time, electronic data will be destroyed by double deleting from the hard drive and Recycle Bin. Hard copy data will be shredded.*

**Edit this language, as necessary. Do not include language that is not relevant to your study.**

Also, the new federal guidelines allow de-identified data to be used in future studies without obtaining additional consent. Therefore, you should include one of the following statements in the protocol and consent document:

- *These data—with identifiers removed--may also be used in future research or distributed to another investigator without additional informed consent.*
- *These data will not be used or distributed for future research studies.*

# Consent types/documents

Although there are also additional formatting options, most Barry protocols use one of the following consent strategies. *All documents must include all informed consent information.*

- Informed Consent Form: Requires signature of the participant & researcher
- Cover Letter: Identical to Informed Consent Form, but requires no signature.
  - Purpose: Additional protection of participant's privacy.
- Electronic Survey (e.g., SurveyMonkey) Consent
  - Opens as the first page of an electronic survey
  - Does not require "I agree to participate in this study". Consent is assumed if the participant completes the survey.

Following Approval

# Reporting Requirements and Forms (IRBNet)

- Annual and Final Reports
  - Approval period is one year
  - You will receive a reminder from the IRBNet 30 days before the report is due.
  - The Annual and Final Report Form is available on IRBNet.
  - Please complete and upload to your project as a New Package.
- Conflict of Interest
- Changes to Protocol (Modification Form)
- Adverse Events
  - Actual direct harm to a participant
  - Procedural breach (e.g., forgetting to get informed consent prior to gathering data)
- Third Party Confidentiality
- IRB of Record (working with collaborating institutions – optional)

# Request Modifications to your approved protocol on the *Modification Form*

- Modifications to your approved protocol *that affect the way that you interact with participants or increase risk to participants* require submission/approval of the change.
- Request approval using Modification Form, available on IRBNet.
- Modifications are reviewed by the IRB Chair/Co-Chair.
- Do not change procedure until you receive approval of the change.
- Submit Modification Form as a NEW PACKAGE in your original IRBNet project (See **IRBGuidance IRBNet**)

# Approval period/ Request for extension

**Barry University**  
Research with Human Participants  
Annual Report Form  
*Form revised August 2019*

Date: \_\_\_\_\_  
Title of study: \_\_\_\_\_  
Protocol Number: \_\_\_\_\_  
Principal investigator name: \_\_\_\_\_  
Faculty sponsor (if applicable): \_\_\_\_\_  
Name of person completing form: \_\_\_\_\_

Please select one.

This study is closed

Request extension

Per federal guidelines, approvals are granted for one year.

Requests to extend the research are made using the Annual Report Form.

# Other IRB issues

- Informed consent waivers
  - Consent
  - Documentation of consent
- Anonymous vs. confidential (Barry definitions)
  - Anonymous: You don't know who your participants are (e.g., anonymous survey)
  - Confidential: You know who your participants are, but you will not disclose.
  - Focus groups are neither anonymous nor confidential.
    - *Include language such as this in consent document: "Confidentiality cannot be guaranteed in a focus group setting. Although the researcher will keep all data confidential, confidentiality of focus group participants cannot be assured."*

# Additional Guidance

- When you submit a protocol, the Barry IRB Contact, IRB Chair, Co-Chair, and Administrators receive email notification.
- Additional guidance available on *IRBNet > Forms & Templates*
  - For guidance on CITI certification, download the most current version of the ***IRBGuidance CITI***
  - For guidance on using IRBNet, download the most current version of the ***IRBGuidance IRBNET***

# Resources

- Barry IRB: <http://www.barry.edu/irb/>
- Barry Policy on Classroom and Student Research: <https://barrystorage.blob.core.windows.net/assets/docs/irb/policyclassroomstudentresearch.pdf>
- CITI: CITI
  - Home: <https://about.citiprogram.org/>
  - Guidance: <https://support.citiprogram.org/customer/en/portal/articles/2736167-login-registration-changes-on-new-citi-program-website#read>
- Federal Policy for the Protection of Human Subjects/Common Rule/45 CFR 46 (Code of Federal Regulations): <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>
- IRBNet: <https://www.irbnet.org/>
  - IRBNet Sandbox for training: <http://training.irbnet.org> (See IRBNet Guidance PowerPoint)
- Office for Human Research Protections of the U. S. Department of Health & Human Services (OHRP): <https://www.hhs.gov/ohrp/>
- OHRP Human Subject Regulations Decision Charts: <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html>
- Revised Common Rule 2019: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>

# Questions?

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