POLICY

1. Purpose

Describes the research Quality Improvement Program included as part of the University of Rochester's Human Research Protection Program (UR HRPP), which ensures that the rights, safety, and welfare of subjects are protected during the conduct of research.

2. Scope

This policy applies to all human subject research conducted or supported by employees or agents of the University of Rochester.

3. Definitions

3.1. *Quality Improvement* (QI) – The effort to assess and take measures to improve the level of performance of a program, process, or institution.

3.2. *Quality Improvement Review* – A comprehensive, systematic, and independent assessment of study-related activities and documents to compare research records to approved documents to evaluate compliance with IRB approved protocols, applicable federal and state regulations, UR policies and guidelines, and OHSP policies and guidelines.

3.3. *Post-Approval Consultation (PAC)* – A comprehensive consultation, after IRB approval and before enrollment begins, to evaluate study documentation (e.g. study site/regulatory file, data collection forms, plans for protocol adherence) to assist the study team in their ability to achieve compliance with applicable regulations, policies, and guidelines. The QI reviewer collaborates with the study team to understand study-specific regulations, policies, and guidelines, providing tools and resources.

3.4. *Quality Management Plan (QMP) Consultation* – A comprehensive consultation to provide resources that guide, integrate, and enhance continuous quality improvement for a research site, research program, or department/division. The QI reviewer focuses on aiding the study team to set-up, implement, evaluate, and/or prioritize areas of potential risk to target within their quality management plan.

3.5. *Quality Improvement Reviewer* – OHSP staff who conduct QI reviews and consultations.

3.6. *Types of Quality Improvement Reviews* - The types of QI reviews established by the QI program are defined as:

3.6.1. *Routine*: A comprehensive QI review to provide a regulatory assessment of study compliance. Routine reviews include a selected sample of human subject research conducted across the University. The selection of studies is a risk-based approach and may be determined based on such factors as study risk determination, enrollment of vulnerable populations, and degree of external oversight.

3.6.2. *Directed*: A comprehensive or targeted (i.e. the consent process) QI review requested by the RSRB or the External IRB Ad Hoc committee to provide an assessment of study compliance.

3.6.3. *Site-Requested*: A comprehensive or targeted QI review requested by an Investigator or study personnel. These reviews are conducted within the limitations of available resources.

3.7. *Review Finding* – A noted deficiency during a QI review.

3.8. *Corrective and Preventative Action (CAPA)* – A plan identified by an Investigator to address any finding noted in the QI report; a straightforward, specific, measurable solution to address the root cause (origin, source, reason for the issue) and prevent the issue from occurring again.

3.9. *QI Review Rating* – A summary rating applied to each routine, directed, and some site-requested QI reviews, based upon the severity and quantity of the review findings. The review rating is dependent upon whether the study design includes obtaining consent from the subjects:

3.9.1. QI Review Ratings for research where consent is required by the IRB:

3.9.1.1. Commendable: No deficiencies identified in a study with consent requirements and with enrolled subjects.

3.9.1.2. Acceptable: Lesser deficiencies are identified that do not appear to involve risk to subjects.

3.9.1.3. Acceptable with follow-up: Multiple lesser deficiencies are identified. Any deficiency in which potential risk to subject needs further consideration. Self-reported deficiencies identified to the IRB and addressed prior to the conclusion of the review.

3.9.1.4. Unacceptable: Major deficiencies are identified. A single major deficiency which impacts human subject safety/welfare is identified. One or more missing consent form(s). No response from the Investigator during the review process after a reasonable effort has been made by the QI reviewer.

3.9.2. QI Review Ratings for no enrollment or consent not required by IRB:

3.9.2.1. Acceptable: No or lesser deficiencies and no local accrual; however, accrual is possible. Lesser deficiencies are identified that do not appear to

involve risk to potential subjects. No deficiencies identified in a study with no enrollment or without consent requirements.

3.9.2.2. Acceptable with follow-up: Multiple lesser deficiencies are identified. Any deficiency in which potential risk to subjects needs further consideration. Self-reported deficiencies identified to the IRB and addressed prior to the conclusion of the review.

3.9.2.3. Unacceptable: Major deficiencies are identified. A single major deficiency which impacts human subject safety/welfare identified. No response from the Investigator during the review process after a reasonable effort has been made by the QI reviewer.

3.9.3. Site-requested reviews conducted in preparation for a regulatory inspection do not receive a rating; the QI report is presented as a summary of findings and improvement recommendations.

3.10. *QI Findings Index* – A central database of review findings maintained by the Director of Research Quality Improvement and maintained on the QI shared drive.

3.11. *Quality Improvement Review Final Report* – A written report incorporating a brief description of the study and the results of the QI Review, including detailed findings, the Investigator Response, and a CAPA plan to each finding, and the review rating. The expectation for an Investigator Response may be removed by the QI reviewer (i.e. minor finding).

3.12. *Quality Improvement Post-Approval or Quality Management Plan Consultation Summary* - A written report incorporating a brief description of the study and a summary of all points from the discussion with the study team. The summary is meant to guide the continued actions of the study team as they progress through the conduct of the study.

3.13. *Quality Improvement RSRB Audits* – An internal audit conducted by the QI reviewer for each review or consultation. Audit content is determined in collaboration with OHSP staff and the Associate Vice President for Human Subject Protection. Audit results are discussed bi-annually with the OHSP staff.

4. References

4.1. Food and Drug Administration (FDA) 21 CFR parts 50, 56, 312, 812; 36 CFR part 16; HHS 45 CRF 46;
Good Clinical Practices (ICH-GCP E6 guidelines as adopted by the FDA)

4.2. Policy 102 University of Rochester's HRPP
Policy 103 Organizational Structure of HRPP
Policy 301 RSRB Scope and Authority
Policy 302 RSRB Membership and Composition

RSRB Guideline for Institutional and Regulatory Reporting of Suspension, Termination, Non-Compliance, UPIRTSO

5. Responsibilities

5.1. The OHSP Division of Quality Improvement is responsible for the ongoing evaluation of the effectiveness of UR's HRPP by promoting and ensuring Institutional and Investigator compliance with human subject protection regulations and requirements.

5.1.1. The Director of Research Quality Improvement is responsible for managing the activities related to the QI program, including but not limited to:

5.1.1.1. Prepare, plan, and execute a routine auditing program applying applicable federal regulations and University and OHSP policies and guidelines;

5.1.1.2. Prepare, plan, and execute a consultation program applying applicable federal regulations and University and OHSP policies and guidelines;

5.1.1.3. Collaborate with OHSP Senior Leadership to enhance educational opportunities, as necessary.

5.1.2. The QI team is responsible for conducting routine, directed, and site-requested QI reviews, consultations for compliance with IRB approved protocol, applicable federal and state regulations, UR policies and guidelines, and OHSP policies and guidelines, when applicable.

5.1.2.1. During a review, if the QI review team identifies a circumstance that appear to place human subjects at risk, the Associate Vice President for Human Subject Protection will be notified promptly by the QI review team for further assessment; the RSRB Director and RSRB Chair may also be consulted. The RSRB Chair may suspend or terminate approval of research that has been associated with serious events/problems, according to Policy 301 RSRB Scope and Authority.

5.1.3. The QI team is responsible for collaborating with members of the UR's research community to improve the Institution's efforts to uphold high ethical standards, to meet regulatory requirements, provide ongoing education, facilitate the sharing of best practices, develop and encourage use of tools for Investigators and research staff that facilitate compliance, and to improve research practices for the protection of human subjects participating in research.

5.2. The Investigator is responsible for providing access to the study site files/regulatory file, research charts, and any other relevant documentation upon request by the QI team.

5.3. The Investigator is responsible for providing timely written responses to each review finding including a CAPA plan.

5.4. The Associate Vice President for Human Subject Protection, as a representative for the Institution, is responsible for reviewing reports during the QI review process.

5.5. The RSRB or External IRB Ad Hoc committee is responsible for reviewing a QI Review Final Report at a convened meeting to determine if additional action or follow up is required of the Investigator.

6. Requirements

6.1. The QI team will notify the Investigator in advance of a QI review (see Appendix 1 for sample notification letter).

6.2. The QI team will meet with the Investigator, and anyone else designated by the Investigator, after the review to review any potential findings.

6.3. The QI team will provide the Investigator a written report of review findings once the review is complete. The review findings report will include a timeframe for providing a written response to each review finding including a CAPA plan, as applicable.

6.4. The QI team will assign a review rating to the review, in consultation with the Associate Vice President for Human Subject Protection.

6.5. The QI team will copy all Quality Improvement Review Final Reports to RSRB staff so that reports may be submitted for review at a convened board meeting. When the RSRB is the Relying Institution the final report is copied to the External Reliance Specialist so reports may be submitted to the Reviewing IRB. A copy of the QI Review Final Report will also be forwarded to the RSRB Chair, Associate Vice President for Human Subject Protection, the RSRB Director, the Investigator's Department Chairperson and/or Division Chief, as appropriate, and any other individual as determined by OHSP Leadership (see Appendix 2 for Routine Review Final Report Template).

6.5.1. The QI reviewer will complete an internal RSRB audit for each conducted review; findings will be added to the REDCap review database.

6.5.2. The QI team will upload the QI Review Memo, QI Review Final Report, and the RSRB audit statement to the IRB Review system. The IRB Coordinator will upload the RSRB determination memo.

6.5.3. Any final report with a review rating of "Unacceptable" will be copied to University Office of Counsel for appropriate risk management.

6.5.4. Biannually the OHSP External IRB Ad Hoc Committee (Associate Vice President for Human Subject Protection, RSRB Director, Director of Research Quality

Improvement, and Reliance Specialist(s)) will review summary information regarding external IRB QI reports to determine recommendations, as applicable.

6.5.4.1. The Reliance Specialist(s) will add a comment in the Study Workspace to document review by the Committee with notification to the Investigator. If action is required by the Investigator, this will also be included in the comment, and the External Reliance Specialist will provide follow up to the Committee regarding action items at the next meeting, or sooner as needed.

6.5.4.2. The Reliance Specialist(s) will share the final report and applicable follow up with the Reviewing IRB, as appropriate.

6.6. The QI team will include review findings in the REDCap database to quantify review findings and provide data to identify needed resources to target education programs to the research community.

6.7. The Investigator will be an active participant during the review process.

6.8. The QI team will notify the Investigator in advance of a site-requested PAC or QMP consultation.

6.9. The QI team will meet with any member of the study team during the consultation to address questions and provide education.

6.10. The QI team will provide the Investigator and study team members who have attended the consultation a written summary of all discussion points once the consultation is completed.

6.11. The QI team will utilize the QI PAC/QMP templates for standard language to quantify consultation needs and provide data to identify needed resources to target education programs to the research community.

6.12. The QI reviewer will complete the internal RSRB audit for each conducted consultation; audit findings will be added to the REDCap review database.

6.13. The QI team will upload the QI PAC/QMP Memo, the PAC/QMP Final Summary, and the RSRB audit statement to the IRB Review system.

Originator/Authors:

Kathleen Wessman, Director of Research Quality Improvement

Appendices:

Appendix 1: Principal Investigator Routine Review Letter Template
Appendix 2: Routine Review Final Report Template

Revision History:

11/2016: Added Study Start Up Consultations; editorial changes
10/2019: Added RSRB Audits; Added Quality Management Plan Consultations; editorial changes
10/2022: Change title of Study Start Up Consultations to Post-Approval Consultations; Update process for reporting QI Review Reports for studies reviewed by an external IRB; editorial and administrative changes

Supersedes Date:

10/11/2019

Approved By:

DocuSigned by:
Signer Name: Stephen Dewhurst
Signing Reason: I approve this document
Signing Time: 1/30/2024 | 1:31:06 PM EST
E217A323058C451895F16072D41E27E0

1/30/2024 | 1:31:19 PM EST

Stephen Dewhurst, PhD — Date

Institutional Official, Vice President for Research

DocuSigned by:
Kelley O'Donoghue
Signer Name: Kelley O'Donoghue
Signing Reason: I approve this document
Signing Time: 1/31/2024 | 2:38:22 PM EST
01BA85BD9A444F09983AC84603B8E36E

1/31/2024 | 2:38:28 PM EST

Kelley A. O'Donoghue — Date

Associate Vice President for Human Subject Protection, OHSP

DocuSigned by:
Kathleen Wessman
Signer Name: Kathleen Wessman
Signing Reason: I approve this document
Signing Time: 1/30/2024 | 12:59:06 PM EST
23649B5586354D349599202232741C12

1/30/2024 | 12:59:28 PM EST

Kathleen M. Wessman — Date

Director of Research Quality Improvement, OHSP

Appendix 1: Sample Investigator Routine Review Letter Template

MEMORANDUM

TO: XXXXX, MD, PhD - Principal Investigator

FROM: XXXXX - Associate Vice President for Human Subject Protection

DATE: XXXXX

SUBJECT: Routine Quality Improvement Review, RSRB #XXXXX

As part of its responsibilities under the University of Rochester's Human Subject Protection Program, the Office for Human Subject Protection (OHSP) has a quality improvement (QI) program that conducts routine on-site review of approved research. The intent is to provide an assessment of compliance with applicable regulations and requirements. Your study, *IRB #XXXXX: XXXXX*, has been selected for a routine review.

Studies are selected from human subject research across the University. The studies selected may involve use of novel techniques, research without external monitoring systems, high subject enrollment or risk-based research, or vulnerable populations. The intent of the review is to be cooperative, collaborative, and educational.

The study will be reviewed under the following regulations and/or guidelines:

- RSRB approved protocol/modification(s),
- RSRB requirements,
- Good Clinical Practice,
- UR Policy,
- in accordance with applicable federal regulations, International Center for Harmonization of Good Clinical Practice (ICH-GCP), the Food and Drug Administration (FDA), and under the University's Federal Wide Assurance (45 CFR 46).

XXXXX will conduct this review and will contact you in the near future by email to schedule. You do not need to be present during the records review; you may delegate an individual (e.g., study coordinator or assistant) to provide access to the study documentation. However, if you do delegate this task, please note that as Principal Investigator of the study, you must ensure that any and all necessary information and documents are provided in a timely fashion. If you have any questions, please contact XXXXX via email (global).

The intent of this on-site review is to replicate, in part, the types of reviews that could be conducted by a federal regulator or a study sponsor. Many of our investigators have found the process to be quite informative, either to confirm that appropriate study practices and procedures are being followed or to allow for the early detection and correction of problems or concerns when necessary.
We urge you to participate fully in this review, and to promptly implement any recommendations contained in the final report when approved by the Board. The results of the review are treated by OHSP as confidential and, unless a report to internal/external offices is required, they are shared only with the parties listed below. You will be notified if others who may have a need to know receive copies.

Thank you in advance for your cooperation and support of the University's program for human subject protection. For a description of the OHSP Internal Quality Improvement program, visit the website link: http://www.rochester.edu/ohsp/quality/index.html

Investigator rights and responsibilities during the QI process: You have the right to be present during the review and to transparency during the review process. You are encouraged to contact the reviewer with any questions you may have during the process. After reviewing the study documentation, a meeting with the reviewer is held at your convenience. During this meeting, study-specific processes at your site will be discussed and all potential findings will be shared. In addition, options to address any findings can be discussed. After this meeting, findings will be provided to you. Your written response and, if applicable, preventative action plan will be requested within a stated time frame.

You are responsible to provide timely written responses during the review process. Failure to do so may result in an unsatisfactory review. Because all QI Reports are reviewed by the RSRB, unsatisfactory site reviews may lead to actions on the part of the RSRB and/or the University. Per federal guidelines, some of these actions may require mandated reporting to federal agencies and study sponsors.

In the unlikely event that circumstances are identified that appear to put human subjects at risk, you will be notified promptly. I will also be notified immediately for a further assessment of risk. Immediate notification to and action by the RSRB may be required to prevent risk to human subjects.

cc: QI Team Members
XXXXX - Director, RSRB
RSRB Chair
RSRB Specialist
[X], MD, PhD - [Dept Chair/Chief/Director]

Appendix 2: Sample Routine Review Final Report Template

Report Finalized: XXXXX

Final Quality Improvement Review Report **CONFIDENTIAL**

Review of: Study #XXXXX

Protocol Title: XXXXX

Issued to: XXXXX (Principal Investigator)

Notification of Review Sent On: XXXXX
Review Conducted On/Date On Site: XXXXX
Investigator Exit Discussion: XXXXX
Written Findings to Investigator: XXXXX
Extension Granted On (until XXXXX): XXXXX
Investigator Response Received On: XXXXX

Research Site Staff Physically Present During Review: XXXXX
XXXXX

Research Site Staff involved in Exit Discussion: XXXXX
XXXXX

Review Conducted By: XXXXX

cc: XXXXX – Associate Vice President for Human Subject Protection
QI Team Members
XXXXX - Director, RSRB
RSRB Chair
RSRB Specialist
[X], MD, PhD - [Dept Chair/Chief/Director]

Executive Summary: This greater than minimal/minimal risk study was selected for routine review under the Office for Human Subject Protection (OHSP) guidelines. Funding is provided through the XXXXX via grant XXXXX. Vulnerable Populations included: XXX.

Brief Protocol Summary: The purpose of this study is to evaluate XXXXX.
Eligible adults are ….
Enrolled subjects ….
Study procedures include ….
Approximately XX subjects are expected to enroll at XX sites with XX at UR.

The following strengths were noted during the review:
- The regulatory files and research charts were clearly labeled and well-structured.
- The study staff demonstrated active communication and a commendable focus on teamwork.
- Active and continuous quality improvement at the site demonstrated a high level of commitment to the protection of research participants.

In accordance with the rating definitions referenced in OHSP Policy 1001: Quality Improvement Program the review findings for this site resulted in a rating of:

☐ Commendable

Rating Rationale: No deficiencies identified in a study with consent requirements and with enrolled subjects.

☐ Acceptable

Rating rationale:
- Lesser deficiencies are identified that do not appear to involve risk to subjects (includes Reviewer's comments).
- No deficiencies and no local accrual however, accrual is possible.
- No deficiencies identified in a study without consent requirements.
- Deficiencies identified with site-corrected resolutions present prior to QI review.
- A review not encompassing all aspects of a standard review (i.e. consents only).

☐ Acceptable with Follow-Up

Rating Rationale:
- Multiple lesser deficiencies are identified.
- Any deficiency in which potential risk to subjects needs further consideration (i.e. Data and Safety monitoring; adverse event assessment/reporting; wet-ink consent form missing/photocopy present).
- Self-reported deficiencies identified to the RSRB and being addressed prior to the conclusion of the review.
- No regulatory/study site file in a Greater than Minimal Risk study.
- CAPA re-review with repeated subject findings.

☐ Unacceptable

Rating Rationale:
- No response from the Investigator during the review process after a reasonable effort has been made by the reviewer.
- Major deficiencies are identified.
- A single major deficiency which impacts human subject safety/welfare is identified (i.e. data collected before consent).
- Study activity/treatment with subjects during a lapse in approval (without prior submission to the IRB).
- One or more missing consent form(s).

Scope: The study was reviewed under the following regulations and/or guidelines:

- RSRB approved protocol/modification(s),
- RSRB requirements,
- Good Clinical Practice,
- UR Policy,
- In accordance with applicable federal regulations, the Food and Drug Administration (FDA), International Center for Harmonization of Good Clinical Practice (ICH-GCP), and under the University's Federal Wide Assurance (45 CFR 46).

I. General Overview:

1. The site reported XX subjects consented to participate; XX active, XX completed, XX withdrawn by Investigator, XX withdrew their consent, XX failed screening, and XX lost to follow-up. XXX consented since the previous QI review.
2. The site reported the following racial background of enrolled subjects: XX American Indian/Alaska Native, XX Asian, XX Black/African American, XX Native Hawaiian/Other Pacific Islander, and XX White.
3. Enrollment continues for this study. OR Enrollment is complete for this study.
4. A comprehensive review of the research chart and electronic health record was completed for a random sample of XXXX subjects.
5. Consistent with RSRB-approval, the reviewer found evidence/no evidence of the subject's participation documented in the electronic health record.
6. Consent documentation was in accordance with RSRB requirements in the reviewed research charts; current and approved consent forms were used and consent was obtained prior to study procedure initiation. OR Consent documentation was not in accordance with RSRB requirements in the reviewed research charts; however, current and approved consent forms were used and consent was obtained prior to study procedure initiation (see Subject Research Chart Findings).
7. The protocol-specified Data and Safety Monitoring Plan requirements of XXX were met and documented. / The Data and Safety Monitoring Plan did not meet the protocol-specific expectations (See Study Documentation File Findings). / The protocol-specified Data and Safety Monitoring Plan requirements were not yet expected but were reviewed with the site.
8. There was documentation to indicate that adverse events were assessed. / There was no documentation to indicate assessment of adverse events for any subject.
9. The study documentation file was comprehensively reviewed.
10. The Electronic Data Security Form (dated XXX) was/was not present in the study documentation file.
11. Protocol training and re-training for site personnel was documented.
12. The trial is registered (NCT XXXX) on ClinicalTrials.gov.
13. Initial approvals and annual reviews were/were not on file and up-to-date for the following: Clinical Trials Office, Clinical Research Center, Institutional Biosafety Committee, Surgical Pathology, Radiation Safety Committee (+ dates of letters).
14. The study is covered by a Certificate of Confidentiality, which is provided by Department of Health and Human Services. Regulatory References:
15. An OHSP-QI Post Approval Consultation with the study team members occurred on XXXX.

II. Subject Research Chart Findings:

1. XX

Investigator's response:

Investigator's corrective and preventative action plan:

2. XX

Investigator's response:

Investigator's corrective and preventative action plan:

III. Study Documentation File Findings:

1. Consider findings related to the study file, general consent process, study personnel, enrollment during a lapse, etc:

Investigator's response:

Investigator's corrective and preventative action plan:

2. XX

Investigator's response:

Investigator's corrective and preventative action plan:

The Investigator is responsible for implementation of corrective and preventative action plans for the stated findings. The Investigator is also responsible for continued adherence to protocol, regulations, and good clinical practice.

Upon review of this report, the RSRB will make the final determination regarding corrective measures.

Attachments: Appendix A – Corrective and Preventative Action Plan Review
Appendix B - Study Site File Contents

DocuSign

Certificate Of Completion

Envelope Id: 9AB2CF52FBD64FEBAE86848550C27DB7
Status: Completed
Subject: Complete with DocuSign: Policy 1001 QI Program v.3.1 30JAN2024 Final.pdf
Study:
SOP
Source Envelope:
Document Pages: 14
Signatures: 3
Envelope Originator:
Certificate Pages: 5
Initials: 0
Ann Marie Scorsone
AutoNav: Enabled
Ann_Scorsone@URMC.Rochester.edu
EnvelopeId Stamping: Disabled
IP Address: 128.151.71.12
Time Zone: (UTC-05:00) Eastern Time (US & Canada)

Record Tracking

Status: Original
1/30/2024 12:50:00 PM
Holder: Ann Marie Scorsone
Ann_Scorsone@URMC.Rochester.edu
Location: DocuSign

Signer Events	Signature	Timestamp
Kathleen Wessman kathleen_Wessman@urmc.rochester.edu Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 23649B55-8635-4D34-9599-202232741C12 Using IP Address: 128.151.71.12 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 1/30/2024 12:52:12 PM Viewed: 1/30/2024 12:58:14 PM Signed: 1/30/2024 12:59:28 PM
Electronic Record and Signature Disclosure: Accepted: 5/16/2022 5:00:28 PM ID: 77b45c1f-6044-4bb9-89ac-9a55d4f29c31		
Kelley O'Donoghue kelley_odonoghue@urmc.rochester.edu Associate Vice President for Human Subject Protection Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 01BA85BD-9A44-4F09-983A-C84603B8E36E Using IP Address: 128.151.71.12 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 1/30/2024 12:52:12 PM Viewed: 1/31/2024 2:37:32 PM Signed: 1/31/2024 2:38:28 PM
Electronic Record and Signature Disclosure: Accepted: 2/1/2022 3:25:09 PM ID: c120fe80-b7e9-49f4-a85a-b4c84f1d69cd		

Signer Events	Signature	Timestamp
Stephen Dewhurst stephen_Dewhurst@urmc.rochester.edu Security Level: Email, Account Authentication (Required)	 Signature Adoption: Uploaded Signature Image Signature ID: E217A323-058C-4518-95F1-6072D41E27E0 Using IP Address: 128.151.71.23 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 1/30/2024 12:52:12 PM Viewed: 1/30/2024 1:29:48 PM Signed: 1/30/2024 1:31:19 PM
Electronic Record and Signature Disclosure: Accepted: 5/22/2022 6:40:31 PM ID: 25522c23-8df6-403d-9c08-468e0fa75729		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	1/30/2024 12:52:12 PM
Certified Delivered	Security Checked	1/30/2024 1:29:48 PM
Signing Complete	Security Checked	1/30/2024 1:31:19 PM
Completed	Security Checked	1/31/2024 2:38:28 PM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, University of Rochester (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a $0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact University of Rochester:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
To contact us by email send messages to: robert.evangelista@rochester.edu

To advise University of Rochester of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at robert.evangelista@rochester.edu and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from University of Rochester

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to robert.evangelista@rochester.edu and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with University of Rochester

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to robert.evangelista@rochester.edu and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify University of Rochester as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by University of Rochester during the course of your relationship with University of Rochester.