

## University of Southern Maine

### RECRUITMENT MATERIALS: USM IRB GUIDANCE

Recruitment of study subjects is the beginning of the consent process. This guidance is applicable to all forms of recruitment materials, including recruitment flyers, posters, brochures, emails, letters, and oral scripts. Please take care to consider the readability of your recruitment materials and ensure that recruitment language is consistent with consent language, the Research Protocol Summary language, etc. Recruitment materials should be submitted with the initial IRB submission and labeled (i.e., last name, recruitment flyer).

The IRB will evaluate recruitment processes, including advertisements, to ensure a fair and equitable selection of participants.

“Equitable selection of participants” in research means choosing study subjects in a way that fairly distributes the benefits and burdens of research, ensuring that no specific group is unfairly excluded or targeted, and that the selection criteria are based on sound scientific rationale rather than biased factors like race, gender, or socioeconomic status; essentially, it's about selecting participants in a just and ethical manner where everyone has a fair chance to participate if they meet the study criteria.

#### **Further References**

The Program for Readability In Science & Medicine (PRISM) is a Group Health Research Institute initiative to improve the readability of consent forms and other print materials used in communication with study participants. There is a free online training module about plain language created for researchers. It can be accessed at:

<http://prism.grouphealthresearch.org/start.htm>

The Food and Drug Administration (FDA) has a guidance document about recruitment materials titled *FDA's Guidance for Recruiting Study Subjects Information Sheet*. It can be found at:

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm>

Recruitment materials inform potential participants about the availability of research and therefore should clearly present information in an adequate, accurate, and balanced manner. This ensures potential subjects can make informed decisions free from coercion or undue influence. Recruitment materials should be limited to the information the prospective subjects need to determine their eligibility and interest.

The following items should be included (as applicable) in recruitment materials:

- Project title.
- General statement about the purpose of your research study.
- Key inclusion/exclusion criteria in summary form.
- Time and/or other commitment required.
- Location of research.
- Investigator's name (use staff credentials vs. title, i.e. John Smith, MD instead of Dr. John Smith).
- Study contact person's name and contact information.
- Compensation/reimbursement. NOTE: recruitment materials should not emphasize monetary compensation.
- Risks and benefits. Be careful not to overstate benefits and understate risks.
- Language that participation is voluntary.
- End date for the recruitment window.

Recruitment materials should not:

- Present information that is misleading about the purpose of the study.
- Use coercive language such as *free* or *exciting*.
- Use exculpatory language through which the subject or the subjects legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability or negligence.
- Include any inappropriate pictures or images.
- Be exhibited in inappropriate venues.

Points to consider:

- If necessary, obtain approval from the site(s) where recruitment materials will be displayed or distributed.
- Voluntariness is essential; the conditions must be free of undue influence and coercion.
- Ease of comprehension.
- The privacy of the potential participant, particularly for research studies that are sensitive in nature.
- Recruitment methods should allow ample time to consider participation.
- Whether the PI is the best person to recruit (to avoid undue influence).