|  |  |
| --- | --- |
| 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 letter(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 letters, so that only 100 go out at a time)

* How many (if any) reminder letters will be sent to potential research subjects and at what frequency?

[ ]  I will not be sending reminder letters.

Click here to enter text.

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

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

Click here to enter text.

* What UH mail address will be used as the return address? (***Please note that unless appropriately justified, letters may only be sent from a UH mail address.)***

Click here to enter text.

* Provide a plan for monitoring the opt-out requests to prevent contacting an individual who has opted-out.

(Example: monitoring the email / voicemail / mail daily with a plan for an out of office message with an alternate contact, or who will monitor if the usual person is out. Include a description of how opt-out information will be shared if the person checking the email / voicemail / mail is not the same person recruiting)

* How will you find the addresses of potential subjects? What is the source of the 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.)

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

Introduction letter template elements to include:

**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]*.**

**You may or may not qualify to be in this study. 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 visit our website at:** [**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 / email / return postcard [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.