**UAB IRB**

**SAMPLE CONSENT/INFORMATION SHEET FOR EXEMPT RESEARCH**

**ENGLISH (with HIPAA Authorization)**

**VERSION DATE: 09/16/19**

*Note: It is not possible to address all scenarios for all types of studies conducted by UAB researchers. This sample is designed to assist you in creating your information sheet. It is intended to show language preferred by the UAB IRB to address the elements of informed consent. In many cases, the sample language will need to be modified, deleted, or expanded for your particular study.*

If using for the first time, please read all shaded areas first, as the format and content of this document can vary greatly.

Shaded paragraphs like this one are instructions for you, the writer. Do not include them in the document you submit. If the instructions indicate that specific language applies to your study, the specific language will be shown below the instructions outside of the shaded paragraph.

**Formatting Instructions**

* Use 11 or 12 pt font for the consent form.
* Write the consent form in the 2nd person (i.e., you) and keep the pronoun usage consistent throughout.
* Use *Page X of Y* numbering on each page if this is a stand-alone document. Page numbers are not needed if the information is provided in the form of an email, etc.

**Use understandable, non-technical language at an 8th-grade or lower reading level.**

* Readability statistics can be displayed in Microsoft Word. Search Microsoft Office Help for “readability statistics” for further instructions.

**Adaptation of content**

* Consent in Exempt research can take many forms. This document provides content and format for a physical information sheet/consent. However, feel free to adapt the document to fit other common forms of obtaining participant consent such as an email, letter, phone script, or the landing page of an online survey hosting site.

**Consent Form vs. Information Sheet:**

* If the research requires a written signature (e.g., HIPAA-regulated or documented parental consent), then the document should be called a CONSENT FORM and contain a signature block.
* If, however, no written signature is required, then the document should be called an INFORMATION SHEET.
* Exempt projects do not require a Waiver of Informed Consent Documentation.
* Adjust the header on this page as needed.

**Header:** If you are adapting this document for use as an email to participants, the header structure should be removed and incorporated into an additional first section that includes this information as well as an introduction of the sender.

**CONSENT/INFORMATION SHEET TO BE PART OF A RESEARCH STUDY**

***[Insert any clarifying subheaders here, if needed]***

**Title of Research:** Factors Increasing Vulnerability to Health Effects Before and After a Major Flooding Event

**UAB IRB Protocol #:** *[Insert UAB IRB Protocol # beginning with IRB-]*

**Principal Investigator:** John Doe, Ph.D.

**Sponsor:** If the study is being sponsored by UAB departmental funds or is unfunded, put the name of the department here (e.g., UAB Department of Medicine). For student research, include the student’s departmental affiliation.

If additional or other support is being provided, include this information with a heading such as “**SUPPORTED BY**:” after the SPONSOR line.

**Sponsor:** Federal Emergency Management Agency (FEMA)

If no **Sponsor Protocol #**, remove the heading below

**Sponsor Protocol #:** FEMA223

**RESEARCH INVOLVING CHILDREN - WHEN TO INSERT “FOR CHILDREN…” BOX:**

* When a parent or guardian is providing consent only for a child participant & that child participant will sign *the assent section of the consent* form, do not use “you/your child” throughout the form. Instead, use "you" and insert the following text before the Purpose of the Research section:

*For Children (persons under 18 years of age) participating in this study, the term “You” addresses both the participant ("you") and the parent or legally authorized representative ("your child").*

**RESEARCH INVOLVING CHILDREN - WHEN NOT TO INSERT “FOR CHILDREN…” BOX:**

* When a parent or guardian is providing consent only for a child participant & that child participant will sign *a separate assent form or will not provide written assent*, use “your child” throughout the form.
* When a parent or guardian is providing consent for both him/herself and a child participant, specify throughout the consent form when you are referring to the parent and when you are referring to the child. This would allow for the use of “you,” “your child,” and “you and your child” throughout the form when appropriate.

**CONTENT GUIDANCE:**

**SECTION 1 *(NOTE: sections do not have to be labeled or be restricted to a single paragraph. Be concise, but use more than one paragraph, if needed. Alternatively, you may also merge the sections together for brevity)***

* Describe why the participant is being asked to join.
* Explain the purpose of the study in nontechnical language.
* Give some background, if helpful, so that participants understand what issue the research is attempting to solve or learn more about
* State that this is a research study. Use the word “research” specifically.
* If you are collaborating with other institutions, provide some information about that collaboration

**SECTION 2**

* Describe the procedures to be followed, identifying which procedures are for research and which procedures are standard of care or routine educational procedures. Be thorough and describe all data collection and methods.
* If the research involves deception, describe the general aspect of the deception. NOTE: Exemption review only allows for deception to be utilized under Exempt Category 3 (Use of Benign Behavioral Interventions) and only with prospective agreement by the participant.
* Use bulleted lists where appropriate to make easier to read.
* Estimate the amount of time involved in study participation (exclude standard of care or educational procedures that all students will complete).
* Address any extra credit the participant may receive. If none, omit.
  + Note: Non-participants must be offered equal opportunity for extra credit that cannot exceed the effort requirement for the extra credit offered for research participation.
* Address any payment they may receive. If none, omit.
* Note: Payment may not be based upon successful completion of the study.
* Specify the amount of compensation a participant will receive for participating, if applicable, and include the payment schedule. Describe prorated payments for participants who withdraw before the end of the study.
* If children are involved, specify whether the child or parent is being paid.
* The last sentence, “Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit)” should be included instead of specifying the payment method in the consent form.

**SECTION 3**

* Describe the voluntary nature of the project.
* If the research involves students or employees where the research is being conducted, add a statement that participation in the research is not part of their duties as a student or employee.
* Address confidentiality, including who might have access to identifiable data, and privacy.
* If this study is regulated under HIPAA, include the HIPAA language. **NOTE:** no changes can be made to this language without prior approval from UAB’s Office of Council.

**SECTION 4 *(NOTE: It’s possible that this section may not be necessary at all, depending on your research. Omit if it doesn’t apply.)***

* Address risks or discomforts, if needed. If there are no risks, you can omit.
* Address any benefit other than addressing the research purpose. Do not list payment or extra credit as a benefit. If there are no additional benefits, omit.
* Only address alternatives if there is one (e.g., an alternate extra credit option if the research provides for extra credit for participation).

**SECTION 5**

* Provide your contact information and the UAB IRB contact information as noted on page 6.

You are being asked to take part in a research study because your area has recently experienced a widespread flooding event. The purpose of this research study is to determine the potential vulnerability to health issues during these events. Recent research indicates that weather events, such as a large flood, can impact people of lower income more than those in higher incomes. We hope to learn more about why this happens so that we can provide better services for people in this situation. We are working with researchers in Indiana and Michigan, both states that have also seen recent flooding events, so we can gather as much information about this issue as we can.

If you agree to join the study, you will be asked to complete a 1-hour, face-to-face interview regarding the events before and after the flood. This interview will contain questions about assistance you sought, any health issues you experienced, roadblocks you encountered, and demographic information about you. The interview will take place either in your home or over the phone. I will audio-record the interview and transcribe it at a later date. I may call you back once I’ve transcribed the interview to clarify a few items, but this should only take 10-20 minutes. You will be paid $40 at the end of your first interview. Ask the interviewer about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Your participation in this research is strictly voluntary, and you can end the interview at any time. Although I will know your identity and contact information, I will keep this information separate from your interview responses and will destroy this information as soon as it is no longer needed. Your data will be kept confidential; however, organizations involved in the project directly (i.e., FEMA, the UAB Department of Sociology) or those organizations involved the oversight of research (i.e., the UAB Institutional Review Board, The Office for Human Research Protections) may have access to identifiable information about you.

Some of the questions we ask may bring up memories that are emotional or difficult to remember. The interviewer can provide you with a list of resources for emotional support if you would like. During our discussion, the researchers may discover unused resources for disaster management that may help you. If we find this to be the case, we will provide you with this list as well.

* If your research involves the access, use, or collection of HIPAA-regulated data, then include the HIPAA Authorization section as noted below (NOTE: This add several paragraphs/pages to your form). Otherwise delete this content and continue on Page 7 of this document.
* Inclusion of this section will require participant signature, or if a minor, then a parent’s signature.
* If the HIPAA language is included, revise the header of this document to “CONSENT FORM.”
* NOTE: If HIPAA applies and you cannot obtain a written signature, keep this section in the *Information Sheet*, but submit a Waiver of Authorization form detailing why you cannot obtain written authorization.

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

**What protected health information may be used and/or given to others?**

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

ClinicalTrial.gov: If the study will be registered on ClinicalTrials.gov, include the following language (if similar language is not already included in the Sponsor/Lead Site’s template language):

A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Continuation of HIPAA Authorization section:

**Who may use and give out information about you?**

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

**Who might get this information?**

All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

* the Office for Human Research Protections (OHRP)
* the U.S. Food and Drug Administration (FDA)

1. Department of Health and Human Services (DHHS) agencies
2. Governmental agencies in other countries
3. Governmental agencies to whom certain diseases (reportable diseases) must be reported

* Include applicable information only for the italicized portion of the two bullets below:

1. the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, *University of Alabama Health Services Foundation, Children’s of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Healt*h, as necessary for their operations; the UAB IRB and its staff
2. the billing offices of *UAB and UAB Health Systems affiliates and/or Children’s of Alabama* and its billing agents

**Why will this information be used and/or given to others?**

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

Certificate of Confidentiality: If your study is NIH-funded or you have or plan to obtain a Certificate of Confidentiality, include the following:

This research *[is/will be]* covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the *[insert Sponsor]* which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of *[list what will be reported, such as child abuse and neglect, or harm to self or others]*.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Questions about Abusive Behavior: If there will be questions about abusive behavior (e.g., child or elder abuse or neglect, or harm to self) include the following language:

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

Continuation of HIPAA Authorization section:

**What if I decide not to give permission to use and give out my health information?**

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

**May I review or copy the information obtained from me or created about me?**

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

**May I withdraw or revoke (cancel) my permission?**

Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

**Is my health information protected after it has been given to others?**

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

End of HIPAA Authorization Information

Continuation of Consent Sections:

If you have any questions, concerns, or complaints about the research please contact the Principal Investigator, *[specify PI],* at *[specify PI’s phone number with area code].* If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

**SIGNATURES**

* Do not include this section if not needed. This is an unnecessary burden. Some examples of when signatures are advisable or required:
  + Research covered under FERPA
  + Research regulated by HIPAA
  + Research involving deception
* Should be in second person (i.e., you).
* The signature only indicates agreement to participate; do not include other attestations (e.g., I have had all my questions answered, etc.).

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

**It is not possible to address all scenarios for signature requirements that may be needed for various types of research. These instructions and samples are designed to assist you in the preparation of this section. In many cases, you will need to customize this section for the particular study population.**

* The requirements for signature lines depend upon the consent process described in the application.
* Each signature-date line included in the Signatures section, as applicable to the research, must be signed and dated.
* All signatures must appear on the same page, but that page does not need to be a separate page with no other information.
* Each person who signs the consent form must include the date of his/her signature.
* If the research involves children (i.e., individuals younger than 18 years of age for research conducted in the state of Alabama), see examples below. Be advised that only some Exempt categories allow for the use of minors in the research.
* A signature-date line for the participant must be included. The acceptable options are shown and described below.

**Option 1**

Signature of Participant Date

**Option 2**

**Legally Authorized Representatives (LAR)**

* If the research proposes to obtain consent from the participant **or** the LAR, add “(or Legally Authorized Representative)” after “Signature of Participant.”
* If the research proposes to obtain consent from the participant **and** theLAR, include a separate signature-date line for each person.

Signature of Participant or Legally Authorized Representative Date

**Option 3**

Signature of Participant Date

Signature of Legally Authorized Representative Date

**Option 4**

Signature of Participant 14 Years of Age and Older Date

Signature of Parent or Guardian Date

* The UAB IRB usually recommends the following:
  + A separate assent form should be prepared for use with, and to document the assent of, participants who are 7-13 years old.
  + Participants 14-17 years old will document their assent by signing the main consent form.

**Other Signature Lines:**

**Person Obtaining Consent**

* All persons who obtain informed consent must be listed in the application.
* If the Principal Investigator always obtains consent, this line would always be signed by the Principal Investigator.

Signature of Person Obtaining Consent Date