|  |  |
| --- | --- |
| Principal Investigator: | Last name , First name |
| SpartaIRB Study Number: | STUDYXXXXXXXX |
| Study Title: | Click here to enter text. |

* How many people do you plan to enroll?

Click here to enter text.

* What is the maximum number of individuals who will receive the email(s), and how will you protect against over-enrollment?

(Example: We will send to a maximum of 200 people to hit our target enrollment of 30. We will stagger the sending of recruitment emails, so that only 100 go out at a time)

* How many reminder emails will be sent to potential research subjects and at what frequency?

[ ]  I will not be sending reminder emails.

Click here to enter text.

* + If reminder emails will be different from the introductory email(s), please attach the templates for the reminder emails as well.

[ ]  I have attached the template(s) for the reminder emails.

* How will emails be sent out?

(Example: via REDCap)

* What UH email address will be used to send the email? (***Please note that unless appropriately justified, emails may only be sent from an “@uhhospitals.org” email address.)***

(Example: Jane.Smith@UHhospitals.org)

* Provide a plan for monitoring the email address from which recruitment emails are sent. (Examples: 1. Create an “@UHhospitals.org” group email mailbox that is monitored by multiple study team members; 2. Emails to be sent from a current UH employee’s email. If sending from your email, an away message will be utilized if out of the office including a secondary contact.)
* How will you find the email addresses of potential subjects? What is the source of the email list?

Click here to enter text.

* What type of permission do you have to contact these patients?

(Example: they are my patients, I have a letter of support from the treating physician, etc)

**Template Instructions**

Use the templates on the following pages for creating email language intended for research recruitment. **\**Please delete the templates that do not apply to your research.*\***

1. **Survey study workflow** (first two templates) from the subject’s perspective:
2. **Interventional study workflow** (third template) from the subject’s perspective:

“Survey Studies” Email Template

* Use to send an introductory email to prospective research participants to choose to partake in a survey study.
* DO NOT include identifiable information or sensitive data elements such as diagnoses or lab results in this introductory email.
* Include the link to the research survey within this introductory email.

“Sample Consent Form for Online Surveys” Email Template

* Use this template for the information sheet which populates once the prospective research subject clicks on the survey link in the introductory email.
* Sensitive data elements such as diagnoses may be included. DO NOT include PHI.

“Interventional Studies” Email Template

* Use this template to send recruitment emails for interventional studies (not for survey studies).
* DO NOT include identifiable information or sensitive data elements such as diagnoses or lab results.

**Introductory Email - Survey Studies**

*Instructions:* Emails introducing surveys should be short and as general as possible. If an individual clicks on the link to enter the survey, a full information sheet should appear before the survey itself.

If conducting an anonymous survey study and there’s a plan to offer payment, use the below method in REDCap to ensure the subjects’ information stays anonymous and out of the survey information:

* Set up 2 surveys in REDCap (the first is the survey and the second is the contact information site).
* Include the link to the second survey in the first survey that’s sent out to research participants.
* Research participants will then click on the second link and provide their contact information in order to be sent payment, contacted for future research, and etc.

Introduction survey email template elements to include VERBATIM:

* *Email subject line:* **Research Participants Needed at University Hospitals**

**University Hospitals is actively engaged in medical research in order to provide the highest-quality care to our patients, always Advancing the Science of Health and the Art of Compassion. We strive to continuously improve the standard of care, and we do this by leveraging discovery and innovation. Many people who are affected by a particular medical condition also find value in participating in research to help others in the same situation, both now and in the future.**

**A research team at University Hospitals is currently recruiting participants for the following study:**

**<insert 1-3 sentences briefly describing the study>**

**This project is being conducted by [INSERT NAME, TITLE, DEPARTMENT]. It should take approximately [INSERT NUMBER OF MINUTES/HOURS/SESSIONS] to complete.**

**Participation is completely voluntary. If you agree to participate, you can always change your mind and withdraw.**

**Please click the link to the survey below to participate or learn more about this research.**

**[<INSERT LINK TO SURVEY>]**

**If you are interested in learning more about this study, contact the research team at <name, contact information>. To learn more about all studies at University Hospitals click** [**here**](https://www.uhhospitals.org/for-clinicians/research-and-clinical-trials) **<** [**https://www.uhhospitals.org/for-clinicians/research-and-clinical-trials**](https://www.uhhospitals.org/for-clinicians/research-and-clinical-trials)**> .**

**We will send [INSERT NUMBER OF REMINDERS] reminders to participate in this study. If you would prefer not to be contacted for this study, or have any questions about the research, please call [INSERT NAME, TITLE, TELEPHONE NUMBER].**

**All UH research is approved through a special review process to protect patient safety, welfare and confidentiality. The Institutional Review Board (IRB) is a Board that is charged with protecting the rights and welfare of people who take part in research studies. The content of this message, has been approved by the UH IRB.**

**Engaging in medical discovery provides a unique opportunity to have substantial impact. Thank you for considering this request to participate in important medical research at UH.**

NOTE: Surveys are generally granted a waiver of signed consent (please ensure that you have applied for this waiver), but the elements of consent must still be discussed. After you use the above email introduction, the below template should be used to create the first page of the survey.

**Sample Consent Form for Online Surveys**

Sample information sheet for online surveys elements to include:

**You are invited to participate in a survey on**[DESCRIBE RESEARCH PROJECT]*.***This is a research project being conducted by**[INSERT YOUR NAME, TITLE]*.* **It should take approximately**[INSERT NUMBER OF MINUTES/HOURS/SESSIONS]**to complete.**

**Participation**

**Your participation in this survey is voluntary. You may refuse to take part in the research or exit the survey at any time without penalty. You are free to decline to answer any particular question you do not wish to answer for any reason. We hope to gather responses from about**[INSERT NUMBER OF INDIVIDUALS]**individuals.**

**Benefits**
**You will receive no direct benefits from participating in this research study. However, your responses may help us learn more about**[INDICATE THE PURPOSE OF THE STUDY].

**Risks**

**There is always the risk that your information may be** [ACCESSED BY / SEEN BY] **someone who shouldn’t have access. We will work to prevent this by** [INSERT PLAN FOR RISK PREVENTION].

* [*Data is anonymous.* [-OR-] *All identifying information is removed and replaced with a study ID.*]
* **We’ll remove all identifiers after** [INSERT AMOUNT OF TIME OR SPECIFIC EVENT].
* **We’ll store all electronic data on a password-protected, UH encrypted computer.**
* **We’ll keep your identifying information separate from your research data, but we will be able to link it to you. We’ll destroy this link after we finish collecting and analyzing the data.**

**If there is the possible risk of emotional discomfort from dealing with sensitive issues or answering a questionnaire, this risk should also be included.**

**Suggested language: [***There is the risk that you may find some of the questions to be sensitive.* [-OR-] *There is the risk that some questions may cause emotional discomfort.* [-OR-] *Some of the survey questions ask about* [INSERT TOPIC] *and may be distressing to you as you think about your experiences.* [-OR-] *The possible risks or discomforts of the study are minimal.*]

You may feel a little [*uncomfortable* [AND/OR]*embarrassed* [AND/OR]*sad* [AND/OR] *tired* [AND/OR]*etc.*]answering [*personal*[AND/OR] *sensitive* [AND/OR]*many* [AND/OR]*etc.*] survey questions.

**Confidentiality**
**Your survey answers will be collected within** [*UH REDCap is the preferred survey tool*] **where data will be stored in a password protected electronic format.**

[*Your responses will be anonymous because* [INSERT ANONYMITY PLAN]. [-OR-] We *will ask for the following identifiable information* [INSERT REASON].] **However, no names or identifying information would be included in any publications or presentations based on these data, and your responses to this survey will remain confidential.**

**Some surveys may ask participants if they wish to participate in a follow-up interview and to provide contact information. In such a case you can add the following sentences:**

**Suggested Language: At the end of the survey you will be asked if you are interested in participating in an additional interview** [BY TELEPHONE/ IN PERSON/ EMAIL]**. If you choose to provide contact information such as your phone number or email address, your survey responses may no longer be anonymous to the researcher.**

**Students or Employees**

**If this survey is targeting UH or Case employees or students, please include a statement such as the following:**

**Suggested Language: Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisors or professors.**

**Contact**
**If you have questions at any time about the study or the procedures, you may contact** [INSERT NAME, TITLE] **via phone at** [INSERT TELEPHONE NUMBER] **or via email at** [INSERT UH EMAIL ADDRESS].

**If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant’s rights; research- related injury; or other human subject issues, please call the University** **Hospitals Cleveland Medical Center’s Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.**

**Electronic Consent**

**Please select your choice below. You may print a copy of this form for your records. Clicking on the “Agree” button indicates that:**

* **You have read the above information**
* **You voluntarily agree to participate**
* **You are 18 years of age or older**

[ ]  **Agree**

[ ]  **Disagree**

**Interventional Research Studies**

*Instructions:* If you are using email to introduce a research opportunity and will later be following up with a phone call, please use the below email template. Do not include elements of PHI (such as dates) or diagnostic or treatment information.

Introduction email template elements to include:

*Email subject line:* **Research Participants Needed at University Hospitals**

**University Hospitals is actively engaged in medical research in order to provide the highest-quality care to our patients, always Advancing the Science of Health and the Art of Compassion. We strive to continuously improve the standard of care, and we do this by leveraging discovery and innovation. Many people who are affected by a particular medical condition also find value in participating in research to help others in the same situation, both now and in the future.**

**A research team at University Hospitals is currently recruiting participants for the following study:**

**<insert 1-3 sentences briefly describing the study>**

**This project is being conducted by [INSERT YOUR NAME, TITLE, DEPARTMENT] and would involve *[a single in-person study visit* [AND/OR] *multiple in-person study visits* [AND/OR] *X number of years of participation* [AND/OR] *taking a drug* [AND/OR] *etc]*.**

**Participation is completely voluntary. If you agree to participate, you can always change your mind and withdraw.**

**If you are interested in learning more about this study, contact the research team at <name, contact information>. To learn more about all studies at University Hospitals click** [**here**](https://www.uhhospitals.org/for-clinicians/research-and-clinical-trials) **<** [**https://www.uhhospitals.org/for-clinicians/research-and-clinical-trials**](https://www.uhhospitals.org/for-clinicians/research-and-clinical-trials)**> .**

**If you would prefer not to be contacted for this study, or have any questions about the research, please call [INSERT NAME, TITLE, TELEPHONE NUMBER]. If we do not hear from you in 14 days, we will follow up with a phone call to see if we could possibly speak to you about this study.**

**All UH research is approved through a special review process to protect patient safety, welfare and confidentiality. The Institutional Review Board (IRB) is a Board that is charged with protecting the rights and welfare of people who take part in research studies. The content of this message, has been approved by the UH IRB.**

**Engaging in medical discovery provides a unique opportunity to have substantial impact. Thank you for considering this request to participate in important medical research at UH.**

Attach the phone script that will be used to discuss the study once phone contact has been made with participants.