Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Screening Process

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Criteria for Approval

(45 CFR 46.111) (25 CFR 56.111)

- Minimized Risks
- Reasonable Risk/Benefit Ratio
- Equitable Subject Selection
- Informed Consent Process
- Informed Consent Documentation
- Data Monitored for Safety
- Confidentiality/Privacy Maintained
- Vulnerable Populations Protected

Definitions

- **Equitable Selection** – the process of defining the appropriate group of subjects for a research using methods that will encourage a broad cross-section of subjects and will evenly distribute the burdens of research

- **Eligibility Criteria** – the requirements that must be met for a person to be included in the study and that often are established to ensure the safety of the participants

- **Recruitment** – includes all activities where information is provided to the prospective participant (e.g., flyer, ads, word of mouth, website)

Definitions (cont.)

- **Screening process** – starts the moment the investigator obtains information about the prospective participant to determine eligibility for research, which may include:

  1. Any interaction or intervention with subjects (e.g., screening survey, interview screening, task, etc.), OR
  2. Accessing the results of intervention that were performed for purposes other than the study

Screening, recruiting, or determining eligibility 45 CFR 46.116 (g)

The IRB may approve a non-exempt research that includes collecting information or biospecimens for the purpose of screening, or determining eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

Information to give participants

- **Condition 1: Thru oral or written communications**

  The screening consent script should include:

  - Questions that collect data only related to the eligibility criteria
  - A statement related to the retention and protection of data for those who eventually enroll in the study
  - Plans for the data of those who are not eligible or who do not enroll in the study
    - Screening data – immediate destruction
    - Contact info – may be kept separate from the research data for future study

- **Condition 2: Accessing Records**

  - If this includes protected health information (PHI), HIPAA applies, and HIPAA Authorization may still need to be obtained prior to conducting the screening activities or a Waiver of HIPAA Authorization must be requested

Information recorded prior to seeking Informed Consent

- This should be limited to information necessary to establish eligibility and contact information (e.g., presence or absence of medical conditions, date of onset, lab results)

- Administration of questionnaires/surveys that involve collection of additional information (beyond eligibility criteria) or that could possibly increase risk for subjects would require prior informed consent

  - e.g., lengthy standardized questionnaires that make a new, or refute an existing, diagnosis; surveys/questionnaires where subjects' responses may place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing; etc.

- Creation of new data through means other than oral/written communication with the subject or collection of biospecimens solely for research purposes would also require prior informed consent

PROTOCOL: Human Research Participants section

Human Research Participants

1. Targeted Populations - Click "Add" to provide a general description of the targeted participants. See Help text on the right for definition of human subject.:

+ Add

	Targeted Population	Targeted Gender	Age or Age Range	Total Number
Update	Generally healthy individuals	all genders	18 and above	30-40

2. Inclusion Criteria - if there are multiple targeted populations, identity the criteria for each:

3. Exclusion Criteria - if there are multiple targeted populations, identity the criteria for each:

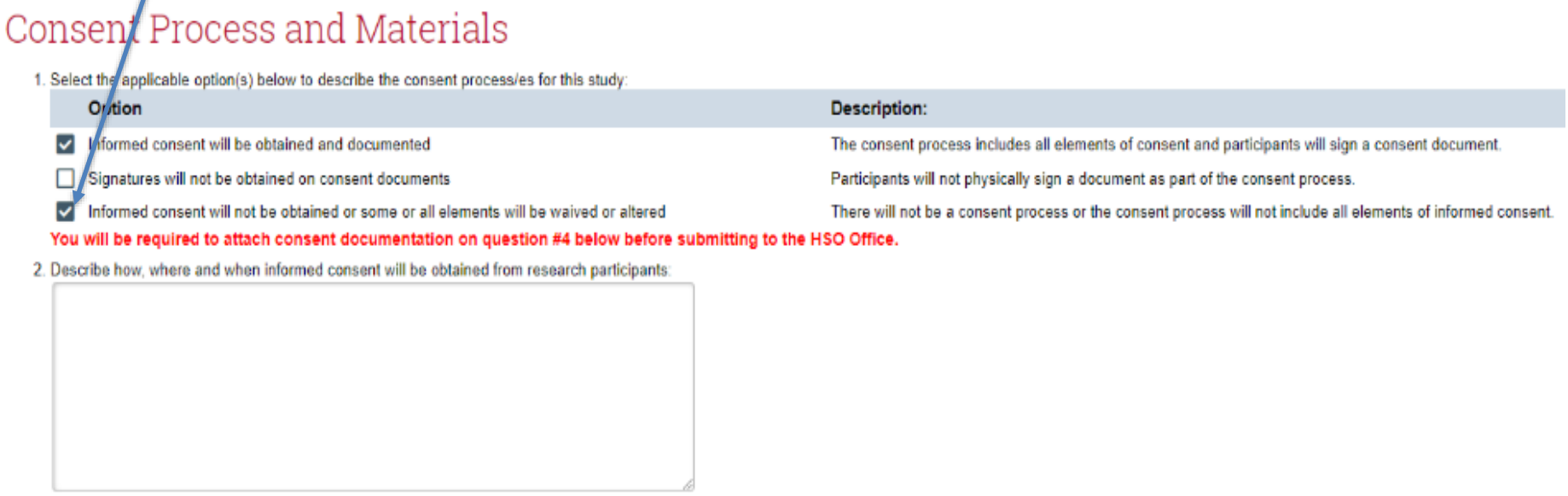
4. Eligibility Criteria - Describe how potential participants will be initially identified and how eligibility will be determined:

Provide details about the screening, recruiting, and eligibility verification process for Q4 (Eligibility Criteria).

Exit

PROTOCOL: Consent Process and Materials section

To indicate that consent will not be obtained for screening prospective participants, choose "Informed consent will not be obtained or some or all elements will be waived or altered" for Q1.



Consent Process and Materials

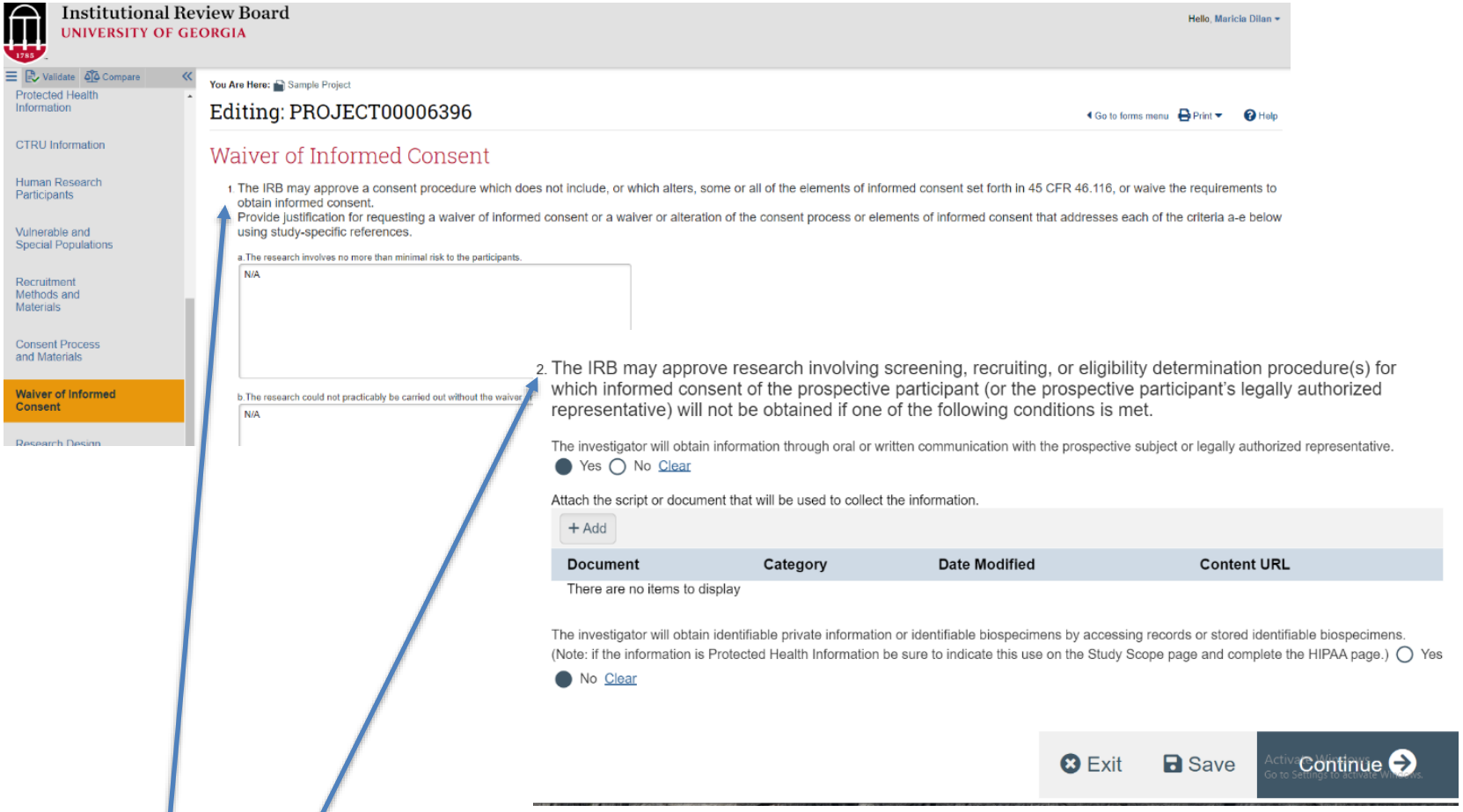
1. Select the applicable option(s) below to describe the consent process/es for this study:

Option	Description:
☑ Informed consent will be obtained and documented	The consent process includes all elements of consent and participants will sign a consent document.
☐ Signatures will not be obtained on consent documents	Participants will not physically sign a document as part of the consent process.
☑ Informed consent will not be obtained or some or all elements will be waived or altered	There will not be a consent process or the consent process will not include all elements of informed consent.

You will be required to attach consent documentation on question #4 below before submitting to the HSO Office.

2. Describe how, where and when informed consent will be obtained from research participants:

PROTOCOL: Waiver of Informed Consent section

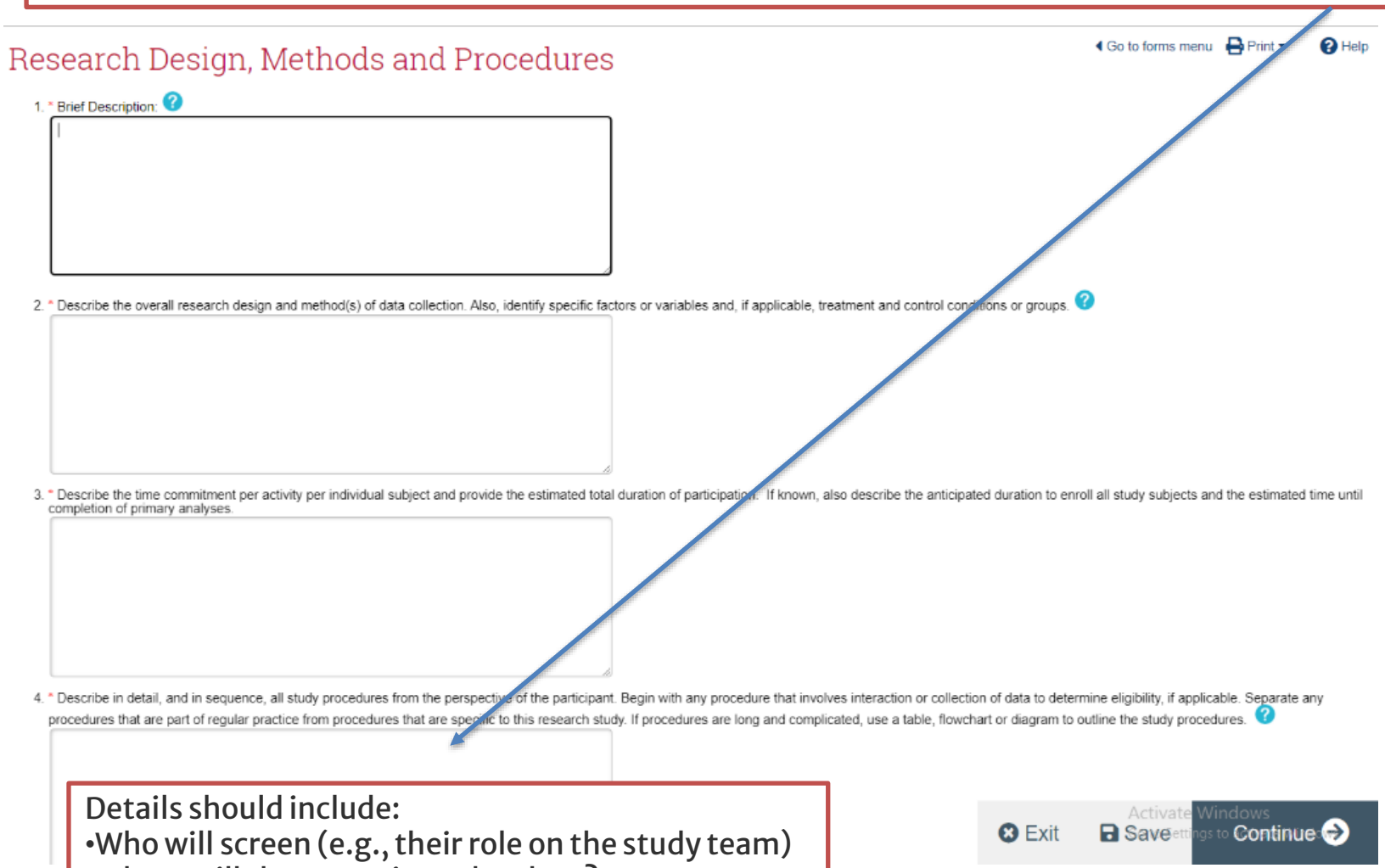


PIs can skip Q1 (a-e) unless they are are wavering or altering the consent processes or elements. Instead, they should focus on answering Q2 regarding the screening process.

PIs should include the final version of the screening questions in a Word document or PDF that the participant will receive, along with any introductory document such as an agreement or partial consent.

PROTOCOL: Research Design, Methods, & Procedures section

Provide the process and procedures for screening potential participants in response to Q4.



Details should include:
- Who will screen (e.g., their role on the study team)
- Where will the screening take place?
- When will the screening take place?
- How will PI collect the data for screening?

IRB Reminder

Screening Data

- Before the informed consent process
- Eligibility information collected thru interaction/intervention or review of previously collected information
- Contact information can be kept separately from research data, especially for those who are not eligible
- Data of ineligible participants should be destroyed right away since they will not continue to take part in the research, unless PI justifies why data should be kept
  - Common reason: data are de-identified immediately and high-level demographics and screen-fail reasons are reported in aggregate

Research Data

- After the informed consent process
- Data of all the research activities (e.g., surveys, interviews, tasks, experimental /control interventions, etc.)
- Data of eligible participants become part of research data since they will continue to take part in the research

MEMORY REVIEW

Memory Review

- Does the cuff inflate to a certain mean arterial pressure, or do researchers determine that there's a lack of distal pulses when the cuffs inflated to prove that it produces ischemia?

- What does mitochondrial capacity mean in lay terms?

- How each test will be conducted (i.e., the specificity of the environment during testing, who will conduct them, what instrumentations employed, and the instructions provided concerning potential risks)?

- Will the home visit include faculty members? What is the protocol for incident reporting during testing?

Helpful Links/Resources:

- HRP-001 – Definitions
- NIH.gov: Eligibility Criteria Toolkit
- 45 CFR 46.116 (g): General Requirement of Informed Consent
- Research.uga.edu/hrpp/ - Develop and Submit – Screening for Eligibility
- **IRB Member Resources – Archived Presentations – November 2, 2022 and November 18, 2022 – Reviewing Recruitment Process and Materials**
- **IRB Member Resources – Archived Presentations – August 19, 2016 – Back to Basics – Approval Criteria**

Thank you!