Quorum

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Participant Materials and Retention Program Guidelines

Quorum Review IRB(Quorum) considers recruiting activities to be the beginning of the informed consent process. Consequently, in accordance with its authority to approve or disapprove all research activities, the Board requires prospective review of all recruitment materials that are intended to be seen or heard by prospective participants to solicit their participation in a study. Likewise, protocol study tools, study materials, and participant retention programs intended to encourage enrolled participants to continue participation in a study or provide participants with study-related information must be reviewed and approved by the Board before implementation.

PARTICIPANT MATERIALS

Recruitment materials include:

- Printed materials: advertisements in newspapers, bulletin boards, posters, flyers, brochures, press releases, "Dear Patient" letters (for recruiting purposes), informational articles for recruitment purposes, newsletters, study synopses, etc.
- Audio/Video materials: radio scripts and recordings, public service announcement scripts and recordings, telephone screening scripts, television scripts and recordings, etc.
- Internet materials: Websites, Internet screening, banner ads, etc.

Non-Recruitment materials include:

- Diaries, instructions, and medication logs
- Other written study specific instructions (for following study procedures, using study devices, following study dietary requirements, etc.)
- Participant information letters
- Appointment reminder cards, emergency unblinding cards
- Summaries of the study screening procedures
- Agreements to comply with study procedures or requirements
- Protocol-required questionnaires, surveys, and medical guidelines

Materials can be submitted for review in several ways:

- For one investigator/site
- For all investigators in a study
- For a subset of investigators in a study
- For sponsor use at the national or regional level
- For generic use, not associated with a specific study

Approval letters can be distributed to Investigators by:

- Sponsor or CRO
- Quorum

This option is only available for studies submitted in 2017 or after

HELPFUL HINTS FOR CREATING PARTICIPANT MATERIALS

When creating participant materials, please note the following guidelines:

Do

- **Do** make plain that the solicitation is for the purpose of participation in research and not for the provision of medical care. Do use the term "research" (or a synonym) when describing the study.
- **Do** use the term "investigational" (or a synonym) if a test article or treatment is referenced in the advertisement.
- **Do** indicate that the research involves the "investigational use" of an approved drug if applicable to the study.
- **Do** make sure that the material complies with applicable state and local laws.
- **Do** submit the material in final format, including site-specific information as appropriate and graphics that will be used.
- **Do** make mention of the research study in the advertisement.

Do Not

- **Do not** use language or graphics that may be coercive or misleading.
- **Do not** state or imply a guarantee of benefits, cures, or favorable outcomes.
- **Do not** emphasize "free" treatment or study products.
- **Do not** claim the study product or treatment is superior to other options.
- **Do not** place emphasis on payment, including bolding or highlighting the compensation language.
- **Do not** use the terms "safe," "effective," "new," "best," "cure," "treatment," "therapy," or "free."

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Types of Material:

1. Recruitment Materials

Study-specific materials must be reviewed and approved by the Board before use if they are distributed to participants as a requirement of the protocol. In reviewing advertisements and participant recruitment materials, the Board ensures that appropriate safeguards exist to protect the rights and welfare of research participants. The Board reviews recruitment materials to ensure that participant selection is equitable, and that the materials abide by informed consent principles (for example, that the materials contain no exculpatory language, are not unduly coercive or misleading, and do not promise a certainty of cure beyond what is outlined in the consent and the protocol).

2. Non-Recruitment Materials

Consistent with the review of recruitment materials, the Board requires the review of non-recruitment materials to ensure that that the materials are not unduly coercive or misleading, and do not promise a certainty of cure beyond what is outlined in the consent and the protocol.

As a general rule, Quorum requires study-specific documents that require a participant's signature and that address issues routinely included within a consent form to be incorporated into the Board-approved consent form for the study. A "protocol study tool" is a type of participant material generated by the sponsor that is also described in the protocol as being given to participants as part of the study procedures.

3. Radio and Television Scripts

Radio and television scripts will be reviewed and approved subject to the following conditions:

(1) Quorum recommends that scripts are submitted for review before production of the recording is started.

(2) After the script has received Board approval and the ad has been recorded, the final recording *must* be submitted for review prior to broadcast.

(3) After approval, radio scripts for live broadcast use must be read exactly as approved.

To avoid costly post-production revisions to radio or television recordings, Quorum encourages sponsors and investigators to adhere to the guidelines stated above. Please note that the first recording based on an approved script is reviewed by Quorum at no charge. Any additional recordings based on that same approved script are billable, and as such, may require sponsor approval before being submitted for review by Quorum.

4. Participant Retention Programs

A participant retention program is a program that involves the provision of gifts or other incentives to enrolled participants to encourage their continued participation in a study. As an example, an investigator might offer $20 gift cards to participants who reach a particular study visit milestone. Or, a sponsor might provide inexpensive gifts (e.g., tote bags, pens, t-shirts,

mugs, etc.) throughout a study. A pedometer used for the study that a participant can keep once the study is complete should also be considered a gift.

Quorum requires the prospective review and approval of participant retention programs before they are initiated. Consistent with the review of participant recruitment materials, the Board reviews participant retention programs to ensure they are not unduly coercive. If a sponsor/investigator desires to utilize such a program, a detailed description of the program should be submitted for review. Please note that the Board may require revisions to a consent form to reflect the program.

5. Items that do not require review

Please note that Quorum does not review the following materials:

- Spelling corrections to previously approved material.
- Changes to site specific contact information in previously approved material.
- Medical guidelines, recipes, or informational materials (published by third parties) that are not required to be provided to participants by the protocol.
- "Dear Doctor" letters and doctor-to-doctor letters for the purpose of soliciting potential study participants. (However, please note that “Dear Doctor” letters provided to investigators with regard to new or updated safety information should be submitted according to the *Quorum Safety Information and Unanticipated Problems Reporting Guideline*).
- News stories (including informational articles not distributed for recruitment or retention purposes), and publicity intended for audiences other than potential participants (such as financial page advertisements directed toward prospective investors).
- General health care instructions and general use consent forms for medical procedures specific to a medical condition or surgery for which patients are separately consented.
- Investigator’s site “house rules” or instructions.
- Internet listings when the system format limits the information provided to basic trial information, such as title of the study, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the site for further information. **Please Note: Craigslist and other online advertising in which the format is not limited to the format noted above must be submitted for review.**

Types of Participant Material Submissions:

From time to time, Quorum is asked to review material that pertains to more than one study. Such material may qualify for review as generic material. Otherwise, when Quorum reviews and approves material Quorum’s approval extends only to the study of which Quorum has oversight. The investigator is responsible for obtaining the approval of any other IRB(s)/REB(s) that must review the material.

1. Investigator-Specific Participant Materials

When a site submits its own advertising or recruitment materials, the Board’s approval to use those materials extends only to that site. Such investigator-specific materials are usually reviewed within 48 hours of receipt.

Written confirmation of pre-approval from a sponsor representative with submission of the recruitment material is required if the sponsor has requested such approval. To find out if

written sponsor approval is required for site-submitted materials contact Quorum's Client Support team or the sponsor of the research.

2. Model Participant Materials

A study sponsor may submit model participant materials on behalf of all or some of the investigators participating in a protocol. These materials may be approved without investigator-specific contact information, which can be added by the investigator after approval. Generally, model participant materials are reviewed by the Board and approved for use by all investigators in a study. However, a sponsor can identify a subset of investigators to use particular participant materials. Model participant materials are reviewed within 48 hours of receipt and approval documents will be shipped within four business days of approval. A sponsor may distribute approval document(s) to investigators or elect to have Quorum distribute approval document(s) to approved investigators and those investigators who apply after the approval date.

For model participant materials, please note that Quorum corresponds only with the sponsor study contact(s) identified in the Central Study Questionnaire. This is true even if an advertising agency assists in the development of participant materials submitted to the Board for review. All questions and requests for modifications to the submitted materials will be directed toward the primary contact for the study and not the advertising agency.

3. National and Regional Recruitment Campaigns

A study sponsor may submit recruitment materials to be used by the sponsor at the national or regional level. These materials will only be approved with sponsor contact information that is not specific to the investigator. National and regional recruitment and study materials will be reviewed by the Board and approved for use by the sponsor. National and regional recruitment materials are reviewed within two business days of receipt and approval documents will be shipped to the sponsor within two business days of approval. Approval documents will not be sent to any investigators in the study.

For national and regional recruitment materials, please note that Quorum corresponds only with the sponsor study contact(s) identified in the Central Study Questionnaire. This is true even if an advertising agency assists in the development of recruitment materials submitted to the Board for review. All questions and requests for modifications to the submitted materials will be directed toward the primary contact for the study and not the advertising agency.

Participant Materials and Retention Program Guidelines

DEFINING CHARACTERISITICS OF NATIONAL AND REGIONAL RECRUITMENT MATERIALS

- Sponsor will be responsible for running and maintaining the campaign
- Sites will not receive approval for the materials from Quorum
- Materials must be submitted in final format
- No site-specific contact information or placeholders for site contact information (with the exception of a centrally managed site location listing)
- Examples: Recruitment materials containing 1-800 numbers for sponsor-run call centers or sponsor-run websites

4. Pre-Review and Conditional Approval of Recruitment Materials (Phase I Healthy studies only)

A Phase I Healthy Study may submit recruitment materials with a draft protocol to receive conditional approval prior to submitting the finalized protocol to Quorum Review for review. Once approved within the context of the draft protocol, a conditional approval email will be issued to the study's primary contact. Once the finalized protocol is submitted and the presence of conditionally approved recruitment materials is communicated, Quorum Review will only make edits to the materials if they are no longer appropriate due to significant changes from the protocol draft to the finalized protocol submitted for review.

For pre-reviewed and conditionally approved recruitment materials for Phase I Healthy studies, please note that Quorum corresponds only with the sponsor study contact(s) identified in the Central Study Questionnaire. This is true even if an advertising agency assists in the development of participant recruitment materials submitted to the Board for review. All questions and requests for modifications to the submitted materials will be directed toward the primary contact for the study and not the advertising agency.

5. Generic Participant Materials

An investigator or sponsor/CRO/SMO may submit generic participant materials that are not associated with a specific study to Quorum Review for review and approval for generic use. Phase I Healthy sites may also submit generic participant material templates that are later used for specific Phase I Healthy studies. The approval period for generic participant material is one year. A courtesy notification of annual review will be sent prior to the annual review expiration date. If no response is received on the last date of the approval letter, Quorum Review will expire the material.

For generic participant materials, please note that Quorum corresponds only with the main contact(s) identified during the initial submission. This is true even if an advertising agency assists in the development of materials submitted to the Board for review. All questions and requests for modifications to the submitted materials will be directed toward the primary contact and not the advertising agency. Please notify Quorum Review of any changes to the approved material, primary contact, or billing contact information.

Participant Materials and Retention Program Guidelines

- Types of generic participant materials:
  - Generic advertisements such as brochures, print ads, web ads, or posters
  - Generic telephone screening scripts
- Generic participant materials do not contain study-specific information
- The approval period for generic participant materials is one year. Materials will expire after one year unless correspondence is received to indicate the material should be re-reviewed
- Standard review fees apply for each annual review that occurs
- Materials must be submitted in final format
- Changes to approved generic participant materials must be reviewed and approved prior to use

6. Phase I Healthy Generic Screening Consent Forms

A Phase I Healthy site may submit a generic screening consent form to Quorum Review for review and approval for generic use. The approved consent form is associated to the site and not to a specific study. The approval period for a generic screening consent form is one year. A courtesy notification of annual review will be sent prior to the annual review expiration date. If no response is received on the last date of the approval letter, Quorum Review will expire the consent form.

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Participant Materials and Retention Program Guidelines

Submission of Participant Materials and Retention Program

General Submission Guidelines

- Participant or retention materials can be submitted directly by an investigator, the sponsor, or a sponsor/CRO/SMO on behalf of some or all investigators participating in a protocol.
- Materials can be submitted electronically or in hard copy.
- If a submission duplicates material previously approved by Quorum, please submit the previously approved version as a reminder to the Board.

Modifications

- Materials that are "approved with modifications" by the Board must be resubmitted to Quorum with the requested modifications.
- The Board will verify these modifications prior to Quorum issuing an approval letter.
- If materials come back with changes in addition to modifications requested by the Board, Quorum considers the document to be a new submission and will result in additional charges as identified in the *Quorum Pricelist*.
- Once the Board has approved materials, any changes to the content or presentation of those materials must be reviewed and approved prior to use.

Model, Mini-Model, and Sponsor Participant Materials:

- Quorum recommends submitting participant materials along with the *Participant Material and Retention Program Submission Cover Page*. Failure to provide this document may result in a delay in review.
- Participant materials submitted with the initial submission packet (rather than piecemeal) allows for faster, easier, and more cost-effective processing as there is no additional charge for the review of recruitment material if it is included in the initial submission packet. Materials received after initial submission will be subject to additional charges as listed in the *Quorum Pricelist*.

Investigator-Specific Participant Materials:

- Quorum recommends submitting participant materials along with the *Participant Material and Retention Program Submission Cover Page*. Failure to provide this document may result in a delay in review.
- Participant materials submitted with the initial submission packet (rather than piecemeal) allows for faster, easier, and more cost-effective processing as there is no additional charge for the review of participant material if it is included in the initial submission packet. Materials received after initial submission will be subject to additional charges as listed in the *Quorum Pricelist*.
- For studies that require pre-approval from a Sponsor representative, submitting written confirmation of sponsor approval at the time of submission is suggested to prevent a delay in processing.

Pre-Review and Conditional Approval of Recruitment Materials (Phase I Healthy studies only)

- Phase I Healthy recruitment materials for pre-review and conditional approval must be submitted with a *Phase I Healthy Participant Studies - Pre-Review and Conditional Approval of Recruitment Materials* form.
- Any changes to the draft protocol submitted with the materials for pre-review may require additional revisions to the materials.

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Generic Participant Materials:

- Generic participant materials must be submitted with a *Generic Material Submission Form* or with a *P1H Studies - Recruitment Material Template Submission Form*.
- Any changes to approved generic participant material, the main contact, or billing contact associated with generic participant material can be submitted using the *Re-Review and Change Notification Form.*

Generic Screening Consent Forms:

- Generic screening consent forms must be submitted with a *Phase I Healthy Participants Studies - Generic Screening Consent Form Questionnaire*.