The IRB reviews recruitment materials to ensure they do not imply a certainty of favorable outcome or other benefits beyond those outlined in the consent document and the protocol. The intent of these guidelines – to avoid coercion, and ensure that recruitment is fair, equitable, and not misleading - applies whatever the recruitment medium. See GPM 207.1 Equitable Selection.

**Attach the following recruitment tools to the Attachments section in the eProtocol application (as applicable):**

* Social media ads - e.g., on Facebook, Twitter, Instagram, Craigslist, or other sites
* Flyers
* Email recruitment scripts
* Phone scripts and phone screens: Attach in eProtocol under Waiver of Documentation (not in the Attachments section)

**Avoid the following content:**

1. Payment: Although advertisements can explain that subjects will be paid, they **should not** emphasize the payment or the amount to be paid, e.g.:
   1. **Do not** use larger font size, italics, underlining or bolding of the payment amount
   2. **Do not** use statements such as “$10 for 10 minutes”, “$20 research study!”, “Participate in a fun research study for $10!”
   3. **Do not** list payment or amount in the heading/title of the advertisement or in an email or Craigslist subject line.
2. Avoid language such as “fun research study,” since this is the researcher’s subjective opinion and would not necessarily describe the experience of the participant.
3. Avoid any guarantee that participation will benefit participants in any way (cure, improvement, etc.)
4. **Studies involving a test article** (investigational drug, biologic or device):
   1. No claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.

*Such representation would not only be misleading to subjects but would also be a violation of the FDA’s regulations concerning the promotion of investigational drugs [21 CFR 312.7(a)] and of investigational devices [21 CFR 812.7(d)].*

* 1. Recruitment materials should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational*.*

*A phrase such as "receive new treatments" leads study subjects to believe they will be receiving newly improved products of proven worth.*

1. Advertisements should not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation.
2. Advertisements should not have any exculpatory language in which the participant is made to waive or appear to waive any of his/her legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

**Consider including the following:**

**Generally, advertisements to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.**

**When appropriate, the following items may be included in advertisements:**

1. Name, phone number and address of the investigator and/or research facility;
2. Where an email address is included, it should be the institutional email address, e.g., “xxx@hawaii.edu” (not Gmail, etc.).

A UH email list (listserv) can be created for a specific lab or protocol so that several study personnel can receive the same email.

1. The condition under study and/or the purpose of the research;
2. In **summary** form, the criteria that will be used to determine eligibility for the study;
3. A **brief** list of participation benefits, if any (e.g., a no-cost health examination);
4. The time or other commitment required of the subjects; and
5. The location of the research and the person or office to contact for further information
6. A statement, “Participant’s rights questions, contact 1-866-680-2906.”
   1. At the consent observation meeting, the observer will:
      1. Introduce herself /himself to the potential participant;
      2. Explain the reason for her/his presence; and
      3. Obtain the participant’s verbal permission for observing consent.
   2. Documents the observations on the Worksheet: Consent Observation Checklist (WKSH)
   3. May discuss any initial observations privately with the POC after consenting is completed.
   4. Prepares a written report which is forwarded to the CQI Associate Director and the Senior Compliance Analyst.