Remote Consent: Strategies & Considerations

Obtaining consent remotely is not necessarily a new notion in the conduct of human subject. However, the onset of the COVID-19 pandemic has resulted in a tremendous increase in the number of study teams seeking options for obtaining consent from subjects in a remote manner. Study teams often assume that ‘remote consent’ equates to electronic consent (or e-Consent) but this isn’t always the case. Remote consent can be accomplished through a variety of approaches and which approach is best, will depend on the nature of the research.

First and foremost, in consideration of your consent process (remote or otherwise), it is helpful to think of consent documentation as a separate, yet related, component of your consent process. The consent process generally includes assessing a subject’s interest in a study, disclosing the necessary information about the research to the subject, ensuring the subject understands the information, and obtaining the subject’s decision on whether or not to participate in the research. Whereas the consent document is only meant to act as a foundation for that exchange of information (providing a written version of the information that needs to be disclosed) and affords a place to document the subject’s agreement to participate in the research; the document is a part of the process, and is not the process in and of itself.

So, when considering remote consent for a study there are two key, processes to determine: 1) how will information be exchanged between the potential subject and the study team (inclusive of the consent discussion and verification of the subject’s understanding); and 2) how will the subject’s consent be documented?

Information Exchange Strategies

Remote consent discussions can take place over the telephone or via remote video conferencing (e.g., Zoom). Additional written or multi-media materials, including the use of an e-consent platform, may be used to further supplement or facilitate the consent discussion. Under limited circumstances (e.g., when the research involves only minimal risk and no subject interaction), written or multi-media materials may be used in lieu of the formal consent discussion. Ultimately, whichever strategy is employed, it is critical to understand that the same consent requirements set forth in the federal regulations (45CFR46; 21CFR50) that apply to in-person consent discussions, still apply when the consent process is conducted remotely. This includes:

- Obtaining consent prior to participation in the research;
- Providing sufficient detail about the research (i.e., the information needed for a reasonable person to make a decision about participation), including basic and additional (as applicable) consent elements and excluding any exculpatory language;
- Providing information in a language that is understandable to the subject; and
- Providing sufficient opportunity to consider participation, including reading the consent form, discussing the subject’s participation, and answering any questions. (continued on next page)
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(continued from previous page) It is critical to note the use of the word ‘discussion’ in this context. For a consent process to be successful, regardless of the media used to disclose information about the research, study teams need to ensure they are able to provide an opportunity for a back-and-forth conversation with the potential subject. Certainly this can be accomplished when consent discussions take place over the telephone or via remote video conferencing. But care must be taken in circumstances where there is little (or no) interaction with the potential subject (e.g., online surveys). More specifically, study teams must ensure that potential subjects are provided the opportunity to ask questions to the study team about the research prior to providing consent. In other words, subjects should be instructed to contact the study team with questions and direct contact information must be provided.

Documentation Strategies

When conducting consent remotely, consider the following options for documenting consent:

- **Waiver of Documentation of Consent:** Federal regulations (45CFR46; 21CFR56) permit Institutional Review Boards to waive the requirement to obtain a signed consent under specific circumstances. To clarify, this waiver applies only to the documentation (e.g., signature) component of the consent process; it does not waive the requirement to obtain consent entirely. In remote consenting scenarios, this is often applied when/if verbal consent will be obtained from a study subject (e.g., via telephone or video conferencing) or when there is no direct with potential subjects (e.g., online surveys). To qualify for the waiver, the study protocol must clearly indicate that the waiver is requested and provide (continued on next page)

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**Utilizing Zoom to Interact with Study Subjects**

When utilizing Zoom to interact with study subjects keep the following points in mind:

- Only use your University of Rochester (UR) Zoom account (as opposed to a personal account) to create and log into study-related meetings. If the research is being conducted under the University of Rochester Medical Center (URMC) and Affiliates covered entity, the URMC HIPAA-compliant log-in must be utilized.

- To secure the meeting, at a minimum, it should be locked once all attendees have joined the meeting to prevent uninvited attendees from joining. To lock the meeting, the host can click ‘Participants’ in the meeting toolbar and then select ‘More’ and ‘Lock Meeting’.

- If the meeting requires recording, be aware of what folder the recording will download into on your computer following completion of the meeting. **Recordings must be stored in the manner described in your IRB-approved study protocol and in compliance with University of Rochester IT requirements.** Based on the computer used for the Zoom meeting (e.g., personal vs. UR computer) and your Zoom settings, the recording may automatically download to your desktop. Recordings that download to a location inconsistent with your IRB-approved protocol, must be moved to a location that aligns with your IRB-approved protocol immediately. All files remaining on the desktop must be subsequently deleted (including permanently deleting the files from your computer’s recycle bin).

Additional information regarding University Zoom access and security is available [here](#). Want to use a different video conferencing platform? Utilizing video conferencing platforms other than Zoom is permitted provided the platform undergoes review, and receives approval, in accordance with the University’s [Guideline for Human Subject Research Data Security Requirements](#).
Remote Consent: Strategies & Considerations

(continued from previous page) adequate justification for how the research meets waiver requirements. The Reviewing IRB will also likely require that written information about the research be provided to the subject (i.e., an information sheet). See Section 9 of Office for Human Subject Protection [OHSP] Policy 701 Informed Consent for details.

- **E-Consent:** Generically, e-consent provides a mechanism to share written or interactive information, evaluate subject comprehension, and ultimately document consent electronically. It can be used in a variety of manners, as well in both in-person and remote consent scenarios. Based on the platform utilized, subjects can document their consent to participate by typing or ‘signing’ their name into a signature field using a mouse, stylus or finger. Of note, in addition to consent-related regulations, research utilizing e-consent is further subject to:
  - UR Data Security review and approval (in accordance with the University’s Guideline for Human Subject Research Data Security Requirements); and
  - Food & Drug Administration (FDA) regulations regarding electronic records and electronic signatures (21CFR11), if the research is FDA-regulated (see FDA Guidance on Use of Electronic Informed Consent for additional information).

- **Posted Mail/E-Mail/Fax:** Consent forms may be mailed, e-mailed or faxed to subjects for ‘traditional’ handwritten signatures and then returned back to the study team for signature by the person obtaining consent. Careful consideration and forethought must be paid to how subjects will be instructed to complete and return the form and what resources they may need in order to do so (e.g., a printer for emailed consent forms and self-addressed stamped envelopes for returning the completed document). Lack of (or unclear) instructions commonly result in consent documentation errors (e.g., incomplete checkbox options, missing signature dates).

As with the information exchange strategies identified above, federal regulations (45CFR46; 21 CFR50) also set forth documentation-related requirements that apply when informed consent needs to be documented (i.e., when the research does not qualify for a waiver of documentation of consent and consent is obtained in-person, electronically or via posted mail/e-mail/fax). These requirements specify that consent documentation must include the handwritten or electronic signature of the subject and a copy of the form must be provided to the subject. FDA and HIPAA regulations and guidance, as applicable, further require the subject to date the form and for the person obtaining consent to sign and date the form (similarly, OHSP Policy 701 indicates that the Research Subjects Review Board will consider when the signature of the person obtaining consent is required).

**Customizing Your Strategy**

Once you’ve weighed your information exchange and documentation options, customize your overall remote consent strategy by selecting the options that will best meet the needs of your research. When doing so, consider:

- What methods will be most accessible and feasible for your study population (e.g., utilizing e-consent and/or remote video conferencing requires a computer or smart device and internet access, as well as a certain level of computing skills)?

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Remote Consent: Strategies & Considerations

**Utilizing REDCap for e-Consent**

**REDCap** is a secure, web-based, electronic data capture system that includes an e-consent feature. REDCap is available for free to UR faculty, staff and students (including River Campus). Guidance on how to use REDCap for e-consent is available in the [Guideline for Use of REDCap for eConsent](#); additional information is also available via Academic IT’s June 17, 2020 presentation ([slides](#); [video](#)).

The benefits of utilizing REDCap is that it is readily available and cost-effective for UR study teams; it has also already undergone review and approval by UR Data Security. However, even though the platform has the ability to be [21CFR11](#) compliant, the University’s instance of REDCap is not compliant. Therefore, REDCap should not be utilized to document consent where an electronic signature is required, more specifically in FDA-regulated research. Furthermore, to be clear, the use of REDCap for e-consent is not required; study teams are able to utilize other e-consent platforms provided their use is approved by the Reviewing IRB and the UR Data Security team.

To initiate the process, complete the **REDCap e-Consent Request Form** once IRB approval for the use of REDCap for e-Consent has been granted. Similarly, when modifications to the REDCap consent process or documentation are required, submit the revisions to the Reviewing IRB first. Following IRB approval, the request form linked above should then be completed to request the modification in REDCap.

**Additional Suggestions from ‘the Field’** - When obtaining consent using e-Consent in REDCap:

- Ensure the subject authentication/verification process built into your e-consent process is consistent with your IRB-approved study protocol. Revisions to the authentication process in REDCap will require an IRB-approved modification to the study protocol prior to implementation in REDCap.

- Based on the nature of the research and your consent process, it may be helpful to e-mail a blank copy of the consent to potential subjects prior to initiating the consent process in REDCap (this should be included in your IRB-approved consent process). Once the e-consent invitation (or link) is sent to subjects they have the ability to work through the e-Consent at their own pace saving and returning as needed until submission.

- REDCap should not be utilized as a means for maintaining documentation of consent, nor any other required regulatory documentation. Completed e-consents should be downloaded from the ‘File Repository’ as soon as possible and maintained in paper or electronic format with your regulatory files, in accordance with data security and storage parameters defined in your approved protocol. Completed e-consents should be downloaded from the ‘File Repository’ only (not the Record Status Dashboard or Add/Edit Record section of REDCap). Only users with file privileges will be able to view and downloaded these files.

- Be aware of subject enrollment that occurs during the turnaround time that occurs between the time of IRB approval and REDCap implementation of the revised e-consent; subjects that sign the e-consent after IRB approval occurs but before the revised version is implemented in REDCap will be signing a version of the consent that is no longer current with the IRB approval.
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- (continued from page 3) What is an appropriate level of interaction with a potential subject, based on the nature of the research, to assess and ensure their understanding of the research (e.g., greater than minimal risk and more complicated minimal risk research may require multiple conversations, through multiple mediums, over time to ensure understanding)?

- What level of identity verification might be necessary in order to confirm that consent is obtained from the appropriate individual and ensure the validity of the data? E-consent platforms, as supported by FDA guidance, will generally require subject identity verification prior to consent. Internet-based research (e.g., online surveys) may similarly need to consider subject authentication strategies in order to minimize misrepresentation (see OHSP’s Guideline for Computer and Internet Based Research for additional information).

- For research that does not require the collection of identifiable information, consider requesting a waiver of documentation of consent over written or e-consent. Written or e-consent minimally requires the documentation of the subject’s name, signature, and IP address (for e-consent) and therefore negates that anonymity of the data.

As a final step, ensure that your consent process, inclusive of the information exchange and documentation strategy is clearly detailed in your study protocol. As a reminder, all consent processes must be approved by your Reviewing IRB prior to implementation (including modifications or additions to already approved consent processes).

Questions? Contact your IRB Coordinator.

Document Management in Click IRB

Institutional Review Boards (IRBs) conduct their reviews and make determinations based primarily on the documents provided by the study team within a submission (e.g., study protocol, consent documents, recruitment materials, study assessments). Responses to questions in an IRB submission should similarly be based on the content of the corresponding study documentation. Appropriate management of study documents within an IRB review system is therefore critical for facilitating the review process. Keep the following ‘golden rules’ in mind when utilizing Click IRB:

**Rule #1: Maintain the document audit trail.**

An audit trail provides a chronological record of all changes or transactions within a given system or database. Like the audit trail of a bank record that documents the amount and timing of every deposit or withdrawal over time, online IRB review platforms (including Click IRB) record information every time a document is uploaded into a submission form and every time a response to a submission form question is provided (or changed). Maintaining this information is necessary because it documents the history of the submission and it allows the IRB to quickly and easily identify changes from one version of a submission or document to the next.

While there is programming built into Click IRB that maintains the audit trail ‘behind the scenes’, the accuracy of that audit trail is only as accurate as the user’s actions. To maintain an accurate audit trail of a document in Click IRB, users must correctly ‘layer’ revised versions of existing documents. This is done utilizing the ‘Update’ button adjacent to the existing document (continued on next page)
Document Management in Click IRB

Adding revised documents via the ‘Add’ option and deleting old versions does not maintain the audit trail; the ‘Add’ button should only be used when adding new documents into the system, not previously reviewed documents.

In other words, think of a Click IRB submission as a traditional paper filing cabinet. Each smart form in the submission is one of the drawers and each field on the form, including each document within a field, is a separate file folder in the drawer. In this scenario, the audit trail of a given field or document is maintained in their respective file folder. Every time a field or document is revised, the revised version is added to the field’s/document’s respective file folder in front of (or on top of) the old version – this is the equivalent of using the ‘Update’ button to upload a revised version of a specific document. Whereas, filing a revised document in a brand new folder (hence breaking the audit trail) is the equivalent of using the ‘Add’ button.

**Rule #2: Use consistent, short, but descriptive, file naming conventions.**

When a document is uploaded into Click IRB, users are given the option to identify a file name (see Image 2). The name identified in the field then pulls through to the submission form and, later (upon IRB approval) to the submission approval letter. The naming convention used to identify the document should allow reviewers (as well as any individuals that might view IRB approval letters – e.g., Study Monitors, Food & Drug Administration Inspectors) to quickly and easily identify the type and purpose of the document; this is particularly important when a submission includes a large number of documents (e.g., multiple consent documents and recruitment materials). Naming conventions should be short (less than 25 characters) but descriptive, and consistent across document versions (see examples in Table 1).

<table>
<thead>
<tr>
<th>Table 1. File Name Examples (STUDY1234)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Version 1</strong></td>
</tr>
<tr>
<td>Protocol.v1</td>
</tr>
<tr>
<td>STUDY1234_Protocol_v1</td>
</tr>
<tr>
<td>Consent_CohortA_v1</td>
</tr>
<tr>
<td>1234_Consent_05MAR2020</td>
</tr>
</tbody>
</table>

When no name is assigned to the document, which is often the case, Click IRB will default to the file name of the document. Consequently, study teams should be mindful of the naming convention recommendations above (i.e., consistent and short but descriptive) when they create and/or modify study document files in their word processing software. In other words, when a document is created by a study team, if the name applied to the document file is appropriately named when the document is saved in MS Word, for example, the appropriate file name will pull into Click IRB automatically when/if the document name field is left blank in Click IRB.  

(continued on next page)
Rule #3: Use consistent versioning methods.

(continued from previous page) Similar to document names, Click IRB also gives users the option to identify an alphanumeric version number when a document is uploaded into the system (see Image 2 on previous page). A version date, version number or a combination of a version date and number may be entered. The version identified in the field also pulls through to the submission form and approval letter, as with the document name. When the field is left blank, Click IRB will automatically assign a version number each time a revised version of the document is uploaded.

Ideally, the version identified in Click IRB should be consistent with whatever version, if any, is identified in the document itself (e.g., in the document footer). This is particularly true for sponsored research; sponsors and monitors will often require that the approval letter identify the version of an approved document. However, the accuracy of the version that appears in the approval letter is only as accurate as what is entered into the system by the study team.

Ultimately, whichever version method is utilized – allowing Click IRB to create a default version or identifying a version date consistent with what is identified in the document itself – it should be consistently applied across all revisions or modifications throughout the life of the research. Inconsistent versioning will result in an unclear document history (e.g., if a protocol is versioned with a date in one instance [28JAN2021] and a number in a second instance [v.1.4], based on the version formatting, there is no way to determine the chronology of the document).

Warning! When Document Management Goes Wrong

As referenced in the second ‘golden rule’, these practices ultimately apply to how a study team should organize their own study files. Although file organization, naming conventions, and versioning might seem like they’re only for Type A personalities or the organization-obsessed, failing to maintain study files in a manner that is not clear, orderly and consistent can have tangible consequences on the conduct of the research.

Consider, for example, what happens when a study team member can’t readily identify the current approved version of a protocol and they need to reference a schedule of assessments, verify eligibility requirements, determine whether a research event needs to be reported according to a data and safety monitoring plan, or revise the protocol. Each scenario could potentially result in exposing a subject to unnecessary risk and non-compliance.

Reminder! Study Documentation Maintenance

Principal Investigators (PIs) are responsible for maintaining documentation that demonstrates their compliance with applicable federal regulations and institutional policy, as well as the study protocol (see Office for Human Subject Protection [OHSP] Policy 901 Investigator Responsibilities). PIs cannot rely on Click IRB (or any other IRB review platform) to maintain documentation of their IRB approval letters and corresponding IRB-approved study documents. All necessary study documentation should be saved by the PI/study team as soon as a submission is approved or acknowledged. For additional information on what types of documentation must be maintained by the PI, click here; guidance is also available through the OHSP Division of Quality Improvement’s Study Documentation Tool Box and Study Start-Up Consultation.
Use of a Protocol Deviation Log

Federal regulations require that the researchers carry out the research in compliance with the IRB-approved protocol, but research occurs in the real world, therefore protocol deviations happen. But protocol deviations (or protocol non-compliance) can lead to issues regarding subject safety and the integrity of the study data and its outcomes. Therefore, it is important to document these deviations from the approved protocol. Best practice is to use a deviation log to document protocol non-compliance occurring throughout the study.

Examples of protocol deviations (or non-compliance) include:
- Consenting errors
- Out of window visits
- Missed study assessments
- Investigational product dosing errors
- Incomplete or missing data collection forms

The following information should be noted on a protocol deviation log:
- Description of the deviation
- Date the deviation occurred
- The reason the deviation occurred
- Date the IRB was notified (as applicable) – Each protocol deviation should be evaluated to determine who needs to be notified (e.g. IRB, sponsor, funding agency)
- The Principal Investigator’s acknowledgement with their signature and date reviewed

As a study team, routinely review protocol deviations to consider whether the event is a single occurrence or a systemic problem. While the single occurrence may be explained by the reason the deviation occurred, system problems may require an analysis of the problem and implementation of a corrective and preventative action plan (CAPA) to alleviate the likelihood of the deviation being repeated. Ensure your CAPA is EXACT: Examine the root cause, execute the specific plan, adequately document the action, carry out for current and future protocols, and timely follow up to ensure the plan is still effective. This is a long-term solution that prevents reoccurrence, should be measurable, and documented.

This log should not be confused with the IRB Report of New Information (RNI); RNIs are reported through the Click IRB System. Report adverse/research events to the IRB per the reviewing IRB’s policies and procedures (for Research Subject Review Board reporting requirements see Office for Human Subject Protection Policy 801 Reporting Research Events and the corresponding Guideline for Reporting Research Events).

The editable protocol deviation log and other useful checklists to aid in protocol documentation and compliance can be found in the QI Study Documentation Tool Box.

Research QI ‘Gold Star’ Award

The QI division is recognizing Kirsi Jarvinen-Seppo, MD, PhD and Miranda Klein within Pediatric Allergy and Immunology for their quality work on the ‘Saliva Peanut IgE as a Biomarker of Peanut Allergen Sensitization’ study. The study site received the OHSP-QI ‘Gold Star’ award for their focus on teamwork, openness to educational opportunities and using available resources, demonstrating respect for the subjects and their families, and high quality, organized study-related documentation. Congratulations!
Timing of Continuing Review Submissions

Federal regulations (45CFR46; 21CFR56) require continued Institutional Review Board (IRB) review of some types of minimal risk (expedited) research and all greater than minimal risk human subject research at least annually. In order to maintain IRB approval of the research, it is the responsibility of the Principal Investigator (PI) to ensure timely submission of a continuing review (also referred to as a progress report) prior to a study’s expiration date in order to provide the Reviewing IRB adequate time to review the submission and request clarification, as necessary. Based on the required review level, board scheduling, and workload, Reviewing IRBs cannot guarantee timely renewal of research for continuing reviews submitted on, or just shortly prior to, study expiration. If IRB approval of the research lapses, all research activities, including recruitment, enrollment, interventions, interactions and data analysis on current subjects must cease until re-approval is provided. Furthermore, lapses in IRB approval are considered to be non-compliance and multiple incidents of lapses in approval may be considered continuing non-compliance.

For research reviewed and approved by the Research Subjects Review Board (RSRB), study expiration dates (or approval end dates) can be found in the upper left corner of the study workspace in Click IRB (see Image 3). Note that this field is not included (does not appear) when continuing review of the research is not required.

As a courtesy, reminder e-mails concerning approaching expiration of RSRB-approved studies are sent to the PI, PI Proxy, and Primary Contact at 30 and 60 days prior to expiration (see Image 4). To help ensure timely review, as a general rule of thumb, the RSRB recommends submitting continuing review no later than 45 days prior to expiration.

For additional information on completing continuing review submissions see the Click IRB Study Staff Manual and the Q3 2019 OHSP Newsletter.
UR-HRPP Educational Forum: Informed Consent Series

On November 12, 2020, the Office for Human Subject Protection (OHSP) initiated a ‘mini’ seminar series on informed consent. The series is embedded within the monthly University of Rochester Human Research Protection Program (UR-HRPP) Educational Forum. The goals of the series are two-fold. The primary goal is to provide a platform to learn, discuss, share, and ultimately improve issues related to informed consent in human subject research. The secondary aim is to record all sessions to create an archive of sessions/materials that can be used by study teams in the future for reference and/or training new research staff. To date, the following sessions have been conducted (recordings are available in Blackboard):

- Back to Basics: Informed Consent – Translating Requirements into Practice
- Building from Basics: Informed Consent – Planning Your Process

Additional sessions related to health literacy and permission/assent in pediatric research are tentatively planned for 12pm on May 13th and June 8th, respectively; additional details to follow via the OHSP listserv.

Wanted: Future Presenters! OHSP is currently seeking presenters interested in participating in this series on informed consent. Do you regularly engage with a vulnerable population? Do you have a creative approach to the consent process? Do you have experiences and lessons you want to share? If interested in presenting, please contact Kelly Unsworth.

Input Needed: Study Documentation & Self-Audit Tools Update

The Office for Human Subject Protection Quality Improvement (OHSP-QI) Study Documentation Tool Box is soon-to-be updated! If you have any documents you would like added to the toolbox and share with the research community, please email them to OHSP-QI. Additionally, the self-audit tools have been updated and are available for use on our website for your use.

Reminder: OHSP-QI Consultations

Contact the Office for Human Subject Protection Division of Quality Improvement any time to schedule your team for a study start-up and quality management plan consultation which includes a review of the study’s applicable regulations. All consultations are currently conducted via Zoom as a meeting venue.

Redacting Study Records for Remote Monitoring

Although not new to research, the onset of the COVID-19 pandemic forced many sponsors and coordinating centers to re-think their monitoring approaches, specifically their level of and ability to perform remote monitoring. As a result of this, study teams may now find themselves with the time-intensive task of providing monitors with redacted source documentation for the purpose of source data verification. When/if you are asked to do so, attention must be paid to the redaction process as it is prone to error. To minimize errors, export (or print) applicable files to PDF and (continued on next page)
Redacting Study Records for Remote Monitoring

(continued from previous page) use Adobe Pro to redact identifiable content (instructions are available from Adobe here). As part of this process:

- Use the ‘search and remove text’ function to ensure all identifiers are found and redacted. Search multiple iterations of names, nicknames and other applicable identifiers (e.g., search Michael, Mike, and Smith for a patient named Michael Smith).

- Beware of scanned documents. The text in scanned documents may not be accurately ‘read’ by search functions; manual review and redaction may be necessary.

- Once content has been marked for redaction, as part of the process Adobe will be asked if you want to ‘sanitize and remove hidden information’; answer yes. This will remove hidden text, comments, file attachments, metadata, etc. Document metadata is data about the document, such as the document title (separate from the file name), author, description, key words, and tags. Instructions for viewing/editing metadata (e.g., the document title, author, description, and key words) are available here.

Finally, please be reminded that:

- Taking the time to adequately and comprehensively redact and review records is a worthwhile endeavor. The nature of source documentation is such that information that might require redacting can easily be missed or overlooked. Committing the time up front to do the process justice is far less time consuming then dealing with potential breaches in confidentiality, if identifiable information is inappropriately disclosed.

- Your ability to share study materials (redacted or not) is limited by the data protection measures and data sharing entities identified in your study protocol, consent form, and, if applicable, any clinical trial agreement and sub-contracting agreements.

Contact Information

Department Administration
Kelley O’Donoghue, Director OHSP (585) 273-4631
Nicole Mason, Director RSRB (585) 273-4574

Research Education & Training
Kelly Unsworth, Director (585) 275-5244

Clinical & Regulatory Systems
Thai Nguyen, Director (585) 273-4583
James Wanzenried, Sr. Programmer (585) 273-4579

Quality Improvement
Kathleen Wessman, Director (585) 273-2118
Jennifer Dolan, QI Specialist (585) 276-5709

Administrative Staff
Janice Taylor, Administrative Asst (585) 273-4127

RSRB Board Specialists
James Filingeri, Board 1 (585) 273-2117
Kathleen Buckwell, Sr. Specialist, Board 2 (585) 275-7446
Suzanne Coglitore, Board 3 (585) 276-4578
Michelle Giglio, Board 4 (585) 273-4576
Katherine Zanibbi, Board 5 (585) 276-3856
Kristin Dauenhauer, Reliance Specialist (585) 276-4577
Jamie Biear, Assistant Specialist (585) 276-5544
Ann Marie Scorsone, Sr. Specialist (585) 276-5537

Main Office
Phone: (585) 273-4127
Fax: (585) 273-1174

Website
www.rochester.edu/ohsp