UW Medicine

Dear _,

The Department of Obstetrics and Gynecology at the University of Washington is conducting a study ~~about miscarriage and early pregnancy loss and~~that you might be eligible to participate. You were identified through a review of the medical record as a possible participant.

~~This study will look at satisfaction with care surrounding miscarriage in the emergency room. If you have been seen in the emergency room for a miscarriage, you may be eligible to participate.~~

If you are interested and eligible, ~~W~~we will ask you to ~~participate in a~~complete a survey ~~over the~~by phone with a member of the research team. The survey will take about x minutes to complete. Your information will be kept confidential and not shared with anyone outside the study team. ~~There is no cost to you to participate in the survey and~~ aAfter completion, you could be eligible for compensation. ~~This study will help to answer important questions regarding miscarriage care in the emergency department and improve the counseling and management that women receive during what can be a sensitive time in their life. Studies like this help to improve patient satisfaction and are reviewed by an Institutional Review Board (IRB) which makes sure that the rights of participants are protected, and that there are no unnecessary risks involved in the study. For more information, speak with a member of the study team.~~

Please note:

- Participation in a clinical research study is always voluntary.
- You may withdraw at any time and for any reason.
- If you decide that you do not want to participate, it will not affect any care you receive now or in the future.

If you are interested in learning more about this study, please call the research coordinator, [redacted], at [redacted] or via email at [redacted]. *This call or email is merely informative and does not commit you to joining the study.*

Best regards,

[redacted], MD, Principal Investigator
Department of Obstetrics and Gynecology // UW Medicine

Department of Obstetrics and Gynecology

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Box 356460
Seattle, WA 98195-6460

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Commented [JM1]: It would be acceptable to indicate something like, "You were identified through a review of the medical record as someone who was seen at UWMC within the past x months" (i.e. it is ok to indicate the basic timeframe and institution where they were seen to give the person some context as to why they might be getting this letter without disclosing anything that would be considered private information).

Commented [JM2]: Edits made are with the assumption that this is the only study procedure and not a screening survey for more extensive study procedures. If that's not the case then more details about what the study involves should be included. Alternatively you could just describe the next step (i.e. participate in a screening call to learn more about the study and if you're eligible).

Commented [JM3]: Not appropriate or necessary unless there will be a cost associated with participation.

Commented [JM4]: The language here should be specific. Example – "Those who participate will receive $15 for their time." "Those who participate will be entered into a chance drawing to receive a $100 Amazon gift card." Etc.

Commented [JM5]: This could stay in or come out. I don't think it needs to be here as it would be addressed in any consent process but it's ok to leave in.

SCHOOL OF DENTISTRY
UNIVERSITY of WASHINGTON

Dear [*participant name*],

My name is [redacted], and I am a PhD student at the School of Dentistry, University of Washington. I am writing to invite you to participate in my study on the gum health of adults ~~with Cystic Fibrosis (CF)~~. The information from this study may help us design dental care programs to help adults with ~~CF~~ certain conditions benefit from good oral health. I obtained your contact information from the ~~CF clinic~~, University of Washington Medical Center.

The purpose of this study is to help us understand how common gum disease is in adults with ~~CF~~certain conditions. It will also answer the following questions:

- Is there a link between ~~diabetes~~ certain conditions and gum disease ~~for individuals with CF~~?
- What factors (e.g. diet, medicines) are associated with gum disease?
- Does gum disease interfere with quality of life for adults with ~~CF~~certain conditions?

You might be eligible to participate in the study if you ~~have CF and~~:

- You did not take intravenous antibiotic in the last 4 weeks
- You did not take intravenous or oral corticosteroids in the last 4 weeks
- You do not need to take prophylactic antibiotics before dental checkups
- You do not smoke
- You are not pregnant

If you decide to participate in this study, we will ask you to take part in a single visit to our UW dental research clinic to complete questions about health history and medications, an oral health survey, a dental exam, and a diet survey. This visit is expected to last 1.5 hours. This visit may be scheduled after your medical appointments at UW medical center or while you are in the hospital or you may come on another day.

As compensation for your time and the cost of parking at UW medical center, we will give you a $95 gift card.

This study is completely voluntary. You can choose to be in the study or not. If you would like to participate or have any questions about the study, please contact me at [redacted] or email me at: [redacted]. We will follow up with you by phone to schedule a study visit if you are interested in participating.

Sincerely,

[redacted]
PhD. candidate
Department of Oral Health Sciences, School of Dentistry
University of Washington, Seattle
Email: [redacted]
Cell: +[redacted]

Commented [JM1]: Inclusion of this information implies private health information about the recipient. Alternatively one could be very general and say something like, "on the gum health of adults with certain conditions."

Commented [JM2]: Again, cannot include any information that implies something private about the individual. Restating it as edited here avoids implying anything private about the individual's health while still making clear it's not healthy adults the researcher is targeting.

Commented [JM3]: This type of specifics could be described over the phone if the person responds to the recruitment but it needs to come out here in this initial cold-contact because it implies private health information about this person. Presumably the researcher has already pre-screened the EMR for people with a CF diagnosis so it doesn't need to be stated here. Again it can be confirmed as part of screening.

~~***STUDIES OF BILIARY DISEASES***~~

We are conducting a study to identify new screening tests for biliary diseases. We are seeking male and female volunteers, ages 18 ~~–~~ 75 to participate~~, who are undergoing evaluation of their bile ducts here at the University of Washington~~. This letter is to provide information about an ongoing study.

Through a review of the UWMC medical records, we have identified you as someone who may potentially qualify to participate. ~~General information about this research study is being sent to patients who are scheduled for a procedure called endoscopic retrograde cholangiopancreatography (ERCP), for the evaluation of a biliary disorder.~~

Purpose of the study:
We have developed an experimental ultrathin camera called a mini-cholangioscope, or MC scope. This camera allows doctors to see inside certain small parts of the human body to image indicators of early disease. In this study we will test the camera to see if we can get good images of the bile duct ~~after the fluorescence dye QRH-882260 has been used to label inflammation~~. We plan to enroll 12 patients to test this new ultrathin camera to image the inner surface of the bile duct ~~and any tissue highlighted with the fluorescence dye~~.

Research Volunteers:
~~We are looking for individuals who have been scheduled for ERCP for evaluation of a biliary disorder.~~ For this study we would use the MC scope to examine the inside of your bile ducts following the completion of your routine ERCP. We expect the ~~additional~~ exam with the MC scope to take 10-15 minutes. This will be the third time the camera is used in human studies of the GI tract.

We realize that by participating in this research study you would be giving up some of your time. We will compensate you for that time with $100.

If you are interested in participating please email our research coordinator, [redacted], at [redacted] or call him at [redacted]. Participation in this research study is completely voluntary and will not affect your standard clinical care.

Thank you for considering this study. Study doctors are available to answer your questions here at the UWMC Digestive Health Center. Should you have additional questions, please feel free to contact the principal investigator of this study, Dr. [redacted] at [redacted].

Sincerely,

[redacted], MD
Clinical Professor of Medicine
University of Washington

[redacted], MD
Clinical Asst. Professor of Medicine
University of Washington

Commented [JM1]: Information that discloses private health information about someone cannot be included.

Commented [JM2]: Information that discloses private health information about someone cannot be included. It is also necessary to identify how the individual was identified/where their contact information was obtained.

Commented [JM3]: Same comments as above. Cannot include personal health info. If someone contacts them in response to the letter they can then go over more details about the study and what qualifies them.