



**Human Subjects**

*Office of Research*

**UNIVERSITY OF GEORGIA**

# **IRB Review on the Recruitment Process and Materials**

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# What is recruitment in research?

- The process of asking an individual to take part in the research
- Generally **the first contact between researchers and prospective participants** . This includes answering research questions from potential participants.
- A prelude to the informed consent process



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# What does the IRB need to review in the recruitment process & materials?

- When, where, and how participants will be initially contacted



Talking to people about the research  
(Face-to-Face Interaction)



Calling or emailing, USPS



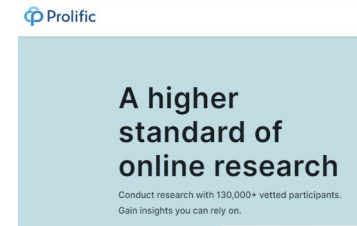
Posting or handing out flyers



Social Media Ads



TV, radio, newspaper, or billboard ads



Other online participants pool platforms

# Advertisement does not:

- State or imply a certainty of **favorable outcome** or other benefits beyond what is outlined in the consent document and the protocol
- Promise “**free treatment**,” when the intent is only to say subjects will not be charged for taking part in the research
- Emphasize the **payment** or the amount to be paid, by such means as larger or bold type or symbols
- Include **exculpatory language**



# What should be in the recruitment materials/advertisement?

Recruitment materials should be limited to the information prospective subjects need to determine their eligibility and interests, to wit:

1. **Name** of the **principal investigator** (PI), his/her affiliation, and contact information; the name of primary contact (if not the PI)
2. Word “**research**”
3. Condition under study or **purpose** of the research
4. Summary of the **criteria** to determine eligibility for the study
5. A brief list of participation **benefits**, if any
6. A description of any reasonably foreseeable **risks**, if any
7. Time or other **commitment required** of the subjects
8. **Location** of the research and the person or office to contact for further information



**For Amazon MTurk or similar participant panels with text/character limitations for posting:**

- The word “research”
- Summary of the **criteria** that will be used to determine eligibility for the study
- Condition under study or the **purpose** of the research
- Time or other **commitment required** of the subjects
- Amount of **compensation** that will be provided

**For Student Pools (SONA) where standard pool format is required:**

- The word “research”
- Summary of the **criteria** that will be used to determine eligibility for the study
- Condition under study or the **purpose** of the research
- Time or other **commitment required** of the subjects



# For FDA-Regulated research, the advertisement DOES NOT:

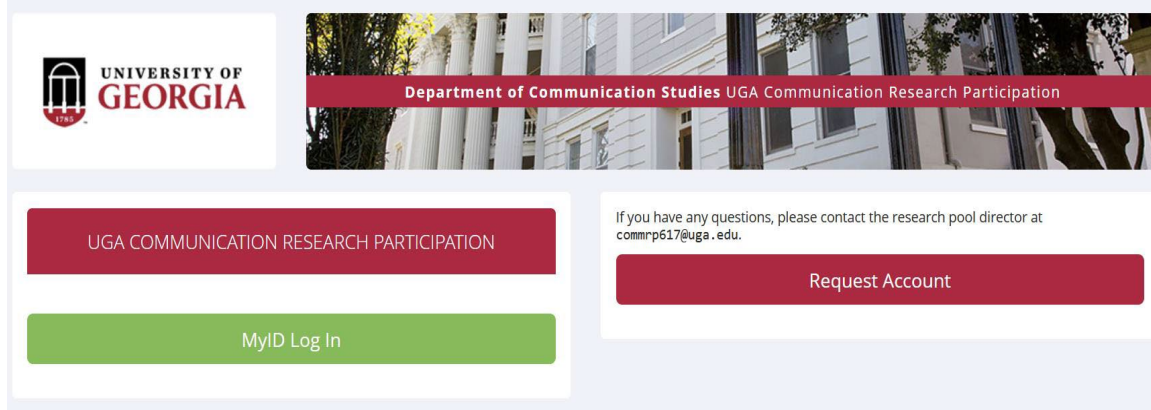
- Make claims, either explicitly or implicitly, that the **drug, biologic or device is safe or effective** for the purposes under investigation
- Make claims, either explicitly or implicitly, that the **test article is known to be equivalent or superior to any other drug, biologic or device**
- Use terms, such as “**new treatment,**” “**new medication**” or “**new drug**” without explaining that the test article is investigational
- Include a **coupon** good for a discount on the **purchase price of the product** once it has been approved for marketing.



# What is SONA Systems?

## SONA Systems

- A research participant pool used by several UGA Departments
- An online management system that makes creating surveys and signing up for research participation much easier for students, and allow researchers to manage appointments in real time





# How the SONA Systems work?

1. Participants have accounts in this system, and they use it to view studies and sign-up for the studies they would like.
2. Each study posts a brief description of it (SONA recruitment ad).
3. Sona allows PI to show studies only to people who have completed a screener and indicate qualifying (e.g., being a woman would see the study description and time slots).
4. PI post available time slots, participants take them, and provided with research credit when they show up.
5. Research data is completely separated from participant's data (e.g., online studies), unless PI collects it during the lab visit.
6. This system reduces the risk of coercion or undue influence or the appearance thereof.

**NOTE:** *No-show will not result in penalty or deducting credit to previously earned credits.*



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# External Site vs. Engaged

- **External Site** – organization where participants will be recruited
  - Examples:
    - Teacher will forward recruitment email to students
    - Hospital Clerk will hand out flyers to patients
  - Letter of Support from the external site may be required
- **Engaged** – does the recruiting and consenting
  - Examples:
    - Teacher/Hospital Clerk will answer questions about the research aside from forwarding the recruitment email/handing out flyers.
    - Providing the consent form and answering questions
  - Non-UGA team member own IRB Approval is required; or if no IRB, Individual Investigator Agreement may be considered



# Special considerations when recruiting children

1. Children vs. Minors in Research – not all “minors” meet the federal criteria for being “children” as defined in 45 CFR 46.402.
  - Some states permit some minors to consent to research. E.g. California
  - Legal Age/Majority Age
    - 18 – most states including Georgia
    - 19 – Alabama and Nebraska
    - 21 – Mississippi
2. Wards (45 CFR 46.409) – wards of the state or any other agency, institution, or entity can be included in research only if such research is:
  - (1) Related to their status as wards; or
  - (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
3. Pregnancy Testing for Minor Girls
  - If MRI, fMRI, MRS, similar procedures and drugs will be used in research

# Special considerations when recruiting children (cont.)

## 4. Minors in long-term studies

- Minor during enrollment but reach the age of majority while study procedure or follow-up are still ongoing

## 5. Educational Setting –

### • Family Educational Rights and Privacy Act (FERPA )

- is a Federal law that protects the privacy of student education records

### • National Student Lunch Act (NSLA)

– is the federal policy governing free lunch service to students in K12 settings. It protects the data (who gets free or reduced-price lunches). As such, specific parent (or student if they are over 18) consent is required to use/access the data

- **For Recruitment purposes**

- If the data are used to identify a population, clearly, they have not given their consent yet. Thus, this recruitment process is not NSLA compliant

## Special considerations when recruiting children (cont.)

- Protection of Pupil Rights Amendment (PPRA) – is a federal law that provides certain rights for parents of students regarding, among other things, student participation in surveys; the inspection of instructional material; certain physical exams; and the collection, disclosure, and use of personal information for marketing purposes.
  - Opt-out consent process – a letter is sent to parents that serves as the recruitment and consent form. This will only be returned with parent's signature if they want their child to opt-out for research
    - Waiver/Alteration of Consent required
  - Some schools prefer opt-in consent process – consent form is required
- 6. Parent/s participation requirement
  - Studies where parents are also participants – if parent/s allowed their child to participate but not themselves, will the child be excluded?

# Recruitment section in the protocol

From the study workspace, you may see the entire study in PDF by clicking **PRINT PROJECT**.

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Hello, Maricia Dilan

My Inbox Meetings Library SPA Access Site Administration

Page for Staci Belcher > HR-pQCT Performance Study Admin View Help

**Project Editor**  
HR-pQCT Performance Study ID: PROJECT00005603

Edit Project  
Print Project  
View Differences

**Activities**  
Submit Changes  
Submission Checklists  
Administration  
Send to Pre-Review  
Add Public Comment  
Add Internal Comment  
Add Additional Readers  
Submission PDF  
Take Snapshot

Principal Investigator: Kindler  
Reviewer: Dilan  
Funding Source: No results found.  
Committee: IRB 2  
Review Category:

Contacts: Belcher  
Review Level:  
Approved Date:  
Expiration Date:  
Project Status: Deferred

**Documents**

Draft	Category	Date Modified
Excludable Medical Conditions	Consent Form	5/6/2022 11:03 AM
Screening form	Consent Form	5/5/2022 3:34 PM
Consent form	Consent Form	5/11/2022 9:20 AM
Demographics questionnaire	Materials for Data Collection	5/5/2022 3:40 PM
Health History Questionnaire	Materials for Data Collection	5/5/2022 3:40 PM
Anthropometrics form	Materials for Data Collection	5/5/2022 3:46 PM
Scan protocol	Other	5/10/2022 7:55 PM
Scan protocol HRpQCT	Other	5/11/2022 11:38 AM
Email Script	Recruitment Materials	5/10/2022 2:43 PM
Flyer	Recruitment Materials	5/10/2022 2:44 PM
Follow up scripts	Recruitment Materials	5/10/2022 2:43 PM
Social Media Post	Recruitment Materials	5/10/2022 2:44 PM
Social Media Caption	Recruitment Materials	5/10/2022 2:44 PM
Classroom Script	Recruitment Materials	5/10/2022 2:44 PM

To see the reviewer's comments, click **VIEW PROJECT (top link)** or **VIEW DIFFERENCES**.  
Note: Only the admins have the **EDIT PROJECT** link.

# Recruitment section in the protocol (cont.)

## PRINT PROJECT View (PDF Version)

Scroll down to see the recruitment section.

ovpr-click-prod.ovpr.uga.edu/irb/app/portal/smartform/printProject/\_Submission/64D1015D696A284AB984A88A09031830?packetids=c

PROJECT00005603 Recruitment Methods and Materials

### Recruitment Methods and Materials

1. Will you recruit individuals to take part in the study? ?  
 Yes  No

2. Describe when, where, and how participants will be initially contacted: ? ← Q2 – recruitment process  
Initial recruitment for this study will include the following:  
- Social media postings  
- University email list-serves  
- Webpage announcements  
- Classroom announcements (Dr. Kindler will NOT announce the study in his courses)  
- Bulletin board (campus and community) flyers

Interested individuals will contact the study team to inquire into the study. If interested in determining eligibility for the study, potential participants will provide verbal consent indicating their intention to complete the screening questionnaire.

3. Describe any follow-up recruitment (e.g. multiple attempts/contacts for the purpose of inviting someone to participate):  
For individuals that contact the study team due to interest in participating in this study, these individuals will be contacted either by telephone or email. Subsequent recruitment contact will be made through these means, but only for individuals who indicate that they are interested in learning more about the study.

4. Documents:

Document Category	Date Modified	Content URL
View Email Script	Recruitment Materials 5/10/2022	<a href="https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/1UF157CN78IKP32FUQRFI38OD4/5603_email.docx">https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/1UF157CN78IKP32FUQRFI38OD4/5603_email.docx</a>
View Flyer	Recruitment Materials 5/10/2022	<a href="https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/S1SL44BT7V3474IGU69A39AN66/5603_Flyer.png">https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/S1SL44BT7V3474IGU69A39AN66/5603_Flyer.png</a>
View Follow up scripts	Recruitment Materials 5/10/2022	<a href="https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/CJILIF8A3H7KR0M30EJCUM4FF5/5603_fu_scripts.docx">https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/CJILIF8A3H7KR0M30EJCUM4FF5/5603_fu_scripts.docx</a>
View Social Media Post	Recruitment Materials 5/10/2022	<a href="https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/7P6Q4RQ1C2LK3F6R19026H5L3E/5603_Social%20Media.png">https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/7P6Q4RQ1C2LK3F6R19026H5L3E/5603_Social%20Media.png</a>
View Social Media Caption	Recruitment Materials 5/10/2022	<a href="https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/8K1SDUEUB1T4N2FM001A6M179C/5603_socialmediacaption.docx">https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/8K1SDUEUB1T4N2FM001A6M179C/5603_socialmediacaption.docx</a>
View Classroom Script	Recruitment Materials 5/10/2022	<a href="https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/MIRT24R6RG94579IMFO6F5OS8F/5603_classroom.docx">https://ovpr-click-prod.ovpr.uga.edu/irb/sd/Doc/0/MIRT24R6RG94579IMFO6F5OS8F/5603_classroom.docx</a>

PROJECT00005603 Consent Process and Materials

### Consent Process and Materials

1. Select the applicable option(s) below to describe the consent process/es for this study: ?

Option	Description:
Informed consent will be obtained and documented	The consent process includes all elements of consent and participants will sign a consent document.

You will be required to attach consent documentation on question #4 below before submitting

Materials should include all recruitment mentioned in Q2 & Q3, even the follow-up email/script to schedule lab visit or interview.

You should be able to open the **attachments** from Print Project View.

# Helpful Links/Resources:

- 092 – [Participant Selection and Recruitment](#)
- 095 – [Students as Research Participants](#)
- 096 – [Family Educational Rights and Privacy Act \(FERPA\) and Use of Education Records](#)
- [UGA Research Participant \(RP\) Pool Information](#)
- [Use of Penalties for Students Who Fail to Show up: Letter to SONA SYSTEMS, \(January 8, 2010\)](#)
- [Children in Research \(berkeley.edu\)](#)
- [FERPA \(https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html\)](https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html)
- [PPRA \(https://studentprivacy.ed.gov/faq/what-protection-pupil-rights-amendment-ppra\)](https://studentprivacy.ed.gov/faq/what-protection-pupil-rights-amendment-ppra)
- [NSLA \(https://www.georgiaencyclopedia.org/exhibition/food-power-and-politics-the-story-of-school-lunch/\)](https://www.georgiaencyclopedia.org/exhibition/food-power-and-politics-the-story-of-school-lunch/)



# Thank you!



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