UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION
Box 359470
Seattle, WA 98195-9470
Phone: 206-543-0098
Fax: 206-543-9218

SUPPLEMENT:
Waiver Request, Consent or Consent Requirements

DO NOT SUBMIT THIS PAGE TO HSD

PURPOSE

Use this form if you are requesting one or more of the following:

- A waiver of the requirement for written documentation of consent
  This means that consent will be obtained from the subjects, but there will be no verifiable written document signed by subjects or subjects legally-authorized representatives. Examples:
  - *Obtaining consent with an oral process (for example, face-to-face or over the phone).*
  - *Obtaining consent by an electronic process that does not involve a verified electronic signature. Examples: subjects provide consent with a web-based form or by email.*

- A waiver of the requirement for consent
  This means that you will not be obtaining consent of any kind from the subjects. Examples:
  - *Screening (sometimes called "pre" screening) of records to identify possible subjects*
  - *Doing a retrospective review of medical records for over 1,000 subjects, many of whom cannot be contacted to obtain consent because they have moved or died.*

- A partial waiver or alteration of consent
  This means that your consent process will alter, or not include, one or more of the required elements of consent. Example:
  - *For a study involving deception, you may wish to exclude the description of some aspects of the purpose and procedures by requesting a waiver.*

- Use of the "short form" consent process (an alternative method for documentation of consent)
  This method for documenting consent may be used with subjects who are illiterate, do not speak English, are blind, or cannot talk or write due to physical limitations.

INSTRUCTIONS

1. Answer every applicable question. Do not refer to information in other documents (such as your IRB application). This may mean that you need to repeat some information contained in the IRB application. Though some information may appear self-evident, please include it nonetheless; federal regulations require that all information supporting a request for a consent-related waiver must be documented.
2. Text boxes will expand to the size of your answers. Use an "X" to mark the check boxes: [X].
3. This form does not need to be printed in color. Do not submit this first page with your waiver request.
4. Submit three copies for Full IRB review, and two copies for Minimal Risk review. When preparing double-sided copies, please make sure that each item (e.g. Waiver Request: Consent or Consent Requirements, any attachments, etc.) begins on the front of a new piece of paper.)

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SUPPLEMENT:
Waiver Request, Consent or Consent Requirements

1. Research Study Information

PART 1

Lead Researcher Name:	
XXXXX XXXXXXX	
Full Application Title:	
Reduce Energy Consumption through Integrated Design: How do Engineers Translate and Teams Synthesize Energy Modeling in Successful High Performance Building Design?	
IRB Application Number (if known):	IRB Committee (if known):
XXXXX	EJ
This form is being submitted as an attachment to:	
[ ] IRB Initial application **[X] IRB Modification application** **[ ] Other.....describe:**	

FOR HSD OFFICE USE ONLY
DATE RECEIVED STAMP:

2. Nature of Request

Indicate which of the following you are requesting, and then complete the relevant sections

PART 2

Select all that apply

[X] 2.1. Waiver of written documentation of consent ***(complete Part 3)***.

[ ] 2.2. Waiver of consent or required elements of consent ***(complete Part 4)***.

[ ] 2.3. Use of an alternative method for documentation of consent, *i.e., "short form" consent* ***(complete Part 5)***.

3. Waiver of Written Documentation of Consent

Section 1: Description

PART 3 -SECTION 1

3.1.1. Briefly describe the procedures and/or subject populations for which consent will be obtained without written documentation of the consent (i.e., without a consent form). Do not refer to your IRB application.

This waiver of documentation of consent is for oral consent of **case study interview subjects**. We will submit to subjects prior to the interview an information statement about the study. During the oral consent process on the day of the interview we will ask if they received the information statement and if they have any questions. If they have not received the statement, we will resend the statement to them by email and read through it with them and ask if they have questions, answer any questions that they have, then obtain oral consent using our brief oral consent script. If they did receive and read the information statement, then we will ask them if they have any questions, answer any questions, and then proceed to conduct oral consent using the brief oral consent script. We are requesting to conduct oral consent with an information statement as most of our potential subjects will be located outside of Seattle and therefore will be interviewed via phone or by skype. Subjects in the architecture/construction/engineering industries as well as hospital owner representatives also tend to have very busy schedules and streamlining our consent process through providing them with an information statement that they can read at their own convenience and keeping the oral consent process relatively simple will help them to have the information in hand and the time dedicated to the interview can be spent with the interview.

3.1.2. Indicate how you will provide the subjects with the required consent-related information about the research.

Select all that apply

[X]	An oral explanation of the research. *Examples: person-to-person, tape recording, or video recording*
[X]	A written Information Sheet. *Examples: paper: in-person, faxed, mailed or electronic: email, website or webpage, text message, other*
[ ]	Other, describe below:

describe here

Section 2: Criteria for Approving Waiver

PART 3 -SECTION 2

3.2.1. Check the box next to the condition that best fits your study and then answer the questions for that condition. Provide specific details in your answers. *NOTE: the IRB cannot waive the requirement for documentation of consent for FDA-regulated research unless it meets Condition 1 below. The FDA does not accept Condition 2. Most research that involves giving a drug, device, supplement, botanical, or biologic to subjects is FDA-regulated.*

[X] CONDITION 1: Minimal risk

a. Does your research involve greater than minimal risk to the subjects?

"Research" means the specific procedures and subject groups for which you are requesting a waiver of consent. This may be only a portion of your research study.

"Minimal risk" means that 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.

[ ] YES → If "YES", a waiver of consent documentation cannot be granted under this Condition. *Look at the questions for Condition 2 to see if your research qualifies for a waiver of consent documentation under Condition 2.*

[X] NO → If "NO", justify your answer below:

This research project was designated minimal risk under category 7 as we were not collecting data that could harm a subject's reputation or workplace status. The new procedure of the case study where we will interview subjects about their experiences working on the project would also fall under minimal risk as the questions would not put the subject at risk of harming their workplace reputation and the primary risk is breach of confidentiality of interview data. All building projects selected for the case study are successful, high performing projects that are often the pride and joy of their firm. We will also provide subjects with an information statement about our study that will clarify information on confidentiality and we will be conducting oral consent on the day of the interview where we can confirm that the information statement was read and ask if they have questions about the study.

b. Does your research involve any procedures for which written consent is normally required outside of the research context? *Examples: in everyday life, written consent is needed for surgery but not for many surveys or for non-invasive health measurements by your health care provider.*

[X] NO

PART 3 -SECTION 2

[ ] YES → If "YES", a waiver of consent documentation cannot be granted under this Condition. *Look at the questions for Condition 2 to see if your research qualifies for a waiver of consent documentation under Condition 2.*

[ ] CONDITION 2: Signed consent document is the primary risk

c. Is the existence of a signed consent document the only document or record that would link the subject to the research? (This means that data and specimens will not be recorded or stored with identifiers or links to identifiers.)

[ ] NO → If "NO", a waiver of consent documentation cannot be granted under this Condition. *Look at the questions for Condition 1 to see if your research qualifies for a waiver of consent documentation under Condition 1.*

[ ] YES

d. Is the principal risk associated with the research the potential harm to subjects that might occur if there was a breach of confidentiality about their participation*? Example: a study that involves subjects who use illegal drugs.*

[ ] NO

[ ] YES → If "YES", justify your answer below:

justify here

e. Will subjects be asked whether they want documentation linking them with the research, and the subjects' wishes will govern?

[ ] YES

[ ] NO → If "NO", a waiver of consent documentation cannot be granted under this Condition. *Look at the questions for Condition 1 to see if your research qualifies for a waiver of consent documentation under Condition 1.*

4. Waiver of Consent Waiver/Alteration of Elements of Consent

Section 1: Basic Eligibility

PART 4 SECTION 1

4.1.1. Is your research regulated by the FDA (Food and Drug Administration)*? Most research that involves a drug, device, supplement, biologic, or botanical is FDA-regulated. If you are not sure, please contact the Human Subjects Division for assistance before completing this form. Email: hsdinfo@u.washington.edu Phone: 206-543-0098*

[ ] NO

[ ] YES → If "YES", is your request for a waiver of consent ONLY for the activity of screening (or "pre" screening) records to identify possible subjects for the research?

[ ] NO → If "NO", do not complete this form. FDA regulations do not allow a waiver of consent for any research activities except specific types of emergency medicine research or treatment. If you are planning emergency medicine research, contact the Human Subjects Division for assistance. Email: hsdinfo@u.washington.edu Phone: 206-543-0098.

[ ] YES → If "YES", complete this form.

Section 2: Description

PART 4 - SECTION 2

4.2.1. Which of the following are you requesting?

Select all that apply

[ ] A waiver of the requirement to obtain consent.

[ ] A waiver or alteration of one or more of the specific required elements of consent. See Section 3.3 of the SOP Consent for more information.

4.2.2. Briefly describe the procedures and/or subject populations for which you are requesting a waiver of consent or partial waiver/alteration of consent. Do not refer to your IRB application.

describe here

Section 3: Criteria for Approving Waiver

PART 4 -SECTION 3

4.3.1. Check the box next to the condition that best fits your study and then answer the questions for that condition. Provide specific details in your answers.

[ ] CONDITION 1: Minimal risk

a. Does the research involve greater than minimal risk to the subjects?

"Research" means the specific procedures and subject groups for which you are requesting a waiver of consent. This may be only a portion of your research study.

"Minimal risk" means that 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.

[ ] **YES** → If "YES", the waiver of consent cannot be granted under this Condition. *Look at the questions for Condition 2 to see if your research qualifies for a waiver of consent under Condition 2.*

[ ] **NO** → If "NO", justify your answer below:

justify here

b. Will a waiver of consent adversely affect the rights and welfare of the subjects?

[ ] **YES** → If "YES", a waiver of consent cannot be granted under this Condition. *Look at the questions for Condition 2 to see if your research qualifies for a waiver of consent under Condition 2.*

[ ] **NO** → If "NO", justify your answer below:

justify here

c. Could the research practicably be carried out without the waiver of consent?

[ ] **YES** → If "YES", a waiver of consent cannot be granted under this Condition. *Look at the questions for Condition 2 to see if your research qualifies for a waiver of consent under Condition 2.*

[ ] **NO** → If "NO", select from the reasons below:

Select all that apply.

PART 4 - SECTION 3

[ ] It is not possible to contact all of the subjects associated with the data or specimens in order to obtain consent.

[ ] The design of the study does not allow the possibility of obtaining consent.

[ ] The potential study population is so large that it would not be feasible to obtain consent.

[ ] The research cannot be conducted with a population for whom consent could practicably be carried out.

[ ] Alternative methods for obtaining consent (for example, consent over the phone) are not feasible.

[ ] Requiring informed consent may introduce systematic bias into the data.

[ ] The risk of contacting the subjects is greater than the risk of the study procedures.

[ ] Other, please describe:

describe here

Provide information supporting your answer, to assist the IRB in understanding why obtaining consent or the indicated elements of consent would not be feasible.

justify your answer here

d. Would it be appropriate to provide subjects with information about the study after their participation? *This is not required in order to grant the waiver. However, answering the question IS a requirement for granting the waiver.*

Select all that apply:

[ ] No, because the data will not be stored with, or linked to, identifiers.

[ ] No, because the information that is found will have no impact on subjects' clinical care.

[ ] No, because there is no feasible mechanism by which to notify subjects.

[ ] No, because of another reason. Explain:

explain here

[ ] Yes. Describe the information that will be provided and the procedures used to provide it:

describe here

[ ] CONDITION 2: State or local public benefit or service programs. *NOTE: This Condition is rarely applicable.*

a. Is the research to be conducted by, or subject to the approval of, state or local government officials?

[ ] **NO** → If "NO", a waiver of consent cannot be granted under this Condition. *Look at the questions for Condition 1 to see if your research qualifies for a waiver of consent under Condition 1. If it does not, then you do not need to submit this form unless you are requesing another type of consent waiver.*

[ ] **YES**

b. Is the research designed to study, evaluate or otherwise examine any of the following?

Select all that apply

[ ] Public benefit or service programs. *Examples: unemployment benefits; state-funded health insurance.*

[ ] Procedures for obtaining benefits or services under those programs.

[ ] Possible changes in or alterations to those programs or procedures.

PART 4 –SECTION 3

[ ] Possible changes in methods or levels of payment for benefits or services under those programs.

[ ] None of the above. → If "None of the above", a waiver of consent cannot be granted under this condition.

c. Could the research practicably be carried out without the waiver of consent?

[ ] **YES** → If "YES", a waiver of consent cannot be granted under this condition.

[ ] **NO** → If "NO", select from the reasons below:

Select all that apply

[ ] It is not possible to contact all of the subjects associated with the data or specimens in order to obtain consent.

[ ] The research cannot be conducted with a population for whom consent could practicably be carried out.

[ ] Alternative methods for obtaining consent (for example, consent over the phone) are not feasible.

[ ] The design of the study does not allow the possibility of obtaining consent.

[ ] The potential study population is so large that it would not be feasible to obtain consent.

[ ] Requiring informed consent may introduce systematic bias into the data.

[ ] The risk of contacting the subjects is greater than the risk of the study procedures.

[ ] Other, please describe:

describe here

Provide information supporting your answers, to assist the IRB in understanding why obtaining consent or the indicated elements of consent would not be feasible.

justify your answer here

Part 5. Short Form Consent - an alternate process for documenting consent

Section 1: Description

PART 5 – SECTION 1

5.1.1. Briefly describe the procedures and/or subject populations for which you would like to use the Short Form consent to document the consent process. Do not refer to your IRB application.

describe here

Section 2: Criteria for approving the use of a Short Form Consent

PART 5 - SECTION 2

5.2.1. Confirm that your research meets each of the following requirements by checking the appropriate boxes and answering the questions. If one or more of the statements does not apply to your research, you cannot use the Short Form consent process for documenting consent.

5.2.1.a. There is a **Short Form** written consent document in the subject's language, stating that (1) the required elements of consent have been presented orally to the subject or subject's representative; and (2) the subject agrees to take part in the research as described.

[ ] YES

5.2.1.b. All of the required elements of consent are presented orally to the subject or subject's representative, in the subject's language. *This may or may not require the use of a translator.*

PART 5 – SECTION 2

[ ] NO, and I am requesting a waiver for some elements of consent.
Complete Part 4, "Waiver of Consent or Elements of Consent" above.

[ ] YES

5.2.1.c. There will be a witness to the oral presentation who is fluent in both English and the subject's language.

When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

[ ] YES → Describe the individual(s) who will serve as the witness, including their relationship (if any) to the subjects and to the research study team.

describe here

5.2.1.d. There is a **Written Summary** of what is to be said to the subject or subject's representative.
If there will be a standard consent form in English (for example, for the literate subjects in the study), the standard consent form can be used as the Written Summary if a Witness Signature Line is added to it.

[ ] NO

[ ] YES

5.2.1.e. Confirm by marking the box below that signatures will be obtained as described below:

[ ] YES

Short Form Signatures (can be X or mark)
- Subject or subject's representative
- Witness

Written Summary Signatures
- Witness (can be X or mark)
- Person obtaining consent

5.2.1.f. Confirm by marking the box below that copies will be given as described below:

[ ] YES

Short Form Received By
- Subject or subject's representative
- Researcher and/or study files

Written Summary Received By
- Subject or subject's representative
- Researcher and/or study files

5.2.2. Do you expect your research to include subjects who do not speak English?

[ ] NO

[ ] YES → If "YES", confirm that your research meets each of the following requirements for use of the Short Form consent process with subjects who do not speak English, by checking the appropriate boxes. If one or more of the statements does not apply to your research, you cannot use the short form consent process for documenting consent.

5.2.2.a. The witness will be someone who is fluent in both English and the language of the subject.

[ ] YES

5.2.2.b. The IRB-approved English language consent form will serve as the written summary.
(See part d of Question 5.2.1, above).

[ ] YES

5.2.2.c. The oral presentation and the short consent form will be in a language understandable to the subject.

[ ] YES

5.2.2.d. The IRB will receive all foreign language versions of the short consent form. This is a condition for receiving IRB approval of this research.

[ ] YES