The 2018 changes to the Common Rule (45 CFR 46) require that consent forms “must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.” This key information is only required to be included for non-exempt research (i.e., Expedited or Full Board review).

**STUDY TITLE**

*List the formal study title (i.e., title as it appears on the IRB Application). If the formal study title is too long or includes technical terminology, you may consider creating a brief title that participants will better understand.*

**PRINCIPAL INVESTIGATORS**

*List the Principal Investigator and any other study personnel that participants may need to contact. Include appropriate contact information*

Example:

**Principal Investigator:** Jane Smith, Ph.D. Office: (402) 472-1000 Email: jsmith@uri.edu

**Secondary Investigator:** John Doe, Ph.D. Office (402) 472-2000 Email: jdoe@uri.edu

**KEY INFORMATION**

Important information to know about this research study:

* The purpose of the study is to <<briefly describe study purpose>>.
* If you choose to participate, you will be asked to <<do what, when, where, and how>>. This will take approximately <<period of time>>.
* Risks or discomforts from this research include <<briefly describe/ or state minimal risks>>.
* The study will <<description of potential direct benefits to subjects – or no benefits>>.
* You will be paid <<X>> amount for your participation
* You will be provided a copy of this consent form.
* Taking part in this research project is voluntary. You don’t have to participate and you can stop it any time.

**INVITATION**

*Invite the prospective subject to participate in the study using the following standard invitation to participate.*

You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to participate. If you have any questions, please ask.

**Why are you being asked to be in this research study?**

*Explain succinctly and simplistically why the prospective subject is eligible to participate. As appropriate, major eligibility criteria may be included in this section.*

Example: You are being asked to be in this study because you are either an employee or a supervisor working a night shift. You must be 19 years of age or older to participate.

**What is the reason for doing this research study?**

*This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential subject understand why the research is being done. The information should be provided in simplistic language without reference to the subject.*

Example: People who work at night employ different strategies for staying awake during their shifts. These methods are likely to be different between employees and supervisors, because of their different levels of responsibility. This research is designed to (1) better understand these strategies and (2) determine whether ‘supervisor strategies’ could be successfully used by employees.

**What will be done during this research study?**

*Describe the procedures and their duration chronologically using simplistic language, short sentences or short paragraphs. The use of subheadings may help organize this section and increase readability for studies with a large number of procedures.*

Example: You will be asked to complete 5 surveys using an internet based questionnaire. Each survey will take 1-2 hours to complete and you may complete them from your home computer, one each week for 5 weeks.

**How will my** **<<data/samples/images>> be used?**

*If the research involves collection and/or sharing of data/biospecimens/images to other researchers include the following statements as applicable. One of them must be included.*

Example: Your **<<**data/samples/images**>>**  will be sent to researchers outside of the University of Rhode Island for <<explain why the samples are being sent outside URI>>. Any personal information that could identify you will be removed before the **<<**data/samples/images**>>** are shared.

*If the research involves collection and/or sharing of identifiable data/samples/images to other researchers include the following statement.*

Example: Your **<<**data/samples/images**>>** will be sent to researchers outside of the University of Rhode Island for [explain why the samples are being sent outside URI]. The **<<**data/samples/images**>>** that are sent to these researchers will contain identifiable information including [describe the identifiable information that will be associated with the data]. Identifiable information is being sent to these researchers because [explain the purpose of sending identifiable data to researchers outside URI.

*One of the following statements must be included about any research that involves the collection of identifiable private information or identifiable biospecimens: this also includes If you are possibly allowing students to use for thesis or dissertation:*

*A statement that Identifiers might be removed from << the identifiable private information or identifiable biospecimens>> and that, after such removal, the << information or biospecimens>> could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you (or the legally authorized representative, if applicable).*

***or*** *A statement that The subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.*

**What are the possible risks of being in this research study?**

*Identify each procedure with a subheading and then state the associated risk(s) using simplistic language. The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and emotional or psychological distress.*

Example: This research presents risk of loss of confidentiality, emotional and/or psychological distress because the surveys involve sensitive questions about your work habits.

*Alternately, if there are no known risks, use the below standard clause.*

There are no known risks to you from being in this research study.

**What are the possible benefits to you?**

*If direct subject benefits can reasonably be anticipated as a result of participating in the study, then describe these possible benefits. Conclude with the following standard clause.*

Example: <<Describe benefits>>. However, you may not get any benefit from being in this research study.

*If direct subject benefits are NOT anticipated, then use the following standard clause.*

You are not expected to get any benefit from being in this study.

**What are the possible benefits to other people?**

*State the possible benefits to society in terms of advancement of knowledge and/or ultimate possible benefits to persons in the prospective subjects’ position.*

Example: The benefits to science and/or society may include better understanding of how to help others working night shifts and their coping strategies.

**What are the alternatives to being in this research study?**

*Describe in reasonable detail, alternatives the prospective subject may have available. If there are no alternatives, this section does not need to be included.*

Instead of being in this research study you can <<X>>.

**What will being in this research study cost you?**

*This section should state the financial obligations the subject may incur as a result of participating in the study. If there are no financial obligations to the subject, then use the following standard clause.*

There is no cost to you to be in this research study.

**Will you be compensated for being in this research study?**

*If the subject will receive compensation for participating in the research, state the amount of compensation and conditions for payment. A prorated payment system should be used when appropriate and commensurate with the degree of participation required. If no compensation will be provided, state that.*

Example: You will receive $5.00 for each survey completed for your participation in this study.

**What should you do if you have a problem during this research study?**

*Your estimation of risk determines what additional information you will include in this section. For studies classified as* ***minimal risk****, use the following standard clause.*

Your welfare is the major concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form.

*Think about also providing resources to participants dependent on the project parameters. For example, provide them with student health or wellness contact information*

*For studies classified as* ***greater than minimal risk****, use the following standard clause.*

If you have a problem or experience harm as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form. If needed, seek immediate emergency care for this problem. Please note, it is the policy of URI not to pay for any required care. Agreeing to this does not mean you have given up any of your legal rights.

*Think about also providing resources to participants dependent on the project parameters. For example, provide them with student health or wellness contact information*.

**How will information about you be protected?**

*Begin with the following standard clause.*

Reasonable steps will be taken to protect your privacy and the confidentiality of your study data.

*Next, if the research requires collection of sensitive information (socially, financially, legally or otherwise) from the prospective subject, follow the introductory standard clause above with a brief description of the precautions which will be utilized to protect the data.*

*For projects that collect paper-records use this standard clause.*

The data will be stored in a locked cabinet in the investigator’s office and will only be seen by the research team during the study and for <<XX>> years after the study is complete.

*For projects that collect electronic records use this standard clause. Describe the security in detail so the participant can understand what protections are in place.*

The data will be stored electronically through a secure server and will only be seen by the research team during the study and for <<XX>> years after the study is complete.

*Finally, for all protocols, conclude with the following standard clause.*

The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law. The information from this study may be published in scientific journals or presented at scientific meetings but the data will be reported as group or summarized data and your identity will be kept strictly confidential.

**What are your rights as a research subject?**

*Use the following standard clause.*

You may ask any questions concerning this research and have those questions answered before agreeing to participate in or during the study.

For study related questions, please contact the investigator(s) listed at the beginning of this form.

For questions concerning your rights or complaints about the research contact the Institutional Review Board (IRB) or Vice President for Research and Economic Development:

* IRB: (401) 874-4328 / [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu).
* Vice President for Research and Economic Development: at (401) 874-4576

**What will happen if you decide not to be in this research study or decide to stop participating once you start?**

*Use the following standard clause.*

You can decide not to be in this research study, or you can stop being in this research study (“withdraw’) at any time before, during, or after the research begins for any reason. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator or with the University of Rhode Island (list others as applicable).

You will not lose any benefits to which you are entitled.

**Documentation of informed consent**

*Use the following standard clause if you are obtaining signed/written consent. If you are not obtained a signed consent (e.g., online survey, use alternate language below.*

You are voluntarily making a decision whether or not to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to be in the research study. You will be given a copy of this consent form to keep.

**Participant Name:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

(Name of Participant: Please print)

**Participant Signature:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Research Participant Date

**Investigator certification:**

*If applicable, include the following investigator certification clause. (Generally utilized for* ***greater than minimal risk studies****).*

My signature certifies that all elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the participant possesses the capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

**ONLINE SURVEY CONSENT**

*For studies involving an online survey, participant signature may not be required. If not collecting a signature, you include Appendix M2: Waiver of Signed Consent in your IRBNet package. Delete this section your study does not involve an online survey.*

Example: I have read and understand the above consent form, I certify that I am <<insert inclusionary criteria>> and, by clicking the submit button to enter the survey, I indicate my willingness voluntarily take part in the study.

*<<insert link/continue button>>*

**AUDIO/VIDEO ADDENDUM TO THE CONSENT FORM FOR RESEARCH**

*An Audio/Video Addendum must be included if audio or video will be collected as part of the study. Delete this section if you do not plan to collect audio or video of research participants.*

*Be sure to describe in the Study Procedures Section above that audio/video recordings may be collected, how they will be stored and what measures taken to protect subjects privacy (e.g., in a locked file cabinet with no link to subjects’ identity; in a locked file cabinet and linked with a code to subjects’ identity; in a locked file cabinet and labeled with subjects’ name or other identifiable information), what will be done with the any video or audio recordings upon the completion of the study (e.g., destroyed, erased, archived, etc.), and when (after transcription, 3 years, 5 years, etc.).*

Example:By signing this consent form, I confirm that I give my permission for *<<audio, video>>* recording(s) of me, to be used for the purposes listed above, and to be retained *<<indefinitely, for \_\_\_ months, years, etc….>>.* You may still participate in this study if you are not willing to be recorded.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

**ADDENDUM FOR HIPAA INFORMATION (PERSONAL HEALTH INFORMATION) ACCESS**

*If your project involves collection, use, access or creation of PHI/HIPAA information, use the following standard clauses.*

*\*If you are working with a covered entity outside of URI, you may want to consider utilizing their PHI authorization template.*

You have rights regarding the privacy of your medical information collected before and during this research. This medical information, called “protected health information” (PHI), typically may include, depending upon the nature of this research, demographic information (like your address and birth date), the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures, as well as your medical history.

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at [add additional personnel/institutions as applicable].

Your PHI will be used only for the purpose(s) described in the section “What is the reason for doing this research study?”

Your PHI will be shared, as necessary, with the Institutional Review Board (IRB) and with any person or agency required by law. You are also allowing the research team to share your PHI with other people or groups listed below all of these persons or groups listed below are obligated to protect your PHI.

You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is not included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

* Researchers at [name of institutions] involved in this study [list this for multi-institution study where PHI will be shared with other researchers]
* Your health insurance company [list this if URI is expecting third party payers to pay for clinical procedures performed in the course of the research]
* The Food and Drug Administration (FDA) [list this for FDA regulated research]
* The sponsor [name of sponsor] which provides funds to URI to conduct this research [list this if the research is sponsored]
* Data Safety and Monitoring Committee/Board (DSMB/DSMC) [list this if the research is sponsored and/or requires a DSMB/DSMC]

*Use one of the following standard clauses depending on planned length of access to PHI.*

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted.

*OR*

There is currently no plan to end this study, so your information may be kept and used indefinitely. (Generally, this could be used when the research is without a foreseeable end-point (i.e., banking or registry studies).

**ADDITIONAL LANGUAGE**

*If applicable, the following may be included to meet the additional elements of informed consent per 45 CFR 46. Depending on the project, some, all or none of the elements below may need to be met.*

*“Additional elements of informed consent, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative.”*

* A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
* Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s or the legally authorized representative’s consent;
* Any additional costs to the subject that may result from participation in the research;
* The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
* A statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject;
* The approximate number of subjects involved in the study;
* If your planned project falls under FDA requirements, state the FDA approval status of all test articles (drugs, devices or biologics which are being evaluated in this research).
* If the study has a commercial sponsor, use the following statement: The sponsor of the research is [name of sponsor]. The University of Rhode Island receives money from the sponsor to conduct this study.
* NEW (2018): A statement regarding whether biospecimens may be used for commercial profit and whether the subject will or will not share in the commercial profit.
* NEW (2018): A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
* NEW (2018): For research involving biospecimens, whether the research will (if known) or might include whole genomic sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).