IWK Research Review Guidelines

IWK Health is committed to the health and well-being of women, children, youth, and families. The Research Review is designed to ensure that we are engaging in due diligence and complying with the ethical standards of the Tri-Council, and internal administrative processes. This Review is a quality control and supportive process through which both Research & Innovation Advancement (RIA) and the Research Team benefit.

Types of Reviews

Overview Assessment: Overview Assessments occur on an ongoing basis through the random selection of studies. Overview Assessments may also occur where concerns are identified by RIA or the Investigator. This type of review is a quality control process that provides RIA a general overview of the compliance of IWK research studies. It **begins with a self-assessment** to allow Investigators to **identify areas of improvement or clarification** that would benefit their research study. Completed self-assessments are sent to the Research Operations Specialist who will work with the Investigator to address questions or concerns.

Detailed Review: Detailed reviews are a quality control process where the Reviewer examines chosen studies to evaluate Research Review compliance to identify and address areas of non-compliance and/or improvement. Detailed Reviews may be randomly chosen, cause driven (wherein RIA has been made aware of safety concerns or complaints from research participants, member of the research team, sponsor, or other institutional personnel), or result from an Overview Assessment. A Detailed Review may involve interviewing the study team, reviewing relevant study documentation, and other observational processes as deemed necessary. This is a more intensive process and may require a Review Team.

What will be appraised?

Overview Assessments will be guided by the results of the self-assessment tool. If no areas of improvement are identified by the Investigator in the self-assessment, the Research Operations Specialist may randomly select one or two areas to assess.

Detailed Reviews will be used to gain a complete picture of the study and may include a review some or all the following, depending on the type of research (see a more detailed list in Appendix A):

- Study Documents
- Study Roles
- Participant recruitment procedures
- Research participants' perspective of the research process
- Documentation of data sources

- Research equipment
- Human Resources
- Research facilities
- Financial processes and budget management

Who is responsible for the Review?

The Research Operations Specialist (Reviewer). Reviews will be conducted by the Research Operations Specialist. When additional reviewers are needed, RIA will assemble a team of 2-3 individuals with research and research ethics experience (Review Team). Volunteer opportunities to serve as members of a Review Team will be offered on a rotational basis.

The Principal Investigator is responsible for ensuring that the requested Review is completed in a timely fashion, attending opening and closing meetings, ensuring information is available to the Reviewer, study staff are available as needed, and that follow-up recommendations are completed and reported back to the Reviewer.

Note.

- Studies will not be selected for a Detailed Review more than once in a 2-year period (the exception being Reviews for cause*).
- Studies that have closed within the past 12 months are still subject to review.

*Where Detailed Reviews are required due to matters such as complaints, safety concerns, or possible misconduct the VP Research and Innovation will initiate an investigation (see RCR policy).

How will I know this is happening?

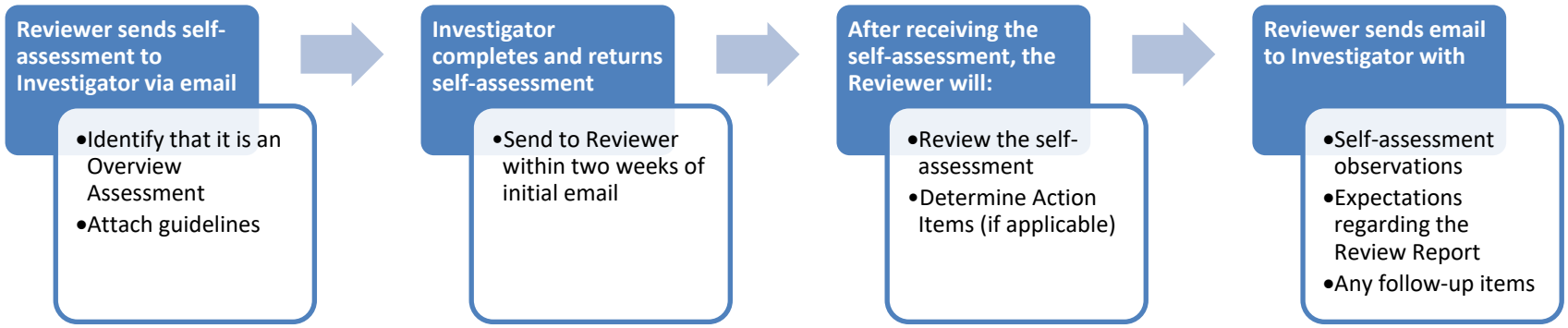
Investigators will be notified by RIA that their study has been selected for review. You will be asked to complete the self-assessment form within two weeks of receiving the initial email that will indicate if you have been selected for an Overview Assessment or Detailed Review.

What happens during a Review?

Reviews begin with the completion of the self-assessment by the Investigator. This will be followed by an email (and possible meeting) with the Reviewer, the Investigator, and any study staff interested in attending. The process for Overview Assessments and Detailed Reviews is similar, but the scope of the review will differ.

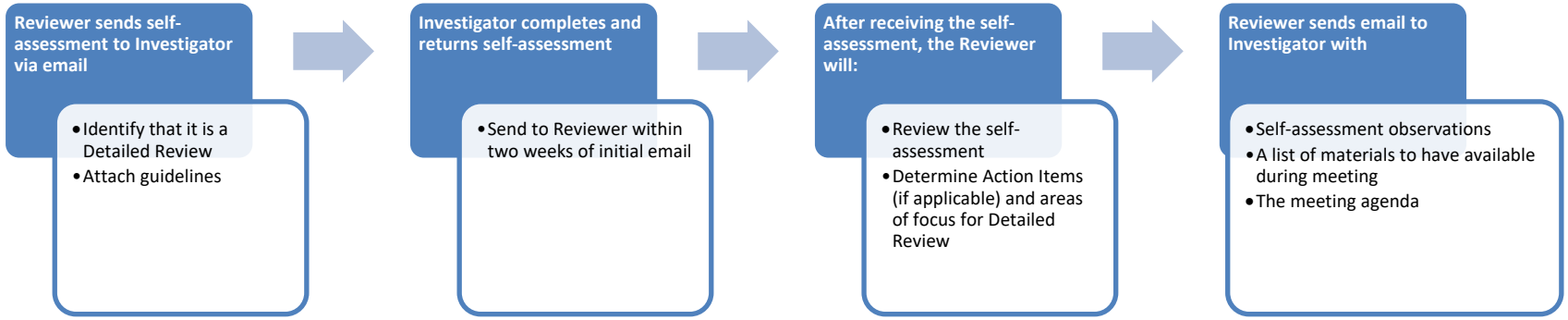
Please see the figures below for the steps for Overview Assessments and Detailed Reviews.

Overview Assessment Timeline

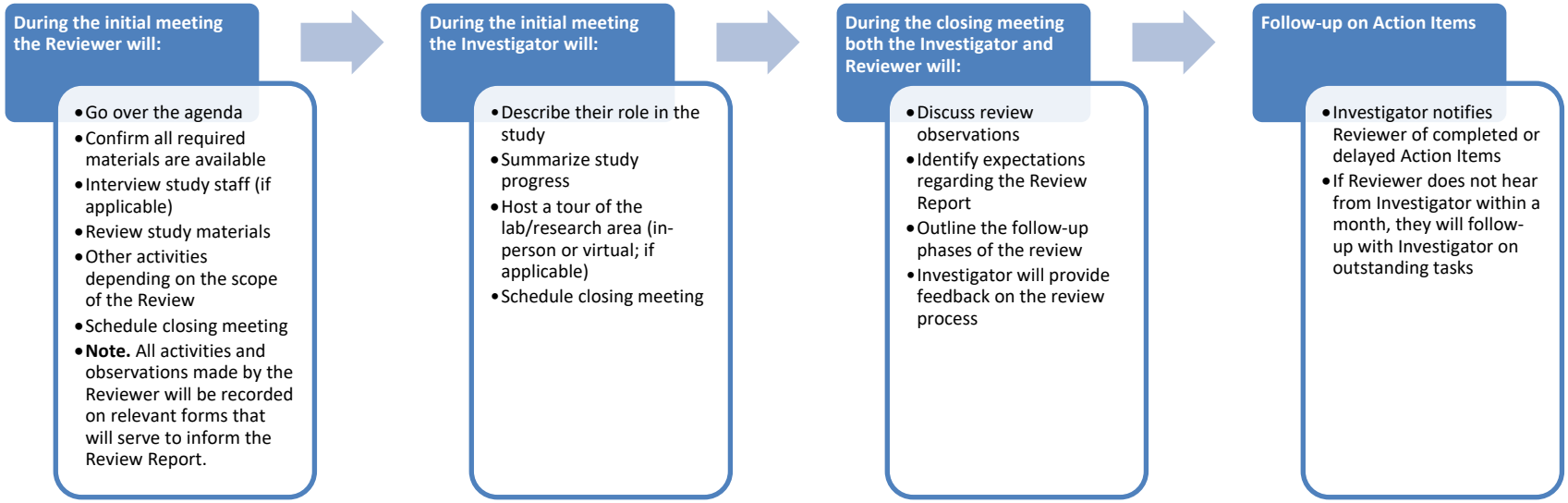


Detailed Review Timeline

Step 1:



Step 2:



What documentation do I need to provide?

All study documentation should be organized in a way that is easy for you and your study team, as well as the Reviewer to understand and follow. A physical binder or folder on the H: drive is the best solution. Binders/folders should be divided (where applicable and appropriate) in an organized fashion (see Appendix B for Binder/Folder examples).

What will the Review Report look like and when will I get it?

The Review Report is a summary of the Reviewer's observations after their assessment of the completed Detailed Review or Overview Assessment.

Review Reports will include, where applicable, the following:

- No action necessary
- Opportunities for improvement, which do not require follow-up
- Action Items - areas of non-conformity to rectify
- Area for Investigator to provide feedback on the review process

What do I do after I receive my Review Report?

A follow-up phase may come after the Review Report. You will be provided with a response template to address any Action Items (i.e., what needs to be fixed) that have been identified in your Review Report. Your response template must be received by the Reviewer **within a reasonable timeframe of the Review Report** and must include plans for immediate corrective action and prevention of the Action Item(s).

It is never the assumption that researchers are deliberately running studies that violate ethical, institutional, and/or RIA operating standards. In the very rare cases where review findings are significantly serious, RIA may be required to take further action that would impact your study's ongoing activity.

We are here to help

If selected for a review, do not fret. Contact the Research Operations Specialist (Megan.lamb@iwk.nshealth.ca) with any concerns. The review process is an opportunity for us to work together, learn from each other, and increase our capacity for research excellence in a supportive environment.

Appendix A: Potential Study Documents to be Reviewed

Study Documents:
- Researcher's study file
- Research Ethics Board study file
- Informed consent forms
- Amendments
- Contracts/Agreements

Study Roles:
- Investigator involvement
- Appropriateness of delegation of study procedures
- Qualifications of study personnel

Participant recruitment procedures:
- Enrolment
- Informed consent
- Remuneration
- Debrief processes
- Participant withdrawal

Research participants' perspective of the research process:
- Participants may be followed up with via telephone or in-person interviews.

Documentation of data sources:
- Health records
- Study records
- Participant diaries
- Test results
- Case report forms
- Record retention plan
- Maintenance of confidentiality

Research equipment:
- Calibration and maintenance records

Research facilities
- Clinic rooms
- Drug storage
- Biological Samples:
  (Areas for the collection, processing, storage, and shipping)
- Document storage
- Work areas
- Safety reporting

Financial processes and budget management:

Study closures
Budget & Protocol adherence
Using relevant cost centers
Personnel updates
Procurement requests

Human Resources:

Personnel are trained
Proper documentation
Updated emergency contact list
Workplace inspections

Appendix B: Study Binder/Folder Examples

Binder dividers for non-clinical trial research studies:

- Grant or Contract with the Sponsor
- Study protocol (grant application)
    - Amendments
    - Data collection forms
- Communication with the REB
- Information given to research subjects
    - Consent
    - Information Forms
    - Websites
- Study recruitment
- Staff qualifications
- Study monitoring
- Final report to the sponsor

Binder dividers for Clinical Trials Phase I to III

- Investigator Brochure and updates
- Contract with the Sponsor
- Budget
- Signed and dated protocol
    - Amendments
- Communication with the REB
- Information given to research subjects
- Study recruitment
- Staff qualifications
- Study monitoring
- Final report to the sponsor

Binder dividers for Clinical Trials Phase IV

- Drug information sheet
- Contract with the Sponsor, Budget
- Signed and dated protocol & amendments
- Communication with the REB
- Information given to research subjects
- Study recruitment
- Record keeping
- Staff qualifications
- Study monitoring
- Final report to the sponsor

Subject and data collection binder

- Consent forms (stored separately from data collection forms)
- Data collection forms
    - Participants identified by numbers
- Secure storage
    - Locked cabinet
    - Locked office.

SOP BINDER (examples)

- Training of Research Personnel
- Responsibilities of Research Personnel
- Research Ethics Board (REB) Communication
- Informed Consent Forms
- Investigator Study Files and Essential Documents
- Patient/Subject Recruitment into research
- Informed Consent Process
- Protocol Amendments, Deviations and Violations
- Sponsor Communication and Monitoring Visits
- Site Data Management and Retention
- Study Closeout
- Reviews and Inspections
- SOP for Continuing Review (REB)

NOTE: Materials needed for Overview Assessments will depend on the self-assessment and areas of exploration identified by the Research Operations Specialist

GENERAL TIPS

- Documentation should be ordered chronologically with most recent documents first
- Documentation should be dated and signed
- Recruitment logs
    - Updated regularly
- Minimize duplication
- Ensure electronic back-up with file names the same as paper documentation

A FEW NOTES ON DATABASES

- No names or other identifying information
- Contact info file stored separately from database
- Separate storage of cross-reference of participant numbers to data in data base
- Codebook for variable codes
- IT should have been notified of any existing databases

Appendix C: Steps for Overview Assessments and Detailed Reviews

	Overview Assessment	Detailed Review
Reviewer sends self-assessment to Investigator via email • Identify if it is an Overview Assessment/Detailed Review • Attach guidelines	X	X
Investigator completes and returns self-assessment to Reviewer within two weeks of initial email	X	X
After receiving the self-assessment, the Reviewer will: • Review the self-assessment • Determine Action Items (if applicable) /need for the Detailed Review	X	X
Reviewer Sends email to Investigator with	X	X
• Self-assessment observations	X	X
• Expectations regarding the Review Report	X	X
• Any follow-up items	X	
• A list of materials to have available during meeting		X
• The meeting agenda		X
During the initial meeting the Reviewer will: • Go over the agenda • Confirm that all required materials are available • Interview study staff (if applicable) • Review study materials • Other activities depending on the scope of the review • Schedule closing meeting **Note.** All activities and observations made by the Reviewer will be recorded on relevant forms that will serve to inform the Review Report.		X
During the initial meeting the Investigator will: • Describe their role in the study • Summarize study progress • Host a tour of the lab/research area (in-person or virtual; if applicable) • Schedule closing meeting		X
During the closing meeting both the Investigator and Reviewer will: • Discuss review observations • Identify expectations regarding the Review Report • Outline the follow-up phases of the review • [Investigator] provide feedback on the review process		X

Appendix D: Definitions

Detailed Review – is a quality control process where the Reviewer examines chosen studies to evaluate Research Review compliance (as defined below) to identify and address areas of non-compliance and/or improvement. This is an intensive detailed review of a research study being conducted at IWK Health.

Investigator – the individual responsible for the study being reviewed.

Overview Assessment – is a quality control process where an Investigator completes a Research Review self-assessment of their research study to identify compliance and/or areas where need help or feedback. This type of review is intended as a general overview of the research study at the IWK.

Research Review - systematic and independent examination of study related activities and documents to determine whether a study has been conducted according to the applicable regulations and/or guidelines. This is to ensure that the rights and well-being of human participants are protected; and the conduct of the study follows the currently approved protocol, Good Clinical Practice (GCP), IWK RIA standard operating procedures (e.g., finance and HR), IWK Research Ethics Board (REB) policies and procedures, and applicable regulatory requirements (ICH-GCP 5.19).

Review Report - a Review Report is a summary of the Reviewer's observations after their assessment of the completed Detailed or Overview Research Review. Review Reports will include, where applicable, the following:

- No action necessary
- Opportunities for improvement, which do not require follow-up
- Action Items - areas of non-conformity to rectify
- Area for Investigator to provide feedback on the review process

Review Team - when additional Reviewers are needed, RIA will assemble a team of 2-3 individuals with research and experience to participate as Reviewers in the Research Review process.

Reviewer – the individual responsible for conducting Research Reviews. Normally, the Research Operations Specialist.