Quorum

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Site Status Report for periodic review or closure

Client guidance with Frequently Asked Questions (FAQ)

Quorum Review's FAQ for the Site Status Report

This document provides guidance for sites completing the Site Status Report. If you have suggestions on what you'd like to see here, please e-mail us at **suggestions@quorumreview.com**.

- **Each colored block in the following chart matches a section on the Site Status Report.** Next to each colored block are commonly asked questions related to that section of the report. Click the question to go to the corresponding answer.
- In addition, **General Questions** about the Site Status Report are located at the end of the chart.

This guidance is intended for use with F-040, Site Status Report. (It does not apply to F-117, Observational Registry & Qualified Minimal Risk Site Status Report – please contact Quorum if you have questions about completing that report.)

If you have questions at any time while submitting your Site Status Report, please call Quorum's Client Support Team at 206-448-4082, option 1 (or 877-472-9883, option 1). Our staff is available 8 AM to 8 PM ET, Monday to Friday.

Thank you for using Quorum Review when performance matters.

Site Status Report sections with FAQ

For more information on the Site Status Report, see F-047, Site Status Report Checklist at **www.quorumreview.com**.

Periodic Site Review or Site Closure

- What is Periodic Site Review?
- When does Quorum consider a site to be closed?
- How do I know if my site should close or go through Periodic Site Review?
- What if my site is scheduled to close before the IRB expiration date?

Note

If you are submitting for periodic site review, please do not answer the "Site Closure" question on page 1 of the form.

Study Status

- What should I indicate as my site's status at periodic site review?
- What is the difference between being closed and closed to enrollment?

Enrollment

- What is the difference between a screen failure and a participant who withdrew?
- How should I account for participants that died during the study?
- How should I account for a participant that transferred from/to another site?
- What does "participants who are currently active in the study" mean?

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Change of Information

- What form do I submit to Quorum for change of information (such as study coordinator change, change in participant compensation, and so forth)?
- What if I have already submitted changes to Quorum as indicated in Question 26? How do I answer this question?

Note

Please submit an updated Curriculum Vitae (CV) if any information in it relating to clinical research or this study has changed significantly.

General Questions

- Where can I get a clean copy of the Site Status Report form?
- Does Quorum need both a faxed and original copy of the Site Status Report?
- Can I submit a report for closure with a closing date that is in the future?
- What do I do with my Site Status Report if I think I am going to close before my expiration?
- What supporting documentation should I submit in addition to this form?
- What will delay my review?
- Will I receive acknowledgement that Quorum has received my report?

FAQ answers

What is Periodic Site Review?

Periodic Site Review is a review that occurs prior to your study expiration date. If you plan to continue to conduct your study after your expiration date listed on your Notice of Approval (or Notice of Re-Approval), then you will need to submit a Site Status Report for periodic site review.

Return to Site Status Report sections with FAQ.

When does Quorum consider a site to be closed?

Quorum considers a site to be closed when all of the following criteria have been satisfied:

1. You have no enrolled participants.
2. You are no longer collecting data from participants.
3. Your sponsor or the sponsor's representative considers you closed.

If your site does not meet all of these requirements, Quorum does not consider you closed. If you do not meet these requirements but your sponsor does consider you closed, please contact Quorum for further guidance on this matter.

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How do I know if my site should close or go through Periodic Site Review?

If you meet the requirements for closing (see criteria above), you should complete a Site Status Report for Closing and submit it to Quorum. If you do not meet all the requirements for closing, and will not meet them before the expiration date listed on your Notice of Approval (or Notice of Re-Approval), then you will need to submit a Site Status Report for periodic site review.

Please note that if a Site Status Report is not received by the IRB approval expiration date, IRB approval to conduct your study will expire. Be advised, conducting research activities without IRB approval is a violation of federal regulations. Furthermore, failure to provide a Site Status Report for periodic site review or closing may lead to a finding of serious or continuing noncompliance which requires notification to the U.S. Food and Drug Administration.

Return to Site Status Report sections with FAQ.

What if my site is scheduled to close before the IRB expiration date?

- If you are closed, or planning to close before your IRB expiration date, you should complete a Site Status Report for closure and submit it to Quorum.
- If you don't expect to close until after your expiration date, you should remain open and submit a Site Status Report for periodic site review.
- If the sponsor or sponsor representative will be closing your site a couple of days prior or on your expiration date, Quorum suggests you send in a Site Status Report for Periodic Site Review to prevent site expiration.
- Please note that if a Site Status Report is not received by the IRB approval expiration date, IRB approval to conduct your study will expire. Be advised that conducting research activities without IRB approval is a violation of federal regulations. Furthermore, failure to provide a Site Status Report may lead to a finding of serious or continuing noncompliance which requires notification to the U.S. Food and Drug Administration.

Return to Site Status Report sections with FAQ.

What is the difference between being closed and closed to enrollment?

Closed to Enrollment	Your site is no longer enrolling new participants into the study. However, you may still have active participants in the study and/or other study activity may still be taking place. Please DO NOT submit a Site Status Report indicating your site is closed when your study is just closed for enrollment. Doing so could result in Quorum closing your file prematurely and may require a new site submission.
Closed	You have no active enrolled participants, you are no longer collecting data from participants and your sponsor or the sponsor's representative considers you closed.

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What should I indicate as my site's status at periodic site review?

Not Yet Initiated	Your site has not yet been initiated for this study by the sponsor, but you still plan to participate in the study.
Active	Your site is currently actively participating in the study and enrollment is still open.
Active – Enrollment is Closed	This study is still open at your site, but you are closed to enrollment.

Return to Site Status Report sections with FAQ.

What is the difference between a screen failure and a participant who withdrew?

Screen failure

Generally, a **screen failure** is someone who does not get enrolled into the study for various reasons, documented during the screening process. Screen failures signed the consent form and may have had screening procedures but did not undergo any other study procedure.

Reasons for the participant to fail screening may include, but are not limited to, the participant not meeting inclusion criteria or meeting exclusion criteria (ineligibility).

Your sponsor or protocol may define a screen failure differently.

Participant who withdrew

A **participant who withdrew** is a participant who either 1.) stopped the study before completing the full schedule of study visits (including follow-up) or 2.) who transferred sites.

Some protocols may have a variable number of visits and consider participants as completing, rather than withdrawing, in the case of disease progression or similar clinical outcome. In such cases, the protocol definition should be followed, with the withdrawal category reserved for participants who withdrew for other reasons.

Return to Site Status Report sections with FAQ.

How should I account for participants that died during the study?

Since death is considered an adverse event, such participants should be listed in question 6. To determine if the death is an SAE (Serious Adverse Event) and reportable to Quorum, please refer to G-036, Safety Information and Unanticipated Problems Reporting Guidelines (at **www.quorumreview.com**).

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How should I account for a participant that transferred from/to another site?

Sometimes participants transfer to other sites because they move or because a site may stop doing the study. If a participant transfers away from your site to another site, they should be counted as a participant who dropped or withdrew early.

If a participant transferred to your site from another site, please include this participant in the question asking for the total number of participants who signed a consent form throughout the course of this study. (See the Enrollment section.)

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What does "participants who are currently active in the study" mean?

Participants who are "currently active" in the study have not dropped early nor have they been terminated. These are participants who have not yet completed the study. Participants who are currently active in the study include:

- Participants who still come to the site for study visits or still receive study product.
- Participants in follow-up (with or without study visits) even if a participant has no other involvement with the study.
- Any other participant who is still in the study.

Return to Site Status Report sections with FAQ.

What if my site has used an advertisement that was not approved by Quorum?

Please submit the advertisement that was used, a letter of explanation, and a completed F-197, Safety Information and Unanticipated Problem Report (at **www.quorumreview.com**) to Quorum with your Site Status Report.

In your letter of explanation, please indicate whether or not you would like Quorum to review the advertisement and give approval for its future use and provide a plan for corrective action to prevent this from occurring in the future.

Return to Site Status Report sections with FAQ.

What if my site has used a translated consent form not approved by Quorum?

Please submit the translated consent form that was used, a letter of explanation, and a completed F-197, Safety Information and Unanticipated Problem Report (at **www.quorumreview.com**) to Quorum with your Site Status Report.

In your letter of explanation, please indicate if you wish to receive a Quorum approved translated consent form for future use and provide a plan for corrective action to prevent this from occurring in the future. You must indicate what language you want the consent to be translated into and who at your site is fluent in that language.

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How does Quorum define a Major Protocol Deviation/Violation (PD)?

Quorum defines a Major Protocol Deviation/Violation as any intentional or unintentional change from the IRB-approved protocol that adversely affects the risk/benefit ratio of the study; the rights, safety or welfare of the participants or others; or the integrity of the study. Please refer to the G-036, Safety Information and Unanticipated Problems Reporting Guidelines (at **www.quorumreview.com**) for more information.

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How does Quorum define a Serious Adverse Event (SAE)?

Quorum defines a Serious Adverse Event as any event that is serious, unanticipated, and related to the study product/procedures. Please refer to the G-036, Safety Information and Unanticipated Problems Reporting Guidelines (at **www.quorumreview.com**) for more information.

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How does Quorum define an Unanticipated Problem (UP)?

Quorum defines an Unanticipated Problem as any problem that adversely affects the risk/benefit ratio of the study, or the rights, safety, or welfare of the participants or others, or the integrity of the study. Please refer to G-036, Safety Information and Unanticipated Problems Reporting Guidelines (at **www.quorumreview.com**) for more information.

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If I have Major Protocol Deviations/Violations or Serious Adverse Events for my study that have not been submitted to Quorum, should I send them now with my Site Status Report?

Yes. Any major Protocol Deviations/Violations or Serious Adverse Events not yet reported to Quorum must be submitted with the Site Status Report for Periodic Site Review or Closing.

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How do I know if I need to submit my Major Protocol Deviations/Violations or Serious Adverse Events to Quorum?

Please refer to G-036, Safety Information and Unanticipated Problems Reporting Guidelines (at **www.quorumreview.com**) for more information about Major Protocol Deviations/Violations and SAE reporting requirements. If you have not submitted Major Protocol Deviations/Violations or Serious Adverse Events to Quorum for a particular study, please do so immediately. If you are uncertain if you have already reported them, or if we have received them, please contact Quorum to verify their receipt.

Return to Site Status Report sections with FAQ.

Do I need to submit Adverse Events, Minor Protocol Deviations or Minor Unanticipated Problems to Quorum Review?

Usually not. Quorum requires sites to submit an analysis of Adverse Events, Minor Protocol Deviations and other Minor Unanticipated Problems that have not been reported to Quorum only if in combination they adversely affect the risk/benefit ratio of the study; the rights, safety, or welfare of the participants or others; or the integrity of the study. Quorum does not review individual event reports or line listings of Minor Deviations, Adverse Events or Minor Unanticipated Problems.

Return to Site Status Report sections with FAQ.

What do you mean by "community attributes or conditions" that could "affect medical research"?

Community attributes or conditions that could affect medical research include (but are not limited to) religious attributes within the local population or recent media reports on clinical studies that may have affected public opinion about medical research.

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How could I find out if there have been any changes in local or state law in my area regarding research participants?

Please contact your legal counsel for updates and interpretations of local and state law.

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What kind of training qualifies as "Human Research Participant Protection Training"?

Training which qualifies as "Human Research Participant Protection Training" includes (but is not limited to) classes, on-line seminars, and self-study about the rights and protections of human research participants.

Quorum expects Principal Investigators to be responsible for the conduct of research trials and all associated research facilities consistent with the IRB-approved protocol, applicable law and regulations, applicable federal and International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice, and ethical principles of the Belmont Report.

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I've received a good practices letter from the FDA. Do I need to submit this?

Yes. if you have not previously submitted this letter to Quorum for consideration in this study. Quorum requires all documentation of FDA audits of the Principal Investigator, Sub-Investigators, and research facilities to be submitted.

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My site/Principal Investigator/Sub-Investigator was recently audited but hasn't received any documentation from the FDA yet. What do I include with my Site Status Report?

Please include a memo stating that no results from the audit have yet been received and include any notifications for audit or correspondence with the FDA leading up to the audit with your Site Status Report. Once you have received the audit results, please submit them to Quorum for review.

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What consent form(s) should I list on the Site Status Report form?

You should list the most current English main/core Quorum approved study consent form received by your site from Quorum (Question 25). Please do not list consent forms such as Translated, Addendum, Assent, Pharmacogenetic or Pharmacokinetic consent forms.

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How do I know which dates to write for the consent form(s)?

Please use the version and date listed in the footer (often on the left hand side) of the main consent form ("Version 1, dated 01/01/00"). Do NOT use the "Quorum Approved" date, which is often stamped on the lower right-hand side of the consent form.

- The "Version Date" is the date the consent form was originally reviewed by Quorum for use in the study.
- The "Quorum Approved" date is the date that Quorum approved your site to use the consent form.

Return to Site Status Report sections with FAQ.

What if no participants have been enrolled in this study? How do I complete the Information & Consent Form section?

If no participants have been enrolled at your site for this study, indicate in Question 25 the most current English main/core Quorum approved study consent form you have received for this study from Quorum and complete Question 26A and 26B stating that no participants have been enrolled in this study.

Return to Site Status Report sections with FAQ.

Do I need to include old versions of the consent form(s)?

No. You only need to list the most current English main/core versions of the consent form. You do not need to list translated versions of the consent form or addenda.

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Do I need to send in a hard copy of the consent form(s)?

No, listing the version and date of the current consent form on the Site Status Report is sufficient. Quorum can verify this internally for discrepancies.

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Do I need to cite an updated version of the consent if our site is done enrolling and no participants have signed it?

Yes. Please indicate on Question 25 the most current English main/core study approved consent form received from Quorum by your site. Please answer Questions 26A and 26B indicating that no participants have signed the updated version and state the reason why. If participants have signed a previous version of the consent form for this study, please answer Question 26C.

Return to Site Status Report sections with FAQ.

What form do I submit to Quorum for change of information (such as study coordinator change, change in participant compensation, and so forth)?

If you have changed any of the information covered by Question 27 and it has not yet been reported to Quorum, then you must submit a completed F-198, Change Request Form for Sites and any accompanying documents noted on the form. This document can be located on our website at **www.quorumreview.com**. Writing your changes on the Site Status Report or attaching a brief letter of explanation is not acceptable, and these changes will not be made unless submitted to Quorum on a completed F-198, Change Request Form for Sites.

Return to Site Status Report sections with FAQ.

What if I have already submitted changes to Quorum as indicated in Question 27? How do I answer this question?

If you have already submitted changes at your site to Quorum, then Question 27 should be answered

No. Return to Site Status Report sections with FAQ.

What if no participants have been enrolled in this study? How do I complete the Information and Consent Form section?

If no participants have been enrolled at your site for this study, indicate in Question 25 the most current English main/core Quorum-approved study consent form you have received for this study from Quorum and complete Question 26A and 26B stating that no participants have been enrolled in the study.

Return to Site Status Report sections with FAQ.

Where can I get a clean copy of the Site Status Report form?

You can download a clean copy of the report from Quorum's website at **www.quorumreview.com**.

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Does Quorum need both a faxed and original copy of the Site Status Report?

No, a faxed (or mailed) copy is sufficient.

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Can I submit a report for closure with a closing date that is in the future?

No. The Site Status report would not be considered valid.

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What do I do with my Site Status Report if I think I am going to close before my expiration?

Quorum requires that all sites submit a valid Site Status Report 45 calendar days prior to expiration. Failure to do so will result in overdue notifications. It is left to your discretion if you wish to hold your Site Status Report at your site until your scheduled closeout visit to avoid going through Periodic Site Review.

If you choose to do so, please bear in mind the following:

- Closing visits are often cancelled or rescheduled. It is a good idea to prepare for Periodic Site Review in case this happens by completing your report and notifying Quorum of the situation.
- If we do not receive the report by the due date, we must adhere to our notification procedures that include a fax and expiration warning letter that is copied to your sponsor. Even if you contact us to let us know that you are planning on closing, you will still receive our overdue notifications as part of our due diligence to assure that no sites expire.
- If the report is not received within 14 calendar days of the expiration date, your site will be scheduled for IRB review. Upon review, the IRB may consider your failure to comply with the requirement to submit a Site Status Report as an instance of noncompliance. Please note that findings of noncompliance are reported to the sponsor and the FDA.

Return to Site Status Report sections with FAQ.

Can you hold my Site Status Report if I think I am going to close prior to expiration?

No. Once Quorum receives a Site Status Report, a process of analysis and scheduling for the Board is started. It is left to your discretion if you wish to hold your report at your site until your scheduled closeout visit to avoid going through Periodic Site Review. For more information, please see the question and answer for What do I do with my Site Status Report if I think I am going to close before my expiration?

Return to Site Status Report sections with FAQ.

What supporting documentation should I submit in addition to this form?

Any FDA audit documentation, letters of explanation as required by the form, and any additional information that you think will help Quorum with the review of your site. Please refer to F-047, Site Status Report Checklist for further guidance.

Return to Site Status Report sections with FAQ.

What will delay my review?

An incomplete or inaccurate form, any missing attachment(s), (i.e. FDA audit documentation, letter(s) of explanation. SAEs, PDs, UPs), and/or missing/blank page(s).

Return to Site Status Report sections with FAQ.

Will I receive acknowledgement that Quorum has received my report?

Acknowledgement will come in the form of your Notice of Re-Approval documents or closing acknowledgment letter. If you wish to verify sooner whether or not we have received your Site Status Report, you can contact our Client Support Team at 206-448-4082, option 1 (or 877-472-9883, option 1).

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