Over the past several years the research community has seen a push by sponsors, regulators and subject advocacy groups to improve the diversity of the populations enrolled into research, particularly in clinical trials. In addition, in order to meet research aims and have results that are generalizable to individuals of varied ethnic backgrounds, the enrolled population must be representative of various demographic groups/subgroups. Based on this need, compounded with the need to meet recruitment and enrollment goals, the enrollment of non-English speaking subjects into research has become increasingly necessary.

Nevertheless, the decision to enroll non-English speaking subjects into research should not be taken lightly; investigators must ensure they understand and have a process for meeting the requirements for enrolling non-English speaking subjects. More specifically, investigators must give careful consideration to how they will communicate with non-English speaking subjects throughout the entire lifecycle of the research. Enrolling subjects when a language barrier exists can affect:

- A subject’s ability to make an informed and voluntary decision about initial and continued (e.g., re-consent) study participation, as well as the study team’s ability to assess the subject’s comprehension of the information provided during the consent process;
- Data collection procedures, particularly when data is collected via subject-completed measures such as questionnaires, surveys, diaries or assessments;
- A subject’s ability to follow tasks, procedures and/or investigational product instructions;
- The identification, assessment, management and follow-up of adverse events and unanticipated problems;
- The ability of both the study team and subject to ask and/or answer questions; and
- The study budget (e.g., costs related to translation services).

When/If an investigator decides to enroll non-English speaking subjects, it’s important to bear in mind that applicable ethical principles and federal regulations (45 CFR 46.116; 21 CFR 50.20) concerning the informed consent process must still be met. The informed consent process must:

- Provide enough information for a reasonable person to make a decision about participating;
- Provide the information in a manner that is understandable to the potential subject;
- Provide sufficient opportunity for the subject to consider participation;
- Present the information in a manner that is free from coercion and undue influence;
- Document subject consent via written signature on an Institutional Review Board (IRB) approved consent document (unless waived); and
- Provide the subject a copy (continued on page 2)
Enrolling Non-English Speaking Subjects

(continued from page 1) of the signed consent document.

Consistent with the obligation to provide information in a manner that is understandable to the potential subject, Office for Human Subject Protection (OHSP) Policy 701 Informed Consent requires investigators to translate all consent documents, subject-completed forms (i.e., questionnaires, surveys, diaries, assessment forms), and any other relevant subject materials (e.g., recruitment materials, instructional or educational forms) into the primary language of the study population. All translated documents, and accompanying translator declaration, must be submitted to the Research Subjects Review Board (RSRB) for approval prior to use (see additional process details in Table 1 on the next page).

Translation ≠ Interpretation

While translating written documentation is an essential part of the enrollment process, it does not solve all communication barriers. Study teams must also consider how they will communicate orally with non-English speaking subjects throughout the study. Routinely, this is accomplished through the use of a professional interpreter who is fluent in English and the subject’s primary language. For benign, minimal risk research, a study team member fluent in the subject’s primary language may act as an interpreter. However, given the complexity of medical information, professional medical interpreters should be utilized to interpret verbal exchanges for biomedical research (information on interpreter services available within the University of Rochester Medical Center and Highland Hospital are available on the web). Note:

- Study teams should not rely on family members or friends of the subject to interpret conversations.
- Study teams should document the use of an interpreter in the study records (on all occasions), including the name of the interpreter, method of interaction [e.g., in-person, via phone or video-conferencing], nature of the information provided via interpreter and verification that answers were provided to the subject’s questions.

RSRB Requirements ≠ Reviewing IRB Requirements

In consideration of the requirements and best practices discussed in this article, bear in mind that study teams utilizing an IRB external to the RSRB may be held to different requirements/standards. Per OHSP Policy 504 IRB Reliance and Collaborative Research, investigators and research staff are required to adhere to the reviewing (external) IRB’s policies and procedures. As such, when presented with the opportunity to enroll a non-English speaking subject, study teams are encouraged to contact the reviewing IRB to ensure they have an adequate understanding of how to remain in compliance.

For questions related to RSRB policies, contact your IRB Coordinator.
Table 1. Methods for Enrolling Non-English Speaking Subjects

<table>
<thead>
<tr>
<th>Full Translation of RSRB-Approved Documents</th>
<th>Short Form Consent</th>
</tr>
</thead>
</table>
| 1. Obtain RSRB approval for English version of all documents that require translation.  
- Generally, it is recommended that investigators first obtain RSRB approval of the research and then, following approval, submit a modification to obtain approval for the research to include the non-English speaking population and all translated documents. | 1. Upon identification of a non-English speaking subject, contact your IRB Coordinator to confirm that use of the short form is permissible. |
| 2. Translate all necessary documents (consent document and all relevant subject-completed forms).  
- Translations should be completed through a professional translation service and a formal translator’s declaration should be obtained, confirming the translation is true, accurate and correct. This should be completed by the individual providing the translated documents. | 2. Submit a modification to request approval of the short form translated into the subject’s primary language.  
- All translated short forms, included the existing translated forms available on the RSRB website, must be revised to include the study title, investigator, investigator contact information, Click IRB study number and version date. |
| 3. Submit a modification that includes: a) clarification of eligibility criteria (as necessary); b) submission of all translated documents; and c) submission of the completed translator’s declaration. | 3. Translated short forms are available in Spanish, Russian, and Mandarin on the RSRB website. |
| 4. Following approval of the modification, non-English speaking subjects may be enrolled. | 4. Following approval of the modification, the non-English speaking subject may be enrolled. |
| 5. At the time of consent…  
- Utilize an interpreter to relay the consent discussion, as provided by the study team member obtaining consent (inclusive of general consent discussion, assessment of the subject’s comprehension of the information, responses and clarification to subject questions, verification of the subject’s willingness to participate in the research and any optional study activities).  
- Ensure the subject has adequate opportunity to read the translated consent document and consider participation.  
- Ensure all questions are answered.  
- To document consent:  
  * Subject signs and dates the watermarked, translated consent document and completes all checkboxes/initial lines, as applicable.  
  * Study team member who obtained consent signs and dates the watermarked, translated consent document as the person obtaining consent. As good practice, the study team member should also provide narrative documentation of the consent process, describing the sequence of events including what information was reviewed, who was present, how the interpreter was utilized, how much time the subject was given to consider participation, whether the subject comprehended the information and confirmation of their agreement to participation. Narrative documentation can be provided directly on the consent document or as a separate note in the subject file.  
  * Interpreter signs and dates the watermarked, translated consent document as a witness. (If a signature block has not been included for the interpreter, the interpreter should print, sign, identify themselves at the interpreter and date their name below the person obtaining consent signature).  
  * Provide a copy of the signed consent document to the subject. | 5. Utilize an interpreter to: a) read the contents of the English version of the consent document to the non-English speaking subject; and b) relay all further consent discussion, as provided by the study team member obtaining consent (inclusive of general consent discussion, assessment of the subject’s comprehension of the information, responses and clarification to subject questions, verification of the subject’s willingness to participate in the research and any optional study activities).  
- An adult witness, fluent in both English and the subject’s primary language must be present during the consent discussion.  
  * The witness must be independent of the study team.  
  * The witness should be a fluent professional.  
  * Ideally, the witness should not be a friend or family member of the subject, as the friend or family member’s role is in support of the subject’s decision-making process.  
  * Ideally, the interpreter should not serve as the witness, as they are part of the consent process (not just observing it). If another witness is not available, the interpreter may serve as the witness provided they are present during the consent discussion and are not a member of the study team.  
- The nature of this process requires that even more focus be placed on the consent discussion, as there is no translated document for the subject to read. Ensure the subject has adequate opportunity to read the translated short form and to re-review each of the points laid out in the document when considering participation.  
- Ensure all questions are answered.  
- To document consent:  
  * Subject signs and dates the watermarked, translated short form consent document.  
  * Study team member who obtained consent signs and dates the watermarked, English version of the consent document as the person obtaining consent. As good practice, the study team member should also provide narrative documentation of the consent process, describing the sequence of events including what information was reviewed, who was present, how the interpreter was utilized, how much time the subject was given to consider participation, whether the subject comprehended the information and confirmation of their agreement to participation. Narrative documentation can be provided directly on the consent document or as a separate note in the subject file.  
  * Witness signs and dates the watermarked, translated short form consent document and the English version of the consent document.  
  * Provide copies of the signed translated short form and signed English version of the consent document to the subject. |
| 6. Upon approval, a copy of the translated consent should be provided to the subject. | 6. Upon approval, a copy of the translated consent should be provided to the subject. |

**This process must be repeated every time re-consent and/or written notification to subjects is required when the research is modified.**  

**Utilization of the short form is only permitted at the time of initial enrollment. The process described in the adjacent column must be repeated every time re-consent and/or written notification to subjects is required when the research is modified.**
Preventing Local Site Consent Documents for
External IRB Submissions

Per Office for Human Subject Protection (OHSP) Policy 504 Institutional Review Board (IRB) Reliance and Collaborative Research, all studies reviewed and approved by an External IRB (i.e., an IRB other than the Research Subjects Review Board [RSRB]), are required to undergo institutional administrative review prior to submission of the research to the External IRB. The purpose of this review is to ensure compliance with institutional policies (including, but not limited to, departmental scientific and resource review, ancillary committee review (as applicable), human subject protection training requirements, and institutional and investigator conflicts of interest). Local site consent documents are also reviewed as part of this process, to verify all required institutional language (as applicable) is included in the document.

To prepare local site consent documents for institutional review, start with the IRB-approved model consent provided by the lead site or study sponsor (if this has not been provided, contact the lead site, sponsor, or Contract Research Organization [CRO] project manager). Prior to editing the document, verify the lead site/project manager’s process for reviewing model consent document revisions. Most project managers will request that sites provide them a tracked copy of all revisions for review and acceptance, prior to submission for institutional administrative review (see FAQ on tracked changes on page 10).

To make the revisions, reference the instructions provided in Table 2 (on the next page). The table identifies general requirements that apply to all research, as well as, requirements that may apply, based on the nature of the research. For each element identified, study teams are directed to:

- ADD additional text to the consent;
- REPLACE text already included in the consent; or
- ENSURE specific content exists in the consent document.

When the instruction is to ADD or REPLACE template language, the specific text to be utilized is available here.

What if the lead site or sponsor does not agree with the revisions made for the local site?

As a first step, study teams should remind the lead site/sponsor that the revisions were made per institutional requirements, as defined in OHSP Policy 504 IRB Reliance and Collaborative Research and the associated Guideline and Flow Chart When the University of Rochester Relies on a Non-UR IRB (note that the documents are publically available and may be forwarded to lead sites/sponsors, as necessary). Objections are often made, particularly by study sponsors, to revisions in the compensation for injury language. Reminding sponsors that indemnification provisions are defined by the clinical trial agreement, not the consent document may be helpful. Finally, if you are unsuccessful in negotiating revisions to the consent document, contact the OHSP Reliance Coordinator.

What about assent forms?

Generally, assent forms do not include the elements identified in Table 2 and therefore do not require revision. If you have questions about whether any language in the assent would require revision, contact the OHSP Reliance Coordinator.
Table 2. University of Rochester (UR) Consent Language Requirements for External IRB Submissions

Note: This table identifies general language requirements and when they are required. The specific text that is required for those elements that require adding or replacing model consent text is available [here](#).

### For ALL research...

**Do this…**

- **ADD** electronic letterhead to the first page of the consent document. Note: Inserting letterhead images/text into consent document may result in formatting errors that require further revision. As an alternative, it may be more efficient to cut and paste the entire contents of the model consent document into the electronic letterhead document and then proceed to making the necessary revisions to the document (tracking the revisions, if necessary). Be aware, however, that margins and headers/footers may also require revision to include version dates, page numbers and provide adequate space for watermarking.
- **ENSURE** the consent document begins with the presentation of ‘key information’.

### If the research...

**Do this…**

- **ENSURE** the consent document indicates that information about the subject’s participation in the research will be included in the EHR, including the risks related to including such information in the EHR. If this information is not included in the consent document, **ADD** the UR’s template ‘Electronic Health Records’ language.

<table>
<thead>
<tr>
<th>Involves documentation of study participation or study results in the electronic health record (EHR)</th>
<th>REPLACE any text regarding taxable income and Internal Revenue Service (IRS) reporting with the UR’s template ‘Payment for Participation’ language (the description of the subject payment provided in the model consent does not require revision). If the information regarding taxable income and Internal Revenue Service (IRS) reporting is not included in the consent, <strong>ADD</strong> the UR’s template ‘Payment for Participation’ language.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Involves cumulative subject payments ≥ $600</td>
<td>REPLACE any text regarding reimbursable travel expenses with the UR’s template ‘Reimbursement for Travel Expenses’ language. If the information regarding reimbursable travel expenses is not included in the consent, <strong>ADD</strong> the UR’s template ‘Reimbursement for Travel Expenses’ language.</td>
</tr>
<tr>
<td>Involves reimbursing subject travel expenses</td>
<td>REPLACE all compensation for injury language with the UR’s template ‘Compensation for Injury’ language.</td>
</tr>
<tr>
<td>Involves greater than minimal risks</td>
<td>ENSURE the consent document includes a statement that identifies the funding source. If the statement is not included, <strong>ADD</strong> the UR’s template ‘Source of Funding’ language.</td>
</tr>
<tr>
<td>Is funded by an entity external to the UR</td>
<td>ADD the consent language identified in the study team member's COI transparency checklist or COI management plan.</td>
</tr>
</tbody>
</table>
| Involves any study team member with a potential conflict of interest (COI) | ENSURE a Health Insurance Portability and Accountability Act (HIPAA) authorization is embedded in the consent document (a separate HIPAA authorization form is not allowed). Per HIPAA Privacy Procedure OP25 Use or Disclosure of PHI for Research Activities, all HIPAA authorizations must include:  
  - A description of the information that will be used or disclosed;  
  - The identification of the person or classes of persons authorized to use or disclose the information;  
  - The name of the person or classes of persons to whom the information may be disclosed;  
  - A description of each purpose of the requested use or disclosure;  
  - An expiration date or an event that triggers expiration;  
  - A statement that the individual has a right to revoke the authorization, with exceptions identified, and a description of how revocation may be done;  
  - A statement that information used or disclosed may be re-disclosed by the recipient and may no longer be protected by the HIPAA Privacy rule;  
  - Signature of the individual and date; and  
  - Consequences of refusing to sign the authorization. |
| Is being conducted under the University of Rochester Medical Center (URMC) covered entity OR involves study team members that are part of the URMC covered entity workforce | If a HIPAA authorization is included in the consent document but does not address ALL of the elements identified above, notify the lead site/project manager and **ADD** any missing elements (utilizing the UR’s template language, as appropriate). If a HIPAA authorization is not included in the consent document, **ADD** the UR’s template ‘Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes’ language. |
2019 Research Quality Improvement—
Our Year by the Numbers

Research Quality Improvement continued its program of reviews and consultations in 2019; below is an infographic to demonstrate our year!

**MOST FREQUENT REVIEW FINDINGS:**
- Incomplete documentation of: Data and Safety Monitoring Plan, Adverse Event Assessment, and Eligibility
- Protocol Compliance (i.e. out of window visits)
- Incorrect Version of Consent Form used
- Regulatory File incomplete

**Review Ratings**
- 47% Acceptable
- 26% Acceptable with Follow Up
- 13% Unacceptable
- 14% Commendable

**50+ Study Start Up Consultations**
**59% Minimal Risk Studies**
**80% Non-Drug or Device Studies**

**REMINDER: Study Documentation & Self Audit Tools**
Study documentation templates and Self Audit tools are available on the OHSP Quality Improvement (QI) website. Questions regarding the use of these templates/tools and scheduling a review or consultation can be directed to the QI team.

Study Start Up Effectiveness Poster was presented three times nationally.
Research QI ‘Gold Star’ Award

The QI division is recognizing Adam Carinci, MD, Tammy Ortiz, Nancy Robertson, and Janet Vaughan for their quality work on ‘A Prospective, Multi-center, Randomized, Assessor Blind, Controlled Study Comparing Lateral Branch Cooled Radiofrequency Denervation to Conservative Therapy as Treatment for Sacroiliac Joint Pain in a Military and Civilian Population’. This vibrant study team is part of the Anesthesia Clinical Research Center in the Department of Anesthesiology and Peri-Operative Medicine. They received the OHSP-QI ‘Gold Star’ award for demonstrating attention to regulatory compliance/protocol adherence, good consenting processes and Investigator oversight, and high quality, organized study documentation. Congratulations!

HHS Single IRB Requirement Effective 1/20/20

As a reminder, effective January 20, 2020 all federally-funded multi-site research (i.e., research involving more than one institution) is required to utilize a single Institutional Review Board (IRB) (45 CFR 46.114). ‘Federally-funded’ means the research is conducted or supported by the federal government. To fulfill this requirement, study teams engaged in multi-site research must:

a) Identify who will act as the Reviewing IRB (i.e., the IRB designated to review and approve human subject research), in accordance with OHSP Policy 504 IRB Reliance and Cooperative Research. Reviewing IRB selection is routinely made by either the funding agency or lead Principal Investigator.

OR

a) Provide written documentation from the funding agency confirming that the funding agency has determined the research is exempt from the single IRB requirement (an email from the program manager is sufficient).

For grants submitted under the NIH Single IRB Policy for Multi-site Research, costs and associated administrative oversight must be included in the original grant submission. For research that will require a single IRB and did not account for this in the grant submission, please contact Kelley O’Donoghue.

If you plan to submit a multi-site grant utilizing the Review Subjects Research Board as the Reviewing IRB, early planning is critical! All study teams are required to meet with Kelley O’Donoghue, Associate VP for Human Subject Research, in advance of the grant submission to ensure adequate budgeting and monitoring.

Additional Resources:
- Guideline for Single IRB Plan in an NIH Grant Application
- OHSP Policy 504 IRB Reliance and Cooperative Research
- OHSP Guideline and Flow Charts When the University of Rochester Relies on a Non-UR IRB
- OHSP Guideline and Flow Charts When University of Rochester is the Reviewing IRB
- OHSP Guideline for Coordinating Center Studies
- ‘Preparing Single IRB Grant Submissions Utilizing the RSRB as the Reviewing IRB’ (recording of previously conducted OHSP seminar) is available for reference via Blackboard.
The quality of the process for onboarding a study team member, be that an investigator, study coordinator, or any other member of the study team, can have a profound downstream effect on study conduct. Ineffective onboarding can lead to job dissatisfaction, disengagement, low productivity, staff turnover, non-compliance, and worst yet, can jeopardize subject safety and data integrity. During the January 9, 2020 University of Rochester Human Research Protection Program Educational Forum, critical considerations for study team onboarding were presented. Key points and best practices reviewed during the session include:

- Orientation and training do not equal onboarding. Onboarding is a ‘bigger picture’ approach for ensuring newly hired staff gain the knowledge, skills and behaviors to not only meet and succeed at their job but also to be an effective contributor to the organization at-large.

- Onboarding plans are more likely to be effective when they are formalized into a written plan and shared with team members engaged in the onboarding process. To assist study teams in developing onboarding plans, the Office for Human Subject Protection (OHSP) in collaboration with the Study Coordinator Organization for Research and Education (SCORE), has created the Study Team Member Onboarding & Training Guide. This guide identifies suggested tasks, activities and training procedures that may be included in an onboarding plan. Study teams should modify the document as needed per applicable departmental, sponsor, and role-specific requirements.

- In consideration of training requirements that may be set forth for new study team members, bear in mind that:
  
  * Trainees need time to digest and absorb the information provided during training; pushing too much information too fast, without context or personal experience, will not aid in retention of the information.
  
  * Skill development methodologies call for training that moves beyond knowledge acquisition alone. Trainees will be more successful when they are provided the opportunity to learn about a specific skill or procedure by acquiring knowledge, observe a demonstration of the skill/procedure, and practice the skill/procedure with correction and reinforcement on multiple occasions prior to performing the skill/procedure independently.

- Beyond providing adequate training at an appropriate pace, onboarding plans are more likely to be effective when they involve:
  
  * Ensuring trainees understand their roles and expectations, including what regulations and policies might apply, where to find applicable regulations and policies, and who to direct questions to;
  
  * Providing opportunities to socially integrate with key colleagues, senior staff, and peers;
  
  * Developing a sense of the work-place culture; and
  
  * Providing appropriate support tools, coaching, and performance feedback.

A recording of the session, including additional resources, is available in Blackboard.
What is the difference between exempt and expedited review?

When research proposals are submitted to an Institutional Review Board (IRB) for review there are three possible review pathways: exempt, expedited, or convened board (also referred to as full board). The review pathway is dependent on the nature of the research, the risks related to the research, and institutional policy.

Exempt research involves very little risk and must fall into one or more federally-defined exemption categories. The term ‘exempt’ does not mean that the research does not require IRB review. Rather, once it’s determined that the research falls into one of the exemption categories, it is exempt from further IRB reporting requirements, provided there aren’t any revisions to the research. Per institutional policy, the Research Subjects Review Board (RSRB) is responsible for making the determination of whether or not the research falls into one of the exemption categories; Investigators are not.

New & Updated OHSP Resources

In addition to the Study Team Member Onboarding Guide discussed on page 8, the following resources have recently been created or updated:

- **HRPP Quick Reference Guide:** This guidance document provides an overview of the primary entities that comprise the UR HRPP, as well as, basic information on how to get research endeavors started.
- **Criteria for IRB Approval Quick Reference Guide:** This guidance document identifies factors taken into consideration by Institutional Review Boards (IRB) when evaluating submissions against the criteria defined by federal regulations for IRB approval.
- **Commonly-Used Abbreviation and Acronyms in Research:** This document identifies abbreviations and acronyms in commonly-used in research, including general and institution-specific abbreviations and acronyms.

New Guidelines Available for International Research Engagement

Academic freedom, global engagement, and the open communication of knowledge and research are core commitments of the University. New guidelines for international research engagement are now available. The guidelines include sources of assistance to facilitate these interactions and help faculty avoid running afoul of University policies or federal regulations. The University’s Committee on Science and Security developed the guidelines in response to mounting bipartisan concerns at the federal level about the security of the nation’s research and intellectual property, particularly at research universities like Rochester. Federal rules and practices are still emerging, but increased scrutiny has accentuated potential pitfalls for individual faculty and institutions as we continue to develop international research partnerships. This is an evolving state of affairs and these guidelines will also evolve as federal policies are established or changed.

Members of the University of Rochester research community are encouraged to continue to reach out and engage with international colleagues, but in doing so, must be sure to use the resources outlined in our new guidelines to identify and avoid potential pitfalls.

Should you have any questions, please contact the University’s export control officer or your Office of Research and Project Administration (ORPA) representative.

What is the difference between exempt and expedited review?

When research proposals are submitted to an Institutional Review Board (IRB) for review there are three possible review pathways: exempt, expedited, or convened board (also referred to as full board). The review pathway is dependent on the nature of the research, the risks related to
What is the difference between exempt and expedited review?

(continued from paged 9) permitted to make this determination independently. Expedited research involves no more than minimal risk (meaning, the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and other themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychology examinations or tests) and must fall into one or more federally-defined expedited categories.

Whether a proposal’s review level is ‘exempt’ or ‘expedited’ affects the IRB review process. While both submissions are initially reviewed by an IRB coordinator, exempt submissions are confirmed by a secondary RSRB staff member (typically either a senior IRB coordinator or a director). Whereas expedited proposals, must be reviewed and approved by a board chair or designated board member (i.e., the vice chair or another experienced board member). Based on this requirement, the term ‘expedited’ is not meant to reflect turnaround time; the term only reflects that the process does not require review by the convened board, which may only meet monthly or bi-monthly, depending on the board.

From the standpoint of the study team, whether the research falls into an exemption category or undergoes expedited review has very little effect on their IRB reporting requirements. In either case, following exempt confirmation or IRB approval, the study team is responsible for: a) submitting any revisions (modifications) to the research for review and confirmation of continued exemption (exempt) or IRB approval (expedited) prior to implementation; and b) reporting research events in accordance with OHSP Policy 801 Reporting Research Events. The primary difference is the requirement for continuing review (i.e., submission of a progress report), which the IRB may require for expedited research. Circumstances where the IRB may require continuing review include (but are not limited to): research involving vulnerable populations; research conducted by investigators with prior incidence of non-compliance; and research involving the collection of sensitive information. When continuing review is required, the research will be assigned an expiration date (per federal regulations, this date cannot exceed a one-year approval period). To locate a study’s expiration (or lack thereof), visit the study homepage in Click IRB (see Image 1).

If you have questions about the review level of your research, please contact your IRB Coordinator.

What are ‘tracked changes’? How do I track revisions to a document?

‘Tracked changes’ is a tool available within Microsoft Word that, when turned on, shows all revisions and additions made to an existing document. Utilizing the tools facilitates review of revised documents by research colleagues, study team members, project managers, and Institutional Review Board (IRB) staff/members by pinpointing the exact changes made to the document. Instructions on how to turn tracking on/off and other functionalities related to the tool are readily available through Microsoft Office and internet searches.

Am I required to submit tracked changes of revised documents to the IRB? This will depend on the Reviewing IRB. If the Research Subjects Review Board (RSRB) is acting as your Reviewing IRB, providing tracked versions of updated documents is not required as functionality within the Click IRB review platform will track revisions for users. However, this function only works when both the new (revised) and old (previous) version of the document are Microsoft Word files. Click IRB will NOT track revisions for any other type of file, including RTF and PDF files. When only PDF files are available, contact your IRB Coordinator to discuss methods for managing PDF revisions. RTF files should NOT be uploaded into the Click IRB; all RTF files should be converted to (or saved as) Microsoft Word documents prior to submission (instructions for doing so are available through internet searches).

**FAQs**

What are ‘tracked changes’? How do I track revisions to a document?

‘Tracked changes’ is a tool available within Microsoft Word that, when turned on, shows all revisions and additions made to an existing document. Utilizing the tools facilitates review of revised documents by research colleagues, study team members, project managers, and Institutional Review Board (IRB) staff/members by pinpointing the exact changes made to the document. Instructions on how to turn tracking on/off and other functionalities related to the tool are readily available through Microsoft Office and internet searches.

Am I required to submit tracked changes of revised documents to the IRB? This will depend on the Reviewing IRB. If the Research Subjects Review Board (RSRB) is acting as your Reviewing IRB, providing tracked versions of updated documents is not required as functionality within the Click IRB review platform will track revisions for users. However, this function only works when both the new (revised) and old (previous) version of the document are Microsoft Word files. Click IRB will NOT track revisions for any other type of file, including RTF and PDF files. When only PDF files are available, contact your IRB Coordinator to discuss methods for managing PDF revisions. RTF files should NOT be uploaded into the Click IRB; all RTF files should be converted to (or saved as) Microsoft Word documents prior to submission (instructions for doing so are available through internet searches).
**FAQs**

**What is the difference between research, clinical research and a clinical trial?**

Depends on who you’re speaking with and the context of the conversation… Consider the following regulatory definitions:

- **Research (HHS):** a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge ([45 CFR 46.102(l)](https://www.gpo.gov/fdsys/grappnell.action?uri=pkg:50FR12012-00410/page-0005.xml)).

- **Clinical Trial (HHS):** a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes ([45 CFR 46.102(b)](https://www.gpo.gov/fdsys/grappnell.action?uri=pkg:50FR12012-00410/page-0005.xml)).

- **Clinical Investigation (FDA – Part 50 Protection of Human Subjects):** any experiment that involves a test article and one or more human subjects… ([21 CFR 50.3(c)](https://www.gpo.gov/fdsys/grappnell.action?uri=pkg:50FR12012-00410/page-0005.xml)).

- **Clinical Investigation (FDA – Part 312 Investigation New Drug):** any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects ([21 CFR 50.312.3(b)](https://www.gpo.gov/fdsys/grappnell.action?uri=pkg:50FR12012-00410/page-0005.xml)).

- **Clinical Investigation (FDA – Part 812 Investigational Device Exemption):** a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device ([21 CFR 50.812.3(b)](https://www.gpo.gov/fdsys/grappnell.action?uri=pkg:50FR12012-00410/page-0005.xml)).

Generally, the term ‘clinical’ relates to the observation of a patient in a health-related setting and the term ‘trial’, in the context of research, relates to the use of an intervention. So, ‘clinical research’ commonly refers to research that is patient- or health-oriented and ‘clinical trial’ commonly refers to a type of research that involves some type of intervention (be that a drug, device or behavioral intervention). That said, these terms are often used interchangeably and the precise definition may depend on the context, funding agency, and applicable regulations/policies.