1. **Date of submission (M/D/YYYY)**
2. **Title of the research proposal:**
3. **Principal Investigator:** [ ]  Faculty [ ] Student [ ] Other

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| Name | Phone Number | Email Address |
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1. **Potential Conflict of Interest**

Is there a potential conflict of interest for the Principal Investigator or key research personnel? (Applicable only if the researcher has a financial conflict of interest). See <http://www.hhs.gov/ohrp/archive/humansubjects/finreltn/fguid.pdf> for federal guidance on this matter.)

Yes [ ]

No [ ]

If yes, supply details:

1. **Names of all researchers engaged in the study.**
	1. If a faculty member intends to involve students in the execution of a research project, the names of the students should be included. If several students are participating in a research project, they should all be listed. The University of Richmond requires that all researchers working with human subjects take online training courses provided by the Collaborative Institutional Training Initiative (CITI). See the [IRB website](http://irb.richmond.edu) section on “Researcher Training Requirements” for registration instructions. The researcher listed first on the form should be the Principal Investigator.

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| Name | Position | Email Address | Date of CITI Training Completion(MM/DD/YY) |
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* 1. **If more than 6 researchers are engaged in the study, list additional researchers and their email addresses here.**

1. **Department or program in which the research is based (e.g., Psychology). If research is for a course, list the course number here (e.g., Psyc 361).**

1. **Approval of the advising faculty member (if student research).**

If a proposal is submitted electronically by a student, it will be forwarded to the faculty advisor by the Chair of the IRB. The faculty advisor should then reply with a statement of endorsement such as “I am the faculty advisor for this research proposal I have reviewed the proposal and approved its submission to the IRB.” If the faculty advisor has not approved the proposal for submission to the IRB, he or she should inform the IRB Chair. The student researcher will be informed and the proposal will be held until the faculty advisor’s approval is obtained. Enter the name and email address of the faculty advisor:

1. **Qualifications of Principal Investigator**

Brief information on the researcher, as it relates to the research proposal (e.g. demonstrating the competence of the researcher to complete the research).

1. **Study Abstract**

A brief summary of the study. (Approximately 200 words.)

1. **Literature Review**

A literature review as it relates to the research benefits and goals of the study. The literature review will generally communicate the role of this study in the broader field of knowledge in which the research is being performed. The IRB uses this information in its assessment of benefits and risks. Recommended length 500 words or less, plus references.

1. **Detailed information on the study proposal**
	1. ***Study hypothesis or objective. What is the purpose of the study?***

* 1. ***What is the overall benefit of the study?***

* 1. ***List the benefits and risks of the study to study participants.*** *(Note that this section must address both benefits and risks. If the researcher knows of no risks, a phrase similar to the following may be used “no more than minimal risks to subjects are anticipated”. If the researcher knows of risks, they should be detailed here. See “Examples” at “Full Proposals” under the “Submitting Proposals” section of the IRB website.) Benefits should focus on benefits to the subjects. If there are no direct benefits to subjects, simply state that “there are no direct benefits to study participants”.*

* 1. ***Study Procedures.*** *(How will the study be carried out? This section will likely be the largest part of the proposal).*
		1. *Description of procedures.*

* + 1. *Description of the subject populations. (Special populations, such as minors (anyone under 18), non-English speaking, etc. may require additional information.)*
			1. *Approximate anticipated number of subjects to be recruited for the study.*

* + - 1. *Rationale for inclusion or exclusion of subjects.*

* + - 1. *Recruitment procedures. Check all that apply. If any email messages, posters, or class announcements will be used to recruit participants, provide the IRB with a verbatim copy of the message as an attachment to the proposal.*

[ ]  Email [ ] Spider Bytes [ ] Poster [ ] Class announcement

[ ] Newspaper Ad [ ] Telephone [ ] Other

* + 1. *Participant compensation, if any.*

* + 1. *Discussion of investigators’ interaction with subjects.*

* + 1. *Provisions for confidentiality and/or anonymity of subjects. “Confidentiality” refers to the process by which a research will keep a subject’s identity from becoming known. “Anonymity” refers to a subject population where the identities of subjects cannot be ascertained by anyone, including the researcher. This section should include a data protection plan that details how data will be stored and when and how the data will be disposed of.*

* + 1. *Will sensitive information be collected, such as information regarding sexual behavior, drug use, or any information that if revealed could result in legal, reputational or employment problems for a subject?*

*[ ]*  No

[ ]  Yes

*If yes, explain how you will give special consideration to the collection and storage of these data.*

* + 1. *Discussion of how the informed consent of subjects will be obtained. (Be sure to provide copies of your consent forms with your proposal. See below for details.)*

* + 1. *Consent procedure for Internet questionnaires.* Generally, internet consent can be obtained by describing the study, its risks, etc. and including a statement similar to the following on the consent form: “I have read and understand the study description and by clicking below and completing the survey, I am indicating my agreement to participate in the study and I attest that I am over 18 years of age.” *Generally, the IRB will only approve internet consent for minimal risk proposals.*

* 1. ***Discussion of how study results will be disseminated.*** *For example, will the results be submitted for publication? Will results be used in the University of Richmond Student Symposium? Posted on the web? Specify use of results in the following space.*

**Other documents to be included:**

1. **Consent forms (see IRB website for examples of consent forms).**

NOTE: Consent forms should be submitted as separate documents to preserve their formatting.

* *Consent forms for adult subjects (persons 18 and over). For persons under 18 years of age, a parental consent form and a subject assent form are required.*
* *Consent forms should be both comprehensive and precise. For most student research, consent forms should be one page. Consent forms should include the following sections:*

***The name of the study.*** *The name of the study should be at the top of the consent form. It should be the same as the title of the proposal in Item 2.*

***Project description and purpose.*** *This section should include a brief project description, information on the purpose of the study, and an estimate of the time that it will take for a subject to participate (e.g. “the survey will take 20 minutes to complete.”*

***Benefits and risks to subjects.*** *Consider whether or not there are “no more than minimal risks” to subjects. If there are “no direct benefits to subjects” state this. It is important that all known risks be made known to subjects.*

***Information on principal investigator****. This section should include brief information on the PI, including contact information. Students should include the name of and contact information for the faculty advisor.*

***A “voluntary participation” section****. This section should inform subjects that their participation is voluntary; that they can withdraw their consent at any time, and they can decline to answer any question(s) they may not wish to answer.*

***Information on the use of the information and data collected.*** *This section should include whether or not the information will be submitted for publication, posted on the internet, and/or used in any other public forum.*

***Confidentiality (or anonymity) provisions****. Subjects must be informed of any confidentiality or anonymity provisions of the study. Remember that “anonymity” means that even the researcher does not know the identity of the respondent.*

***Participants’ rights section****. This section should inform subjects that they have the right to contact the University of Richmond IRB if they have any questions on their rights as participants. Include IRB contact information (email and phone).*

***Documentation of participants’ consent.***  *Usually, the signature of the subjects should be acquired, as well as an attestation that the subject is over 18 years of age. See the* [*UR IRB website*](http://irb.richmond.edu) *for examples of how to handle consent for internet-based surveys and forms.*

1. **Copies of any surveys, questionnaires, or interview protocols to be used in the research, including Internet questionnaires.** Surveys and other data collection instruments should be submitted as a separate document(s) to preserve their formatting. Normally, this form and accompanying documents such as a survey, the consent form, and recruiting materials will be submitted to the UR IRB Chair via email (irb@richmond.edu ) along with a brief explanatory cover statement.
2. **Copies of debriefing information (if needed).**

Debriefings may be used to explain the purpose of the study, give further instruction, address potential participant questions, or provide information on services that may be available to subjects. Studies involving deception must include a debriefing strategy that leaves research subjects in the same condition that they were in prior to participating in the study. *Note that studies involving deception cannot be reviewed using the expedited process. Submit copies of debriefing materials as attachments to the proposal.*

1. **Copies of recruiting information (if applicable), including posters, emails and other relevant materials that will be used.** *Submit copies of recruiting materials as attachments to the proposal.*
2. **Completion of CITI training.**

The University of Richmond requires that all researchers working with human subjects take online training courses provided by the Collaborative Institutional Training Initiative (CITI). See the IRB website section on “[Researcher Training Requirements](http://irb.richmond.edu/training-requirements/index.html)” for registration instructions. The form may be submitted prior to the completion of CITI training by all participants but final approval will not be given until at least the Principal Investigator has completed required training.

1. **Information on grants associated with the research, if applicable.**
2. **Other materials as may be appropriate.**

**COMPLETE THE FOLLOWING SECTION ONLY IF THIS IS A RENEWAL OF A PREVIOUSLY APPROVED IRB**

Submit a renewal proposal as a pdf document with changed dates and other modifications highlighted in yellow (see instructions at the end of this form). A renewal must be submitted prior to the expiration of the approval or exemption period and should allow time for review. (Generally allow two weeks prior to the expiration date). Federal regulations and UR policy both allow for a maximum approval period of no more than one year. *If a renewal is submitted after the expiration date, a new proposal must be submitted.*

1. What was the date of the previous IRB approval (MM/DD/YY)?

2. How many participants have participated in this study?

|  |  |  |
| --- | --- | --- |
| Number consented in last IRB period | Number of withdrawals in the last IRB period | Total completed in the last IRB period |
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3. Were there any unanticipated or adverse effects reported by participants?

 [ ]  No

 [ ]  Yes

If you answered Yes above, provide a detailed explanation of the unanticipated/adverse effect, including how many participants were affected.

4. Is the subject population unchanged?

 [ ]  Yes

 [ ]  No

If you answered No above, provide a detailed explanations of the changes.

5. Is the substance of the proposal changed in any way?

 [ ]  No

 [ ]  Yes

If you answered Yes above, provide an explanation of each change in the proposal in the email that accompanies the renewal and submit a pdf of the renewal application with all changes highlighted in yellow (see instructions below).

***Submit an electronic version of this form AND all attachments directly to the IRB Chair by email at*** ***irb@richmond.edu***

**INSTRUCTIONS FOR CREATING A PDF DOCUMENT WITH HIGHLIGHTS:**

After using WORD to modify the proposal for renewal, you will need to highlight any modifications, including the dates, in yellow. Text in the IRB form cannot be highlighted using WORD. You must first save the document as a pdf and use Adobe Acrobat Pro to highlight your changes.

1. From the WORD FILE menu, choose *Save As* . In the new popup window, select a name and location, and then choose *PDF* from the FORMAT dropdown menu. Press *Save.*

2. Open the document in Adobe Acrobat Pro.

Select the text highlight tool from the menu bar . You can also find this tool in the *Comments and Markup* submenu in the *TOOLS* menu on the main menu bar. Once the tool is selected, simply drag the cursor over the text you wish to highlight. If you wish to undo the highlight, click on the highlighted text and press the delete button on your keyboard. Save the highlighted document.

