# Central Study Questionnaire

## 1. BASIC STUDY INFORMATION

| | | | |
|---|---|---|---|
| **Protocol Number:** | | **Sponsor:** | |
| **Billing Reference or PO #:** (if applicable) | | **CRO:** (if applicable) | |
| **Protocol Title:** | | | |
| **Sites anticipated to submit to Quorum ➔** | Select one or both: | ☐ US | ☐ CANADA* |
| | # sites to Quorum: | # sites | # sites |

**Note: Quorum is able to provide review for sites in most Canadian Provinces. Contact the Quorum Initial Study Support Team for a current list.*

**Study Type:** *Please select study type below:*

| | |
|---|---|
| ☐ Drug/Biologic | ➔ Phase (I, II, III, IV or N/A ) |
| ☐ Device | If the study involves a device, please complete and attach the required form **: F-019 Device Study Submission Form** |
| ☐ Other | ➔ (please describe) |

*Note: Quorum does not review research involving prisoners.*

## 2. Phase I Healthy Participant Studies

This section is only for Phase I Healthy Participant Studies. **If this study is not Phase I Healthy Participant, skip to the next section.**

**2.1 Premium Service for Phase I Healthy Participant Studies**

Premium services are available for qualifying Phase I Healthy studies. Qualifying studies are conducted in the US only. Additional fees apply; see section **2.2**. Premium services include review of the following items:

1. **Protocol and consent form(s)**: Receive approval documents within as few as 4 business days from complete submission.
2. **Protocol amendments**: Receive approval documents within as few as 2-3 business days from complete submission.
   ***Note:*** *Due to the expedited nature of this premium service, there are no consent form negotiations. Changes to a consent form after approval will be treated as a new amendment.*
3. **Generic screening consent forms**: Review of non-study-specific screening consent forms for prospective participants in Phase I Healthy Participant studies.
4. **Pre-review and conditional approval of recruitment materials**: Receive conditional approval on recruitment materials before submitting the protocol.
5. **Recruitment material templates**: Reviewed and approved recruitment material templates. During the template's approval period, these can be submitted to Quorum with study-specific information as study-related recruitment materials.

**Do you want to use Quorum's premium service for your Phase I Healthy Participant study?**

*Please select one:*

☐ **No**; Process my study using Quorum's traditional timelines and services and standard pricing; *skip to section **3***

☐ **Yes**; *continue to section **2.2***

**2.2 Pricing for Phase I Healthy Participant Studies**

Premium services for Phase I Healthy studies have two pricing options, which include:

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| *Option A* | Pay an upfront price for the following services:<br>• Initial review of protocol and one consent form<br>• Initial review of up to 5 investigators<br>• Unlimited review of protocol and site amendments*<br>Pay for any additional services (including premium services) as they are used.<br>**Receive faster approval documents for qualifying amendments and site changes only.* |
| *Option B* | Pay for each of Quorum's services (including premium services) as they are used.*<br>**Receive faster approval documents for qualifying amendments and site changes only.* |

Prices for each option differ. Please contact Initial Study Support for additional pricing information. Once a pricing option is selected, it is locked in for the life of the Phase I Healthy Participant study.

**Which pricing option would you like for your Phase I Healthy Participant study?**

*Please select one:*

☐ **Option A**

☐ **Option B**

**2.3 Pre-reviewed and conditionally approved recruitment materials**

| | |
|---|---|
| Have recruitment materials already been conditionally approved for this study? | ☐ YES<br>☐ NO; *skip to section **2.4*** |
| Has the draft protocol you originally submitted with the recruitment materials been modified since that time? | ☐ NO changes<br>☐ YES, minor changes<br>☐ YES, significant changes<br>If **yes**, please attach a summary of changes |

**2.4 Recruitment material templates**

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|---|---|
| For recruitment materials you are now submitting with the protocol, were any based on Quorum-approved templates? | ☐ YES<br>☐ NO<br>If **yes**, provide all applicable ID numbers for the approved templates ➔ |

## 3. CONTACTS

**3.1** After hours number for study related emergencies: ➔ **(required for drug/device studies)**

**3.2 Primary Contact**

The primary contact automatically receives password access to the **OnQ** portal for secure submissions, study approval documents and reports. The startup report allows Sponsors/CROs to easily monitor their sites during startup. Please indicate if you would like to receive:

☐ Access Site Startup report via OnQ portal only (default)

☐ Access Site Startup report via OnQ portal AND receive email copy of every initial site start-up correspondence sent to each site

*Please select one:*
☐ Sponsor
☐ CRO
☐ Other
➔

| | | | |
|---|---|---|---|
| NAME | | COMPANY | |
| EMAIL ADDRESS | | TITLE | |
| PHONE NUMBER | | FAX | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Mailing Address** for all study related correspondence | | | | | | | |
| CITY | | STATE/ PROVINCE | | ZIP/ POSTAL CODE | | COUNTRY | |
| **If different, physical location** | | | | | | | |
| CITY | | STATE/ PROVINCE | | ZIP/ POSTAL CODE | | COUNTRY | |

**3.3 Secondary Contact**

*Please select one:*
☐ Sponsor
☐ CRO
☐ Other

| | | | |
|---|---|---|---|
| NAME | | COMPANY | |
| EMAIL ADDRESS | | TITLE | |
| PHONE NUMBER | | FAX | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Mailing Address** for all study related correspondence | | | | | | | |
| CITY | | STATE/ PROVINCE | | ZIP/ POSTAL CODE | | COUNTRY | |
| **If different, physical location** | | | | | | | |
| CITY | | STATE/ PROVINCE | | ZIP/ POSTAL CODE | | COUNTRY | |

**3.4 Scientific Contact:**

The Scientific Contact is a resource for information on protocol and/or safety issues.

☐ Same as Primary Contact above

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| NAME | | | | COMPANY | | | |
| EMAIL ADDRESS | | | | TITLE | | | |
| PHONE NUMBER | | | | FAX | | | |
| ADDRESS | | | | | | | |
| CITY | | STATE/ PROVINCE | | ZIP/ POSTAL CODE | | COUNTRY | |

**3.5 Electronic Invoices for services should be sent to:**

| | | | |
|---|---|---|---|
| BILL TO COMPANY | | INVOICING EMAIL ADDRESS | |
| BILLING CONTACT PERSON (Name will appear on invoice) | | TITLE | |
| BILLING CONTACT EMAIL ADDRESS | | PHONE NUMBER | |

**3.6 Accounting Department Contact (for payment status inquiries)**

| | | | |
|---|---|---|---|
| NAME | | COMPANY | |
| PHONE NUMBER | | TITLE | |
| EMAIL ADDRESS | | | |

## 4. OTHER STUDY INFORMATION

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|---|---|
| **4.1 Drug Study Information - US**<br><br>**Quorum will not process approval documents for US sites until receiving written confirmation that the IND is active* | Please complete if submitting sites in US to Quorum<br>IND#:<br>*Check all that apply*<br>☐ IND is active and research can be initiated immediately upon Board Approval<br>☐ *The IND application relating to this study was received by the FDA less than 30 days ago. If checked, please provide IND application date ➔<br>☐ *The IND application has not yet been submitted, date expect to submit ➔<br>☐ An IND is not necessary for this research for the following reasons ➔<br>☐ The FDA has objected to initiation of the research. (Contact Initial Study Support) |
| **4.2 Drug Study Information - Canada**<br><br>**Quorum will not process approval documents for Canadian sites until receiving written confirmation that the CTA is active* | Please complete if submitting sites in Canada to Quorum<br>*Check all that apply*<br>☐ No objection letter received and/or 30 days have passed since we submitted our application.<br>☐ *The CTA relating to this study was received by Health Canada less than 30 days ago.<br>If checked, please provide the application date: ➔<br>☐ *The CTA relating to this study has not yet been submitted<br>If checked, please provide the date expect to submit ➔<br>☐ A CTA is not necessary for this research for the following reasons: ➔<br>☐ Health Canada has objected to initiation of the research. (Contact Initial Study Support) |

| | |
|---|---|
| **4.3 Trial Registration - Canada**<br><br>**Quorum will not process approval documents for Canadian sites until receiving written confirmation of the trial registration number and name of the registry with which the trial is registered.*<br><br>**For more information, please see TCPS Article 11.3* | Please complete if submitting sites in Canada to Quorum<br>☐ Trial registration is active. If checked, please provide:<br>1. the trial registration number ➔<br>**and**<br>2. the name of the registry with which the trial is registered ➔<br>☐ Trial registration is not yet active. If checked, please provide date registration is anticipated: ➔<br>☐ A trial registration number is not necessary for this research for the following reasons: ➔ |

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| **4.4 Previous IRB Review**<br>Has this protocol been withdrawn from or previously reviewed and disapproved by another Review Board? | ☐ YES ☐ NO<br>If yes, please provide explanation: |
| **4.5 Transfer of IRB Review**<br>Is oversight of this protocol being transferred to Quorum from another Ethics Review Board? | ☐ YES ☐ NO<br>If yes, please contact Initial Study Support to obtain **F-055 Transfer of Jurisdiction Form**. |
| **4.6 Data Safety Monitoring**<br>Does the research plan have a provision for monitoring the data collected to ensure the safety of subjects *(e.g., data monitoring that occurs by the Principal Investigator, a Sponsor-initiated data monitoring committee or similar, or a Data and Safety Monitoring Board (DSMB) / Independent Monitoring Board, etc.)*?<br><br>**Note:** If the protocol does not include a data safety monitoring provision, Quorum requires that you submit documentation containing these provisions.<br><br>*Regulations require that, when appropriate, the research plan must make adequate provisions for monitoring the data collected to ensure the safety of participants. Depending on the type of study, there is a range of possible options for data safety monitoring in terms of who conducts the monitoring ("who"), criteria that may trigger monitoring ("when"), the elements to monitor ("what"), and monitoring methods ("how").*<br><br>**For more information regarding Data Safety Monitoring, please refer to the Quorum Review Handbook**. | ☐ YES ☐ NO |
| **4.7 Expedited Review Request**<br>If your research is "minimal risk"[1] and fits one of the expeditable categories of research your research may be reviewed by an Expedited Review process rather than the convened Board.<br>**Do you want Quorum to evaluate this research through an Expedited Review process?**<br><br>****Note – If you request review by an Expedited Review process and the research does not qualify for Expedited Review, this may delay the review of your research. Quorum's Expedited Review pricing applies only if F-179 is submitted and the research qualifies for Expedited Review.***<br><br>[1] *"Minimal Risk"* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (21 CFR 50.3(k); 45 CFR 46.102(i). | ☐ YES ☐ NO<br><br>*If **yes**, please submit required form:<br>**F-179 Expedited Review Request for Initial Review of Research Form.** |

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| **4.8 Investigator Generated Study**<br>The assessment of whether a study is investigator generated is based on a consideration of factors including: the author of the protocol, who initiated the research, and who assumes regulatory sponsor responsibilities. (If you have any questions regarding if your study qualifies as an investigator generated study, please contact Quorum's Initial Study Support Team).<br><br>***Note - All investigator generated studies will be pre-reviewed by Quorum's regulatory group and/or the Board Chair to determine if the submission and protocol are ready for full Board review.*** | ☐ YES ☐ NO<br>If yes, please submit the following:<br>• Indemnification of Quorum by Investigator and/or his/her organization (Quorum has a standard agreement that can be provided upon request).<br>• Written documentation of liability coverage from the Principal Investigator's insurance company for conducting investigator generated protocols and/or clinical research.*<br>***Exception:** Proof of insurance is not required for submissions requesting Expedited Review. If the research is later determined not to qualify for Expedited Review, proof of insurance may be required. |

## 5. PROTOCOL AND CONSENT FORM INFORMATION

Please attach the proposed Protocol and US consent form(s) for this study in Microsoft Word format.

| | |
|---|---|
| **5.1 Related studies with Quorum Review**<br>Does Quorum Review have oversight of any studies related to this protocol? | ☐ YES ☐ NO<br>☐ Unknown |
| If yes, please list protocol number(s) and/or Quorum Review number(s) and relationship to studies | If yes, ➔ |

| | |
|---|---|
| **5.2 Informed Consent Waivers**<br>Are you requesting a Waiver of Documentation of Informed Consent? | ☐ YES ☐ NO<br>If yes, please submit required items:<br>**F-042 Waiver of Documentation of Informed Consent Submission**, and<br>**Participant Information Sheet** (electronic copy, MS Word format) |
| For research not regulated by the FDA, are you requesting a Waiver or Alteration of Informed Consent?<br>If a waiver is necessary and no consent form is submitted for review, at this time you may skip to section **5.8**. | ☐ YES ☐ NO<br>If yes, please submit required form:<br>**F-043 Waiver or Alteration of Informed Consent Submission Form** |

**5.3 US Model Consent Forms Compliance with State Laws**

Several states have laws that impose additional requirements on the written consent form. Even though compliance with state and local laws is ultimately the Investigator's responsibility, Quorum has developed the following options for the model consent form to assist investigators in complying with specific state laws**.**

***Please choose one of the following to indicate how you would like us to prepare the model consent form(s) for this study:***

| | |
|---|---|
| • Quorum will issue one consent form (for use in all states) incorporating California specific***** laws and other state and local laws. California has the most stringent consent form laws we are aware of. | ☐ One Consent Form (for use in all states) |
| • One California-specific* form, and<br>• One consent form that will address other state and local laws. | ☐ Two Consent Forms (one for use for California sites, one for use for all other states) |

*****California-specific elements include a reference to recovery time; a separate signature line for obtaining authorization to release health information; and a font increase to 14 point in the authorization section.

| | |
|---|---|
| | |
| **5.4 Canadian Model Consent Form Compliance**<br>• Compliance with Canadian Provincial Law. Even though compliance with provincial/territorial law is ultimately the investigator's responsibility, Quorum has developed a model consent form with language that may be used in all provinces in Canada where Quorum provides review.<br>• Tri Council Policy Statement (TCPS) Quorum automatically applies TCPS to all studies from Canada. If you do not believe TCPS applies, please provide an explanation. | |
| **5.5 Electronic Informed Consent**<br>Does your study intend to use an electronic informed consent tool? | ☐ YES ☐ NO (*If no, please proceed to **5.6**)* |
| If yes, which electronic informed consent tool will your study use? | ☐ Q Consent<br>By selecting Q Consent, I agree there is a SaaS agreement established for my account and have agreed to additional charges (Please submit required form:<br>**F-208 Q Consent Questionnaire)**<br>☐ Other<br>(Please submit required form:<br>**F-201 Electronic Informed Consent Questionnaire)** |
| **5.6 Broad Consent**<br>In order to seek approval for Broad Consent, consent form(s) must meet the criteria outlined under 45 CFR 46.116(d). | |
| Do you intend to request broad consent for the storage, maintenance and use of identifiable private information or identifiable biospecimens for secondary research? | ☐ YES ☐ NO<br>If yes, please note that Quorum requires the submission of a separate document for Broad Consent independent of any other consent form. |
| **5.7 Compliance with HIPAA**<br>In order to assist investigators, all consent forms approved by Quorum are expected to address privacy and confidentiality issues to the level required by the HIPAA Privacy Rule as well as by federal regulations. Please note that Quorum does not review stand-alone HIPAA authorizations. | |
| Please note any particular issues, requests or concerns about this study's consent form: | |
| **5.8 Does Genetic Testing Occur in this Study?** | ☐ YES ☐ NO<br>If yes, please include the page number(s) where the testing is described in the protocol. |
| **5.9 Human Gene Transfer**<br>Does this study involve recombinant or synthetic DNA? | ☐ YES ☐ NO (*If no, skip to question **5.10***) |
| Is this study subject to the National Institute of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules? | ☐ YES ☐ NO ☐ UNKNOWN |
| Has this study been registered with NIH's Office of Science Policy (OSP)? | ☐ YES, please provide the following:<br>• OSP registration number<br>• RAC review letter (if applicable)<br>☐ NO |

| | |
|---|---|
| Would you like to use Quorum Review's IBC Service?<br>Standard charges for IBC services will apply per site. Quorum's standard IRB processing time does not apply to IBC research sites. | ☐ YES ☐ NO (*If no, skip to question **5.10***)<br>If yes, please attach a list of the sites utilizing Quorum's IBC Service if available. Include the investigator's name, facility name, facility address, and contact information.<br><br>For sites that are not listed, is Sponsor approval required?<br>☐ YES ☐ NO |
| Will the first clinical trial site for this study use Quorum's IBC service? | ☐ YES ☐ NO<br>If yes, Quorum will provide a written RAC review determination from the IBC for protocol registration with OSP. |
| **5.10 US Federal or Public Funding**<br>Is this study supported (in whole or part) by a Federal Department or Agency? | ☐ YES* ☐ NO<br>If yes, please submit required form: **F-015 Federal Funding Addendum** |
| **5.11 FDA Regulated**<br>Is this study subject to FDA oversight? | ☐ YES ☐ NO |
| **5.12 Other**<br>Is this study neither Federally Funded nor subject to FDA oversight? | ☐ YES ☐ NO |
| If neither Federally Funded nor subject to FDA oversight, do you request that the Protocol and Sites forgo Continuing Review? | ☐ YES ☐ NO |
| **5.13 Canada Public Funding**<br>Is this study publicly funded or supported? | ☐ YES ☐ NO<br>If yes, Funding Agency ➔ |
| **5.14 Site Unique Consent Forms (See Pricelist for associated charge)**<br>For sites that submit a site-specific unique version of the Quorum-approved model consent form, are you willing to pay all costs associated with processing this uniqueness? | ☐ YES ☐ NO*<br>**If NO and site requests uniqueness, site will incur processing charge(s) directly.*<br><br>***Regardless of your response, if a site requests uniqueness, Quorum requires:***<br>• Sponsor approval for the unique consent form.<br>• Rationale for <u>each</u> unique edit.<br>• All unique edits be tracked into the <u>current</u> Quorum-approved model consent form (**only Word versions are accepted**). |

## 6. PARTICIPANTS

**6.1 Age of participants**

What is the age range of participants? ➔ **to** ➔

If your study includes minor subjects ages 7 and older an assent form may be required. As a general rule, when Quorum approves a study involving minors Quorum will prepare a consent form that includes a parental permission signature line.

**6.2 Sponsor policies regarding enrollment**

| | |
|---|---|
| Do the Sponsor's policies **allow** the enrollment of sponsor employees and their family members? | ☐ **YES*** ☐ **NO** |
| Do the Sponsor's policies **allow** the enrollment of site employees **directly** involved with the study and their family members? | ☐ **YES*** ☐ **NO** |
| Do the Sponsor's policies **allow** the enrollment of site employees **not directly** involved with the study and their family members? | ☐ **YES*** ☐ **NO** |
| If the Board approves, will the Sponsor **allow** participants with a diminished decision-making capacity to be in this study using a Legally Authorized Representative (LAR) for adults with diminished decision-making capacity to provide consent?<br><br>*Please note that parent/guardian permission is different from LAR consent.* | ☐ **YES*** ☐ **NO** |
| If the Board approves, will the Sponsor **allow** participants (other than young children) who are unable to read (e.g., unable to read due to illiteracy or physical limitations such as blindness, etc.) to be enrolled in this study? | ☐ **YES*** ☐ **NO** |

If the Sponsor's policies vary from the enrollment options above, please describe here:

*If yes and agreed upon by the Board, Quorum will include additional language in the model consent form addressing these populations.

**6.3 Translations**

| | |
|---|---|
| Will participants be enrolled who may require non-English consent forms? | ☐ **YES** ☐ **NO**<br>☐ **Undetermined** |
| Would you like Quorum Review to arrange for the translation of the consent form?<br><br>If yes, for which language(s) do you need translations?<br>Note: If Sponsor provides already translated study materials from a non-approved translator, Quorum will require a comparison translation (QC check) before Board review | ☐ **YES** ☐ **NO**<br>If yes,<br>☐ Spanish<br>☐ French-Canadian<br>☐ Other, please list ➔ |

When would you like the translations process to begin? (select one)

- ☐ Prior to consent form negotiations (Fast-track service is 50% faster, additional fees apply)
- ☐ After consent form negotiations are complete (Standard translation service)
- ☐ After the first site request is received (May delay translations by up to 4-6 weeks)

| | |
|---|---|
| Would you like Quorum Review to provide you a quote prior to beginning the initial translation of the consent form(s)? Note: Not available under the Fast-track service. | ☐ **YES** ☐ **NO** |

## 7. STUDY STARTUP

**7.1 Startup Timeline**

| | |
|---|---|
| Date of planned first participant enrollment or any concerns regarding study startup timelines<br><br>Please note: Quorum cannot issue approval documents until consent form negotiations are complete | ➔ |
| Estimated length of this study | ➔ |

**7.2 Quorum Review Training Orientation**

| | |
|---|---|
| **Sponsor/CRO Orientation**<br>Quorum has a customer orientation module for Sponsor/CROs working with Quorum. Please indicate if you would like to receive the module or participate in a webinar. | ☐ Receive module<br>☐ Webinar |
| **Principal Investigator (PI) Training**<br>Upon request Quorum will provide our "Working with Quorum" Principal Investigator (PI) training free of charge. This training will be conducted either by webinar or through Quorum's attendance at the Investigator meeting (at Quorum's discretion). Please indicate if you are interested in having Quorum provide this training. | ☐ PI Training |

**7.3 Initial Site Submissions**

| | |
|---|---|
| Sites will make initial site submissions for Board review directly to Quorum. | ☐<br>**OR** |
| The Sponsor/CRO will make initial site submissions for Board review on behalf of Sites.<br>(*Under this choice any submission received directly from a site will be held pending Sponsor/CRO approval.) | ☐ |

## 8. SAFETY INFORMATION AND UNANTICIPATED PROBLEMS

**8.1 Submission and Acknowledgment of Study-wide Safety Information and Unanticipated Problems** *(IND Safety Reports, DSMB Summary Reports, FDA Public Health Advisories*)

Quorum suggests that the Sponsor/CRO assume responsibility for reporting to Quorum protocol-level safety information and unanticipated problems (Option 1 or 2). *More information about Quorum's Safety Information and Unanticipated Problems Reporting Guidelines is available at www.quorumreview.com and in the Quorum Handbook.*

**Please select one of the three options:**

| | |
|---|---|
| **Option 1: Sponsor / CRO will assume responsibility for submitting safety information to Quorum and Quorum delivers acknowledgment to each site**<br>Quorum will provide a formal safety acknowledgment letter to all approved/active sites each time new or updated protocol safety information is received. Standard charges for delivering study-wide safety acknowledgments will apply per site. | **Option 1** ☐<br><br>**OR** |
| **Option 2: Sponsor / CRO will assume responsibility for submitting to Quorum and Quorum delivers acknowledgment to sponsor/CRO only**<br>Quorum will send Sponsor/CRO acknowledgment letters only. Sponsor/CRO agrees to assume responsibility for distributing acknowledgment letter to investigators as necessary | **Option 2** ☐<br><br>**OR** |

| | |
|---|---|
| **Option 3: Sites will submit safety information to Quorum and Quorum will provide a standard acknowledgment to the submitting Investigator to document receipt**<br>If you select this option, Investigators will be responsible for submitting information to Quorum. The first submission of protocol level information will also trigger an acknowledgment letter to the sponsor / CRO. | **Option 3** ☐ |

*Please note: Even if the sponsor/CRO assumes responsibility for submissions of protocol-level safety information, occasionally an investigator will continue to submit such information. In such a situation Quorum will provide a standard acknowledgment to that investigator and prepare formal safety acknowledgment letters as requested above.*

*Please note: No matter which option is selected, all Board and regulatory requirements must be followed. This includes the requirement to promptly (within 10 business days) report findings that affect participant safety, the conduct of the study, or the Board's approval of the study. This also includes, for a period of at least two years following completion of the study, the requirement to promptly report findings that directly affect the safety of former study participants.*

**8.2 Submission and Acknowledgment of Product Information** *(Investigator Brochures, Package Inserts or Device Manuals)*

The Sponsor/CRO is expected to submit to Quorum on behalf of Investigators any revisions to the Product Information and a summary of changes.

**Please select one of the following options:**

| | |
|---|---|
| **Option 1: Sponsor / CRO will submit product information to Quorum and Quorum delivers acknowledgment to each site**<br>Quorum will provide a formal safety acknowledgment letter to all approved/active sites each time new or updated product information is received. Standard charges for delivering study-wide safety acknowledgments will apply per site. | **Option 1** ☐<br>**OR** |
| **Option 2: Sponsor / CRO will submit product information to Quorum and Quorum delivers acknowledgement to sponsor/CRO only**<br>Quorum will send Sponsor/CRO acknowledgment letters only. Sponsor/CRO agrees to assume responsibility for distributing acknowledgment letter to investigators as necessary. | **Option 2** ☐ |

| | |
|---|---|
| **8.3 Site Safety Startup Letter**<br>Quorum will issue a Safety Startup Letter to all newly approved sites along with their Notice of Approval material. This letter will include a list of all study-wide safety material (Safety Information and Unanticipated Problems and Product Information) received by Quorum up to the date the site was approved for this study. Standard charges for delivering study-wide approvals will apply per site.<br>Would you like Quorum to issue Safety Startup Letters to newly approved sites? | ☐ **YES** ☐ **NO** |

**8.4 Only for studies with sites in both the US AND Canada:**

Typically, safety information, unanticipated problems, and product information applies across a study to US and Canadian sites. However, sometimes the Sponsor/CRO will decide to have this information submitted and reviewed separately for US and Canadian sites.

**Please select one of the following options:**

| | | |
|---|---|---|
| Only for Studies with US and Canadian Sites. | **Apply all safety and product information submissions to both US and Canadian sites.**<br>If checked, all study-wide Safety information will be reviewed for both US and Canadian sites, unless specifically indicated otherwise. Acknowledgments will be issued according to selections noted in section **8.1** and **8.2**. | **Option 1** ☐<br>**OR** |
| | **Only apply safety and product information submissions to the country referenced on the submission. Submissions submitted to Quorum will have indication of applicability to US, Canada or both.**<br>If checked, Quorum will review study-wide Safety Information in the context of only US or Canadian sites, as indicated on the submission, unless specifically indicated otherwise. Acknowledgments will be issued according to selections noted in sections **8.1** and **8.2**. | **Option 2** ☐ |

## 9. PARTICIPANT MATERIALS

**9.1 Submission of Participant Materials at Initial Study Submission**

Participant materials submitted with the initial submission packet allow for faster, easier, and more cost effective processing. Materials included with the initial submission are reviewed free of charge. Materials received after initial submission will be subject to the fees listed in the Quorum pricelist. For tips about submitting participant materials please refer to the Participant Material and Retention Program Guidelines document on the Quorum website.

**9.2 Submission of Investigator/Site Generated Participant Materials**

Participant materials generated for explicit site use may be submitted by the investigator. Quorum can process site generated materials submitted directly by the site or require Sponsor approval prior to processing.

| | |
|---|---|
| Do you require sponsor approval for investigator/site submitted participant materials?<br>(If yes, Quorum Review will require investigators obtain written Sponsor approval prior to Board review. To facilitate faster processing please make sites aware that Sponsor approval is required) | ☐ **YES** ☐ **NO** |

**9.3 Distribution of Participant Material Approval Letters** *(Brochures, Ads, Flyers, Telephone Scripts, Study Questionnaires)*

Approvals for study-wide participant materials submitted by the Sponsor/CRO may be distributed to the Sponsor/CRO only or distributed to the Sponsor/CRO and all approved/active sites.

**Please select one of the following options:**

| | |
|---|---|
| **Option 1: Quorum will deliver approval letters to Sponsor/CRO only**<br>Quorum will send Sponsor/CRO approval letters. Sponsor/CRO agrees to assume responsibility for distributing approval letters to investigators as necessary. | **Option 1** ☐<br>**OR** |
| **Option 2: Quorum will deliver approval letters to Sponsor/CRO and each site**<br>Quorum will send approval letters to the Sponsor/CRO and all approved/active sites. Standard charges for delivering approvals will apply per site. | **Option 2** ☐ |

## 10. SHIPPING/DOCUMENT ACCESS

**There are several options available for Hard Copy shipping/posting of Quorum documentation. OnQ Portal access is always provided at no cost with all of the below Hard Copy shipping options:**

1. **No Hard Copies (no charge) - OnQ Portal access only. No paper copies of sponsor or site documents will be sent.**
2. **Hard copies of Sponsor documents sent to Sponsor (see pricelist for charge).**
3. **Hard copies of each site document sent to Sponsor (see pricelist for charge).**
4. **Hard copies of site documents sent to individual sites (Applicable to 9.3 below, see pricelist for charge).**
5. **Alternate shipping of Hard Copy documents.**

**10.1 Delivery Preference to Primary Study Contact**

| | |
|---|---|
| **OnQ Portal** access only (No Hard Copies); provided at no charge. **No paper copies of sponsor or site documents will be sent.** | **Option 1*** ☐<br>**OR**<br>***If selected, proceed to section **10.2** |

| | |
|---|---|
| **Quorum Standard** Shipping via USPS standard mail. See Pricelist for cost. OnQ Portal access also provided at no charge. **Available options below:**<br>**2. Hard copies of Sponsor documents sent to Sponsor**<br>**3 Hard copies of each site document sent to Sponsor** | **Option 2** ☐<br>**Option 3** ☐<br>**Both 2 AND 3** ☐<br>**OR** |
| **Alternate Shipper.** See Pricelist for cost. OnQ Portal access also provided at no charge.<br>Select and provide account number (required or documents will be posted to OnQ Portal)<br>☐ UPS Next Day - Account # ➔<br>☐ UPS 2-Day - Account # ➔<br>☐ FedEx Priority Overnight - Account # ➔<br>☐ FedEx Standard - Account # ➔<br>☐ DHL International - Account # ➔<br>☐ Electronic delivery via third-party vendor (e.g., IntraLinks, CRNets)<br>Electronic Method or Vendor**:** ➔ _____ | **Option 5** ☐ |
| **10.2 Delivery Preference to Secondary Study Contact (if applicable)** | |
| **OnQ Portal** access only (No Hard Copies); provided at no charge. **No paper copies of sponsor or site documents will be sent.** | **Option 1*** ☐<br>**OR**<br>***If selected, proceed to section **10.3** |
| **Quorum Standard** Shipping via USPS standard mail. See Pricelist for cost. OnQ Portal access also provided at no charge. **Available options below:**<br>**2. Hard copies of Sponsor documents sent to Sponsor**<br>**3 Hard copies of each site document sent to Sponsor** | **Option 2** ☐<br>**Option 3** ☐<br>**Both 2 AND 3** ☐<br>**OR** |
| **Alternate Shipper.** See Pricelist for cost. OnQ Portal access also provided at no charge.<br>Select and provide account number (required or documents will be posted to OnQ Portal)<br>☐ UPS Next Day - Account # ➔<br>☐ UPS 2-Day - Account # ➔<br>☐ FedEx Priority Overnight - Account # ➔<br>☐ FedEx Standard - Account # ➔<br>☐ DHL International - Account # ➔<br>☐ Electronic delivery via third-party vendor (e.g., IntraLinks, CRNets)<br>Electronic Method or Vendor**:** ➔ | **Option 5** ☐ |

**10.3 Delivery Preference to Investigators**

| | |
|---|---|
| **OnQ Portal** access only (No Hard Copies); provided at no charge. **No paper copies of site documents will be sent to sites.** | **Option 1*** ☐<br>**OR**<br>***If selected, proceed to section **10.4** |
| **Quorum Standard** Shipping via USPS standard mail. See Pricelist for cost. OnQ Portal access also provided at no charge. **Available option below:**<br>**4. Hard copies of each site document sent to individual sites** | **Option 4** ☐<br>**OR** |
| **Alternate Shipper.** See Pricelist for cost. OnQ Portal access also provided at no charge.<br>Select and provide required account number (required or documents will be posted to OnQ Portal)<br>☐ UPS Next Day - Account # ➔<br>☐ UPS 2-Day - Account # ➔<br>☐ FedEx Priority Overnight - Account # ➔<br>☐ FedEx Standard - Account # ➔<br>☐ DHL International - Account # ➔<br>☐ Electronic delivery via third-party vendor (e.g., IntraLinks)<br>Electronic Method or Vendor**:** ➔<br>NOTE: Site copies of safety acknowledgments and participant material approvals will be posted to the OnQ Portal. Site copies of other approvals and correspondence will ship as requested above. | **Option 5** ☐ |

**10.4 Add Additional Contacts: Quorum OnQ Portal Access**

The Quorum OnQ Portal is a password-protected area of our website offering customers access to posted approval documents, secure electronic submissions; and a startup status report for monitoring site submissions. In addition, the portal contains useful resources such as price lists, consent form templates, guidance on preparing consent forms, and the Board Roster. Primary and secondary contacts above automatically receive OnQ portal access. Site contacts will receive site-level access when their site-level submission is processed. If you have more than eight additional contacts, please list and include with your submission.

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|---|---|---|---|---|---|
| Additional Name | | Email Address | | Company | |
| Additional Name | | Email Address | | Company | |
| Additional Name | | Email Address | | Company | |
| Additional Name | | Email Address | | Company | |
| Additional Name | | Email Address | | Company | |
| Additional Name | | Email Address | | Company | |
| Additional Name | | Email Address | | Company | |
| Additional Name | | Email Address | | Company | |

**Sponsor/CRO understands that Quorum Review will be expected to conduct its review functions in material compliance with applicable laws, ethical standards and Quorum Review's policies, including the policies set forth in the current Quorum Handbook (available online at www.quorumreview.com).**

**Signature and Title of Person Completing Form** **Date**

**Printed Name**

**Thank you for your interest in working with Quorum Review. If you have any questions, please don't hesitate to contact us:**

**Please submit via:**

**Quorum's OnQ Portal at www.QuorumReview.com**
**or**
**Email your electronic submission to InitialStudySupport@QuorumReview.com**
**Signature page can be faxed to: (206) 448-4193**

**Please contact Quorum's Initial Study Support team with any questions:**
**InitialStudySupport@QuorumReview.com**
Quorum Review, Inc.
(206) 448-4082 (press 2, then 1)
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Seattle, WA 98101