Receiving Approval for Research Recruitment Material

The process for receiving Creative Communications approval for research recruitment material has been made easier with the inclusion of Creative Communications in the eIRB ancillary process. Now study teams need only to decide which of two approaches they wish to adopt.

The first approach is to work with Creative Communications up front to have the advertisement materials developed, or to receive feedback on ads developed by the study team. For brand approval, e-mail material to brandchampion@wakehealth.edu. Once Creative Communications has signed off on the materials, upload their approval letter and submit the study for review by the applicable ancillary review groups and the IRB. During the ancillary review, Creative Communications will verify their approval in eIRB, along with any other ancillary groups, which will allow the study to move forward for IRB review. If the IRB requires any changes in the text of recruitment materials, the specifics of the required revisions will be sent along with other IRB concerns. The study team will make all required changes and return their response. The ads will be routed back through Creative Communications from final verifications that the revised ads meet Medical Center branding requirements. Once final approval is granted by Creative Communications, the IRB will perform the final regulatory review and a decision on study approval will be communicated back to the study team.

The second approach is to submit the research recruitment materials without prior approval from Creative Communications. The materials will still be reviewed for compliance with branding requirements during the ancillary process (e-mail material to brandchampion@wakehealth.edu.), but Creative Communication concerns will be uploaded into eIRB as a public comment and these concerns will be included with stipulations for approval sent to the study team following IRB review. The study team will make all required changes and return their response. The ads will be routed back through Creative Communications for final verification that the revised ads meet Medical Center branding requirements. Once final approval is granted by Creative Communications, the IRB will perform the final regulatory review and a decision on study approval will be communicated back to the study team.

Be certain to budget for the development of research recruitment materials in your grant or clinical trial agreement. Pricing for Creative Communication services can be found on the Brand Center. Follow the guidance on the Brand Center webpage if recruitment materials will be developed from templates available here.

When creating research advertisements for studies conducted at Wake Forest Baptist Health:

Please **DO** the following:

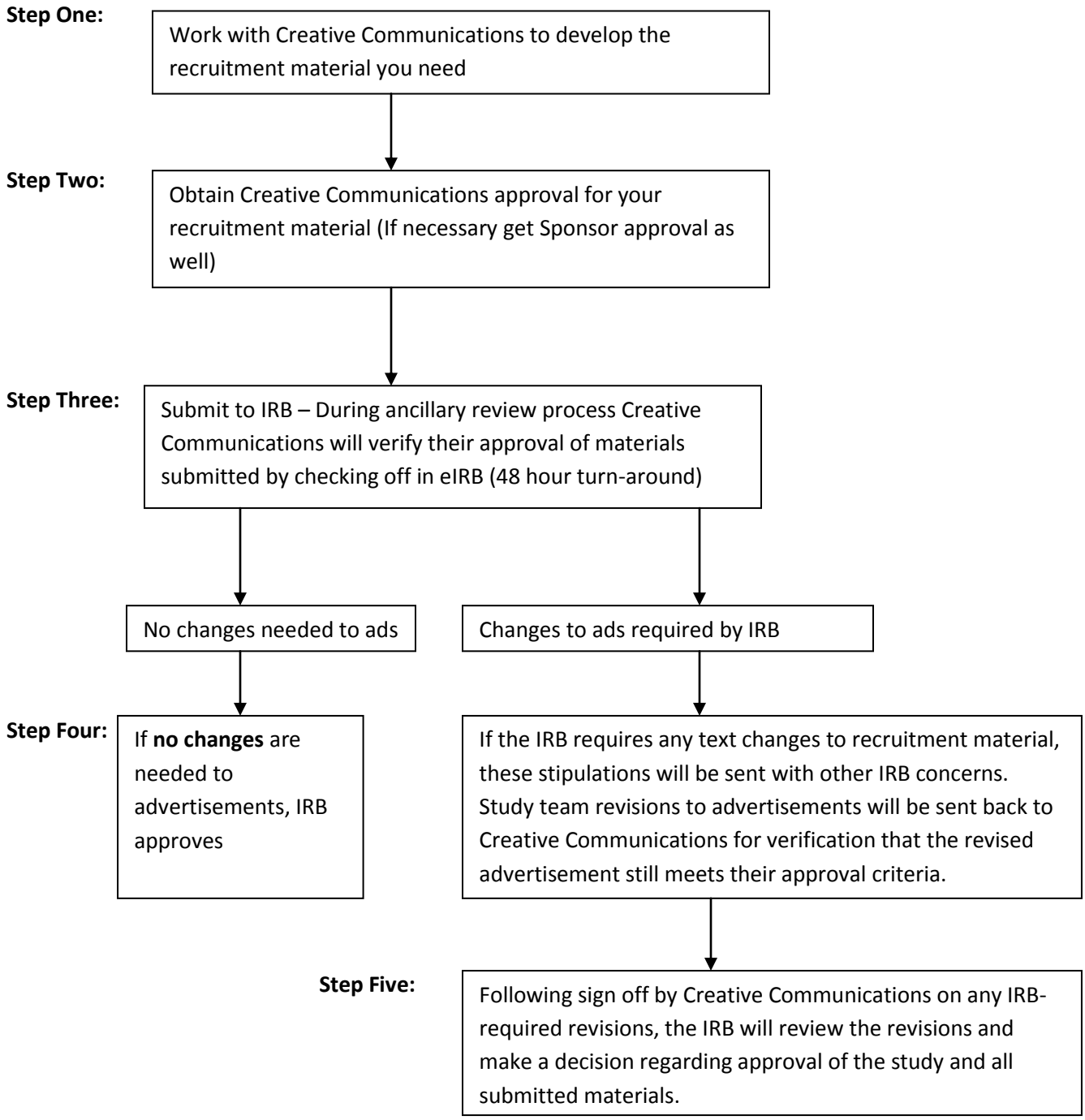
- Use the word “research study”
- List the IRB number
- List a contact number for the study team
- Provide the name of the Wake Forest Baptist Health Principal Investigator
- Use the Wake Forest Baptist Health logo and branding

- If a study has a specific logo and it is possible to co-brand your material, then co-branding within the Medical Center brand standards should be practiced. This is not required for sponsored studies which provide national or regional materials that are unalterable by the sites.
- Keep your verbiage short and to the point; see the Brand Center for guidance
- Follow the design intent of our brand look and feel by becoming familiar with the design examples on the Brand Center website
- Use photographic images that best reflect the integrity of our institution

Please **DO NOT DO** the following:

- Do not use graphic photos that depict surgical procedures, traumatic injury, cartoon-like images or images that could be considered in poor taste or not befitting the image of our institution
- Do not state the *amount* of compensation for subjects. Instead, please state only that compensation for participation is available
- Do not imply through words or pictures, the endorsement of any illegal activities
- Do not imply through words or pictures, the endorsement of any particular political viewpoint
- Do not use statements, pictures, or other symbols that may imply the improper exclusion of subjects from research (exclusion of subjects from research must be based on a scientific justification approved by the IRB)
- Do not state or imply a certainty of favorable outcomes as a result of participation.
- Do not imply that the drug, biological, device, test, procedure, or intervention is safe or effective for the purposes under investigation
- Do not make any claims, either explicitly or implicitly that the drug, biological, device, test, procedure, or intervention is known to be equivalent or superior to any other drug, biological, device, test, procedure, or intervention
- Do not use exculpatory language in any advertisements
- Advertisements should not promise “free medical treatment” when the intent is only to say research subjects will not be charged for taking part in the investigation
- Do not alter the formatting of templates downloaded from the Brand Center

Research Advertisement Approval - Option One



Research Advertisement Approval - Option Two

Step One:

Submit to IRB – During ancillary review process Creative Communications will review the materials submitted (48 hour turn-around time)

Step Two:

Changes required by Creative Communications will be uploaded into eIRB as a public comment. These stipulations will be sent back to the study team along with any requests for revision generated by IRB review.

Step Three:

Response from study team is routed first to Creative Communications for their review of advertisements

No changes needed to ads

Changes to ads required by Creative Communications

Step Four:

If **no changes** are needed to advertisements, IRB reviews and approves

If the Creative Communications requires further changes to recruitment material, these stipulations will be sent as IRB concerns. Study team revisions to advertisements will be sent back to Creative Communications for verification that the revised advertisement still meets their approval criteria.

Step Five:

Following sign off by Creative Communications on any IRB-required revisions, the IRB will review the revisions and make a decision regarding approval of the study and all submitted materials.