Biomedical Template Updates

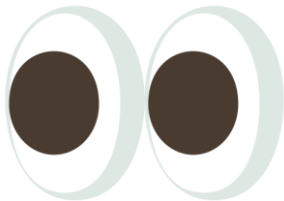
Emory IRB Webinar | September 12, 2024

What we'll cover…

- The "Why"
- Overview of changes
  - Protocol
  - Consent
- Important reminders and tips
- Future expectations
  - Adoption date

…But what about *my* research?

- Changes are coming!
  - Same functionalities, formats
  - Similar expectations
  - Customized scope
- Updates will keep investigator feedback in mind
  - Thank you to those who completed the Behavioral Research Survey!



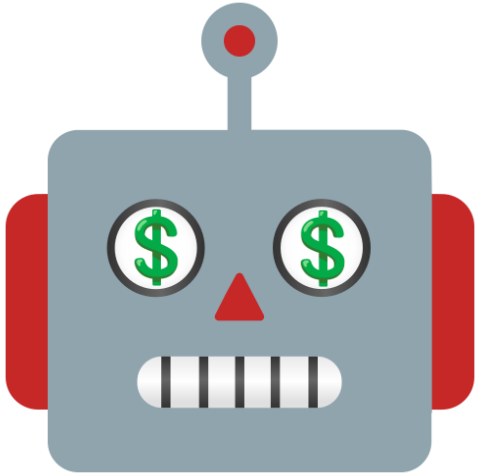
Why?

Minimize redundancies

Save time + effort

Cleaner final products

Why?



New + expanded considerations

Clarify requirements

Illuminate next steps

Protocol Highlights

Biomedical Template Update

Protocol updates: What to expect

- **Template Instructions**
  - Instructional overview on page 1
  - Orange instructional text in each section, delete as sections are completed
  - Improved formatting, links, examples
- **Protocol sections and details**
  - Organized into tables, questionnaires, and narrative boxes
  - Protocol information goes into white text boxes and sections
  - Removed protocol checklist

Reduce Redundancy: Dynamic text fields

Time + Effort: Questionnaires + inventories

11. Population

Complete the Special Population Inventory. Indicate when you will interact with any of the listed populations or collect data about individuals in these groups. Note that if you respond *Yes* to any option listed below, additional details on the special populations may be needed in the Population Narrative, below.

Special Populations Inventory	
For each, indicate if the listed populations *will or may be* included in the study	**Included?**
1. **Children or minors** (i.e., persons under age 18 or the age of majority)	☐ Yes ☐ No
2. **Pregnant persons**, human fetuses, or neonates	☐ Yes ☐ No
3. **Prisoners** (i.e., persons involuntarily confined/detained in a penal institution)	☐ Yes ☐ No
4. **Cognitively impaired adults** (i.e., persons unable to provide consent)	☐ Yes ☐ No
5. **Employees or students** at Emory, CHOA, Grady, or a related research site	☐ Yes ☐ No
6. **Persons who are not able to clearly understand English**	☐ Yes ☐ No
7. **International populations** (specify below)	
a. **Citizens or residents of the EU or UK**, in a country with GDPR protections	☐ Yes ☐ No
b. **Citizens or residents of Mainland China** (i.e., persons protected under PIPL)	☐ Yes ☐ No
c. **Citizens or residents of other countries**: *(list here)*	☐ Yes ☐ No
8. **Persons otherwise vulnerable to coercion or undue influence**: *(list here)*	☐ Yes ☐ No

Questionnaires and Inventories quickly collect relevant, high-level details.

Investigators only need to address the details relevant to their study in the related narrative box.

Clean-up: Summary + narrative boxes

5. Study Endpoints

In the Endpoints Summary box, describe the study and safety endpoints for the study, as applicable.

- An example of how to determine study endpoints can be found here.
- *Reminder:* Study endpoints should not be based on timing/termination of research funding.

Endpoint Summary	
Study Endpoints	
Primary	
Secondary	
Safety Endpoints	

In the Endpoint Narrative box, provide additional details on the primary, secondary and safety endpoints. Include any other endpoints relevant to the research, such as surrogate endpoints or non-clinical and participant-specific endpoints.

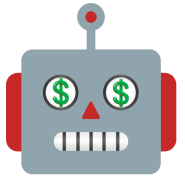
Endpoint Narrative

Protocol section title and instructions

Summary boxes collect key details with minimal text

Narratives boxes expand on key info + study specific details

Expanded + new considerations: Overview



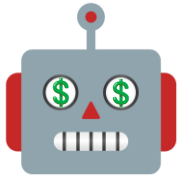
Protocol questionnaires:

- AI/ML in research
- Identifiable data use and storage
  - OIT Security Review
- Data and Safety Monitoring Plan

Improved section instructions:

- Compensation considerations
  - Managing compensation and withdrawals for “bot” and insincere responses
- Populations and Enrollment
  - Special population requirements
  - Inclusion/Exclusion details

Expanded considerations



Artificial Intelligence (AI) and Machine Learning (ML) Questionnaire and Summary	
Question/Description	**Response**
1. Are any AI/ML tools developed, evaluated, or used within this research project? *This includes clinical decision-making and algorithm-based tools, use of data to train or validate an AI/ML, etc.*	☐ Yes → *Complete the questions 2-7 (do not leave any blanks)* ☐ No → *Delete questions 2-7 (the rest of the table, below)*
2. Describe the source/development of the AI/ML tool *(e.g., in-development at Emory, commercially available)*	
3. Describe any key characteristics of the AI/ML, including: • Commercial prototype blackbox system • Federated data system • Adaptative or non-adaptive	
4. Will any data use agreements apply to the study or AI/ML tools? *If yes, note status of OTT/OSP agreements*	
***5.* How will AI/ML tools in this protocol influence decisions affecting participants?**	☐ AI/ML has *no decision-making impact* ☐ AI/ML *informs human-made decisions* ☐ AI/ML *drives decisions,* with human oversight ☐ AI/ML is *fully autonomous* (i.e., makes decisions without human oversight)
6. Is there any intent to test the AI/ML tool clinically now, or in the future? *(i.e., provide any output to healthcare providers or patients)*	☐ Yes, *the current study* intends to test the AI/ML clinically ☐ *Yes,* there is intent to test the AI/ML clinically in a future IRB submission; however no *clinical testing will occur as part of the current submission*

Artificial Intelligence and Machine Learning

Questionnaire informed by subject matter experts on AI/ML research.

Responses inform scope of IRB, OIT reviews and FDA applicability.

Clarified requirements: Data monitoring

22. Data and Safety Monitoring

Complete the Data Monitoring Requirements Assessment below to determine which Data and Safety Monitoring Table should be used in this investigator-initiated protocol. If the below questionnaire does not capture the scope of your research activities or you have questions, send an email to irb@emory.edu to determine the appropriate monitoring plan table to be used.

Note: The IRB may request a different Monitoring Table be used, based on specific study details. Generally, clinical trials with INDs for radiotracers and dietary supplements are able to use Monitoring Table B, even if another table is indicated in the assessment, below.

Data Monitoring Requirements Assessment	
1. Do any of the below, highest-complexity categories apply to the research? *(i.e., did you answer "yes" to 1a or 1b?)*	☐ Yes → *This is a complexity cat. A study, insert table 1* ☐ No → *Go to #2*
a. **This a Phase I/II/III Clinical Trial with an IND or significant risk IDE**	☐ Yes ☐ No
b. **The study or trial includes high-risk procedures**	☐ Yes ☐ No
2. Do any of the below, high-complexity categories apply to the research? *(i.e., did you answer "yes" to one of items listed in 2a-2d?)*	☐ Yes → *This is a complexity cat. B study, insert table 1* ☐ No → *Go to #3*
a. **Study or trial is expected to be IND Exempt, IDE Exempt, or under an Abbreviated IDE/Non-Significant Risk Device**	☐ Yes ☐ No
b. **Clinical trial of drugs or devices used under their FDA-approved indication** (e.g., comparative effectiveness trial of standard of care interventions)	☐ Yes ☐ No
c. **Application of software or algorithm that will inform clinical care or direct care interventions**	☐ Yes ☐ No
d. **Application of other novel clinical techniques or intervention** (e.g., nonstandard surgical step)	☐ Yes ☐ No
3. Do any of the below, medium-complexity categories apply to the	☐ Yes → *This is a medium*

Data Monitoring Requirements Assessment

DSM Questionnaire has been integrated into the protocol template

Clear questions allow for easier determination of monitoring requirements

No more DSM questionnaire to upload!

Clarified requirements: DSM Tables

Monitoring Activity (High Complexity)		Required frequency		Extent of Activity	Responsible Parties and Additional Notes
		No Active Interventions	Active Interventions		
Review of data and forms for completion and accuracy	Confirmation of participant eligibility and documentation in enrollment log	At the time of consent completion and at least annually		100% of enrollments	
	Consent forms reviewed for completion	At the time of consent completion and at least annually		100% of consent forms	
	Comparison of Case Report Forms (CRFs) to source data	At least annually	At least every 6 months		
Review of study events, critical data points, and study checkpoints	Review of test article dispensing records (i.e., drug and device handling/use)	When opening and closing to enrollment	At least every 6 months	100% review of all records	
	Confirm that all possible adverse events have been assessed and follow-up is documented	At least annually	At least every 6 months	100% of possible events	
	Monitor to ensure no study-stopping rules are met	At least annually	At least every 6 months		
	Monitoring progress				

Data Safety Monitoring (DSM) Tables

DSM Tables remain as a separate document, to be inserted into the protocol

Frequency sections are pre-filled, high complexity requirements still vary based on study status.

Clarified requirements: DSM Tables

Compliance Monitoring Overview	
Who will assess compliance with the stated monitoring plans?	☐ Self-Monitoring *(NOT permitted for High Complexity, Category A)* ☐ Independent Study Monitor (ISM) ☐ Contract Research Organization (CRO)
If FDA-regulated: Indicate the Monitoring Method(s) to be used *(check all that apply)*	☐ On-site ☐ Self-monitoring ☐ Centralized (remote) ☐ N/A ☐ Other *(describe)*:
If there are international research sites: How will you ensure clinical research compliance?	☐ CROs with the site country ☐ Consultation with Emory Legal Counsel ☐ N/A
Reminder: **The Principal Investigator maintains responsibility for ensuring that all activities in this Monitoring Table are followed**	

Data Safety Monitoring Requirements

Reduced to two tables:

1. High Complexity: Categories A and B have been combined
   - Key difference: compliance monitoring

Clarified requirements: DSM Tables

Monitoring Activity (Medium Complexity)	Required frequency	Extent of Activity	Responsible Parties and Additional Notes
Confirmation of participant eligibility and documentation in enrollment log	At the time of consent completion and at least annually	100% of enrollments	
Consent forms reviewed for completion	At the time of consent completion and at least annually	100% of consent forms	
Comparison of Case Report Forms (CRFs) to source data	At least annually		
Confirm that all possible adverse events have been assessed and follow-up is documented	At least annually	100% of possible events	
Confirm credentials and training records of study team	During team member updates and at least annually	100% of study team members	
Review of regulatory files and study management processes	During team member updates and at least annually		

Data Safety Monitoring Requirements

Reduced to two tables:

1. High Complexity: Categories A and B have been combined
   - Key difference: compliance monitoring
2. Medium Complexity

Clarifying next steps

Complete the Information Security Questionnaire to determine if an Emory Office of Information Technology (OIT) Security Review is required. Note that, in some cases, an OIT security review may be required, even if the questionnaire does not indicate a review is required.

Information Security Questionnaire	
1. Will this study utilize any of the applications or plug-ins not approved for use by OIT?	☐ Yes → *This is not permitted* ☐ No → *Go to #2*
2. Will any IRB-defined identifiers be processed or stored in an application, plug-in, or software?	☐ Yes → *Go to #3* ☐ No → *Move to next section*
3. Will processing or storage of identifiers only occur with OIT-approved applications, plug-ins, and software for research?	☐ Yes → *Move to next section* ☐ No → *Go to #4*
4. Will any sensitive or health information be processed or stored alongside identifiers in any applications, plug-ins, or software?	☐ Yes → *Go to #5* ☐ No → *Move to next section*
5. Will processing or storage of sensitive or health information only occur with OIT-approved applications, plug-ins, and software for research?	☐ Yes → *Review not required* ☐ No → *Request an OIT Security Review*

Updated instructions and question boxes tell teams…

When **ancillary reviews** are required (OIT Security, Biosafety)

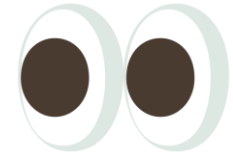
Which **eIRB submission questions** relate to their protocol responses

When **additional documentation and checklists** are required

Consent Highlights

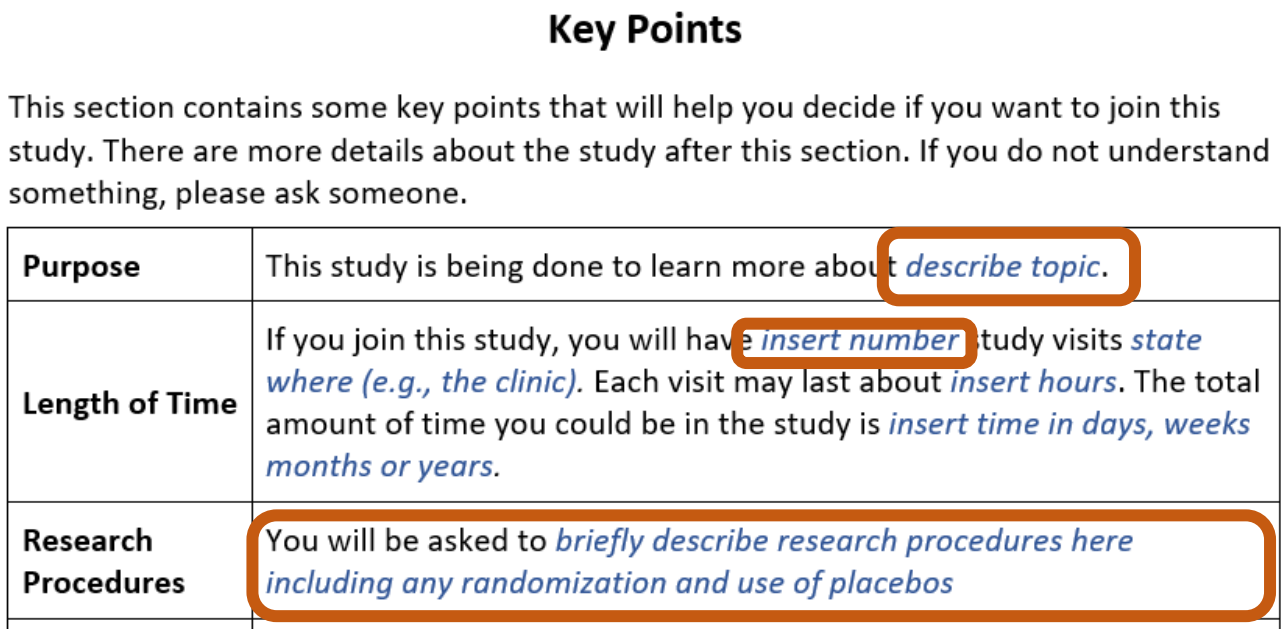
Biomedical Template Update

Consent form updates: What to expect



- **Shifting to *embedded instructional text***
  - Instructions are in blue italics
  - Minimized document comments and highlights
  - *“Remove if...”*
- **Updated formatting, organization**
  - Simplified tables for Key Points summary and study details
  - Accessible font sizes, clearer lay friendly language
  - Removed consent checklist
- **One biomedical template across institutions** *(Children’s, Grady, etc.)*
  - Facility-specific and modular template language included
  - Change Emory to “Emory and XYZ” throughout the document

Embedded Instructional Text



Key Points

This section contains some key points that will help you decide if you want to join this study. There are more details about the study after this section. If you do not understand something, please ask someone.

Purpose	This study is being done to learn more about *describe topic*.
Length of Time	If you join this study, you will have *insert number* study visits *state where (e.g., the clinic).* Each visit may last about *insert hours*. The total amount of time you could be in the study is *insert time in days, weeks months or years*.
Research Procedures	You will be asked to *briefly describe research procedures here including any randomization and use of placebos*

Look for blue text throughout the entire consent document.

Blue text provides prompts, instructions, and examples.

Embedded Instructional Text

Key Points

This section contains some key points that will help you decide if you want to join this study. There are more details about the study after this section. If you do not understand something, please ask someone.

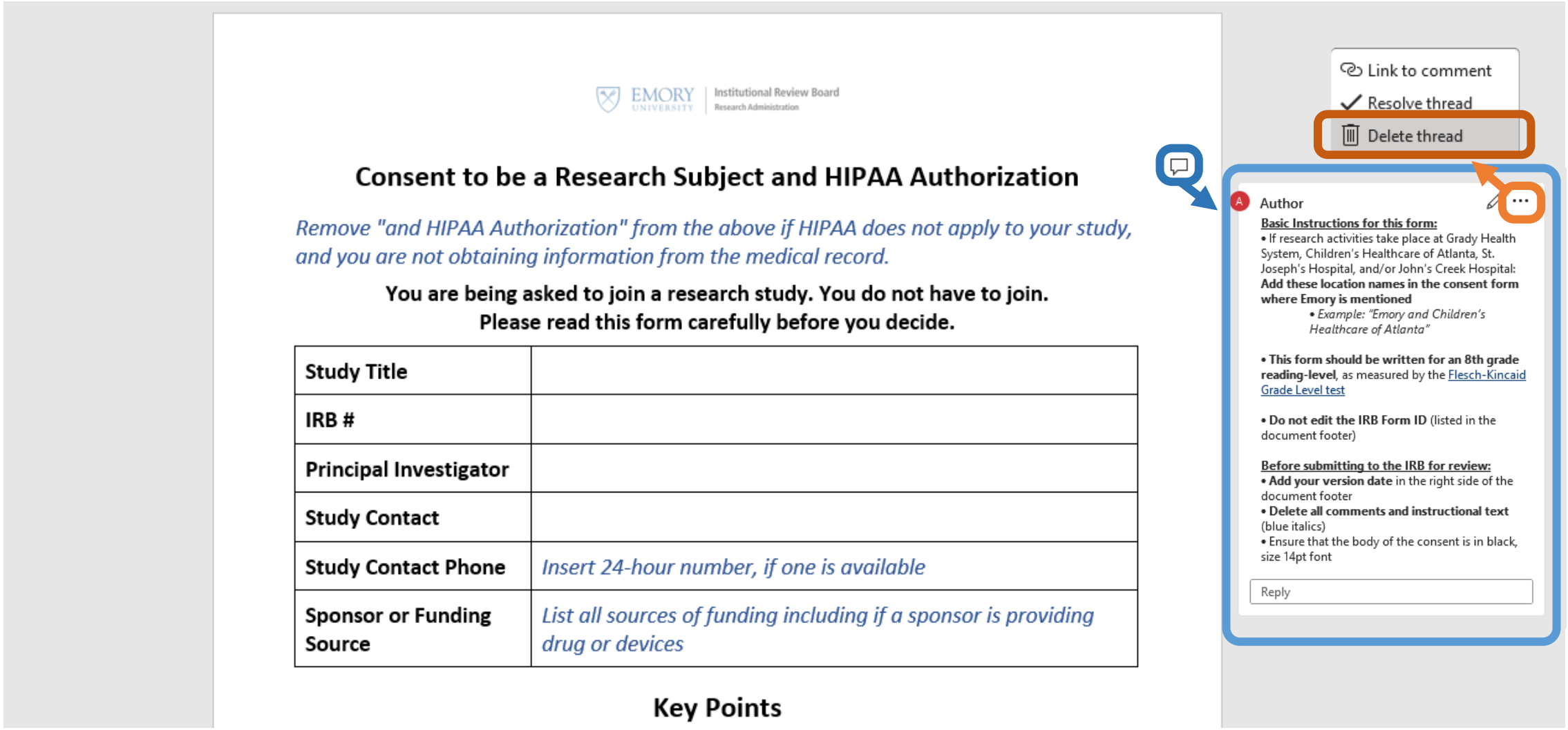
Purpose	This study is being done to learn more about how IRB documents can affect the heart health of researchers.
Length of Time	If you join this study, you will have one study visit at the IRB Office. This visit may last about 1-2 hours. The total amount of time you could be in the study is one day.
Research Procedures	You will be asked to practice completing a study submission. Before and after you begin the activity, we will draw blood from you and get permission to access your Emory medical record. While you complete the activity, we will monitor your heart rate.

Look for blue text throughout the entire consent document.

Blue text provides prompts, instructions, and examples.

Before finalizing, “correct” all formatting and grammar for consistency.

Reminder: Deleting Comments



EMORY UNIVERSITY | Institutional Review Board
Research Administration

Consent to be a Research Subject and HIPAA Authorization

Remove "and HIPAA Authorization" from the above if HIPAA does not apply to your study, and you are not obtaining information from the medical record.

You are being asked to join a research study. You do not have to join.
Please read this form carefully before you decide.

Study Title	
IRB #	
Principal Investigator	
Study Contact	
Study Contact Phone	*Insert 24-hour number, if one is available*
Sponsor or Funding Source	*List all sources of funding including if a sponsor is providing drug or devices*

Key Points

Link to comment
Resolve thread
Delete thread

Author

Basic Instructions for this form:
• If research activities take place at Grady Health System, Children's Healthcare of Atlanta, St. Joseph's Hospital, and/or John's Creek Hospital: **Add these location names in the consent form where Emory is mentioned**
  • *Example: "Emory and Children's Healthcare of Atlanta"*

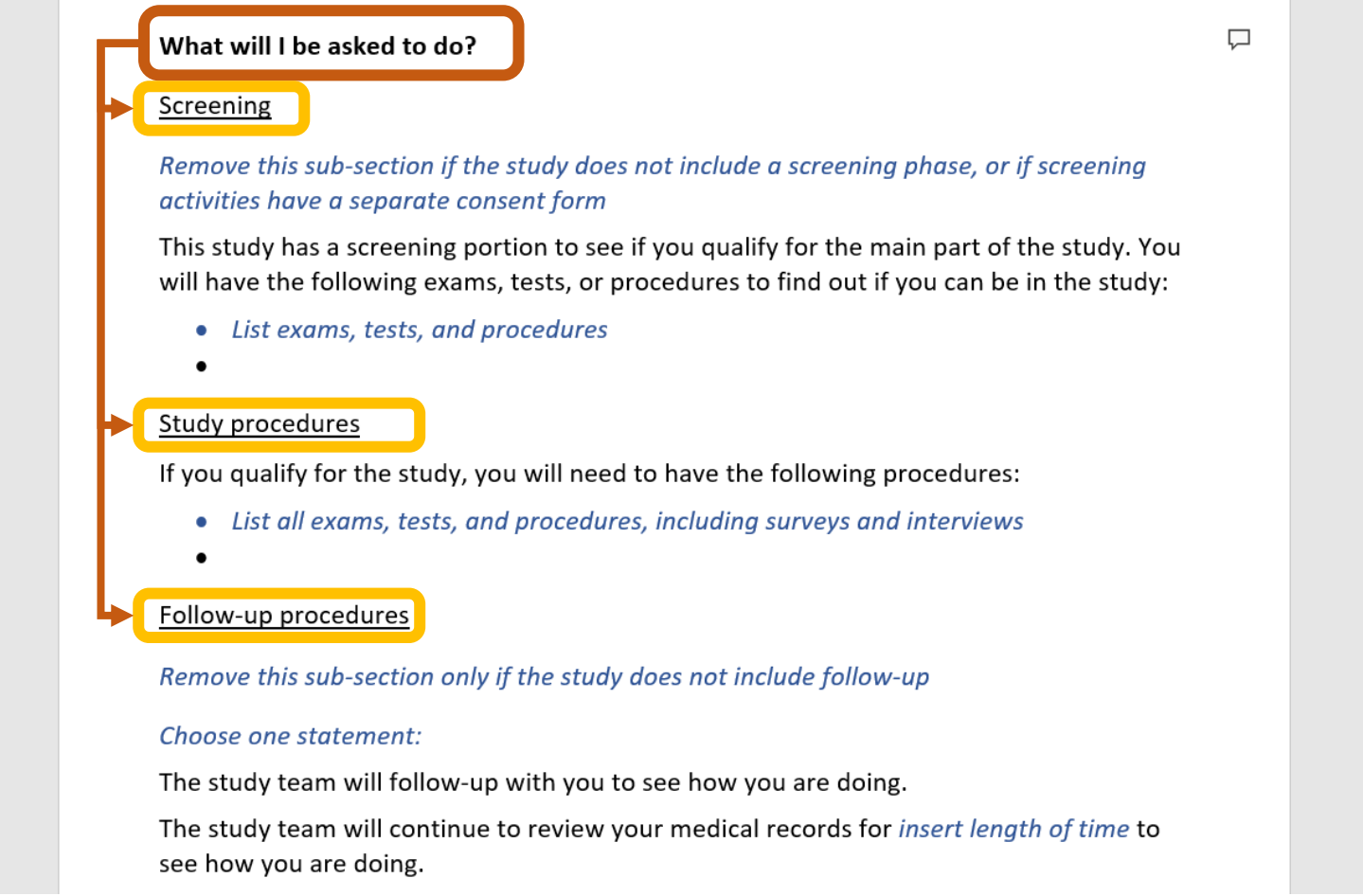
• **This form should be written for an 8th grade reading-level**, as measured by the Flesch-Kincaid Grade Level test

• **Do not edit the IRB Form ID** (listed in the document footer)

Before submitting to the IRB for review:
• **Add your version date** in the right side of the document footer
• **Delete all comments and instructional text** (blue italics)
• Ensure that the body of the consent is in black, size 14pt font

Reply

Updated formatting: Sections and Headings



What will I be asked to do?

Screening

Remove this sub-section if the study does not include a screening phase, or if screening activities have a separate consent form

This study has a screening portion to see if you qualify for the main part of the study. You will have the following exams, tests, or procedures to find out if you can be in the study:

- *List exams, tests, and procedures*
-

Study procedures

If you qualify for the study, you will need to have the following procedures:

- *List all exams, tests, and procedures, including surveys and interviews*
-

Follow-up procedures

Remove this sub-section only if the study does not include follow-up

Choose one statement:

The study team will follow-up with you to see how you are doing.

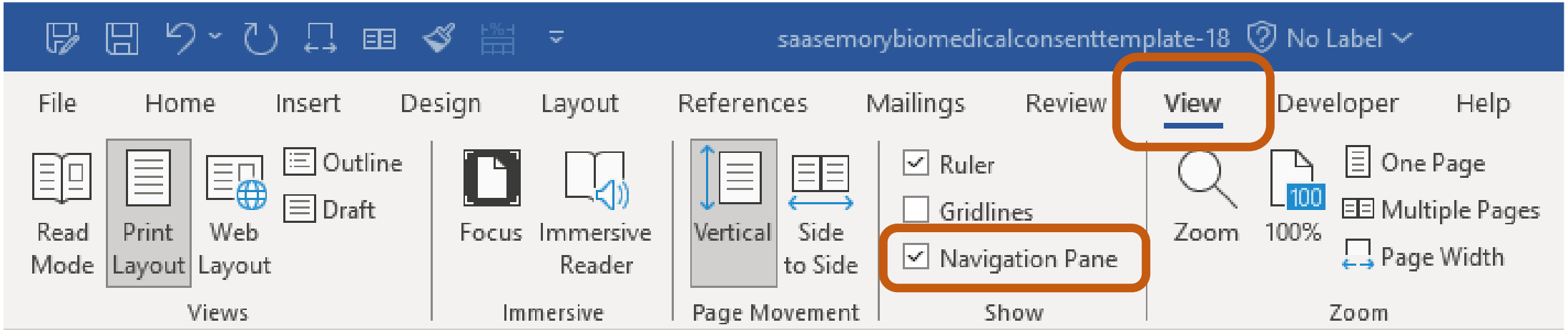
The study team will continue to review your medical records for *insert length of time* to see how you are doing.

Document styles and headings are integrated throughout

Section titles are **bold**, Sub-sections are <u>underlined</u>

Improves readability and accessibility for participants, and document editors!

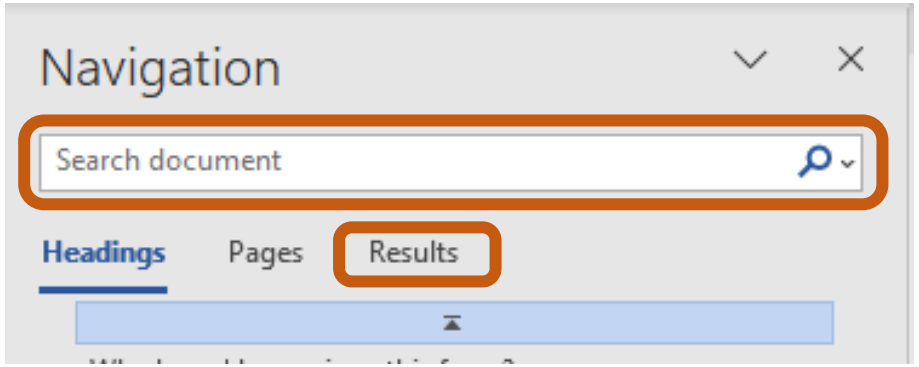
Updated formatting: Sections and Headings



One Template for all facilities

- Grady and Children’s specific statements embedded throughout the consent form
- Insert the applicable facilities wherever “Emory” is referenced
  - Example: “Emory and Children’s Healthcare of Atlanta”
- Note: additional review requirements still apply
  - ERD review for Saint Joseph's and Johns Creek
  - ROC review for Grady

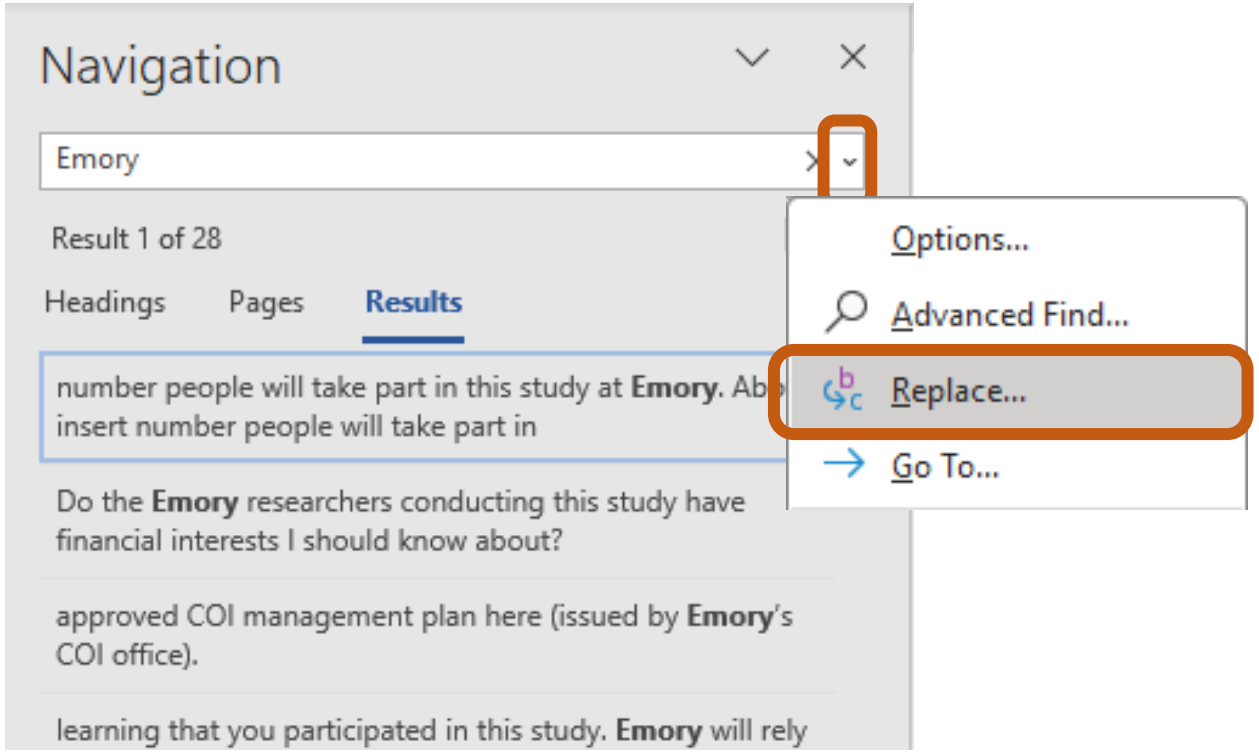
Pro Tip: Find + Replace in the Navigation Pane



To find a word or phrase:

- Type in the word you want to find and select “Results”

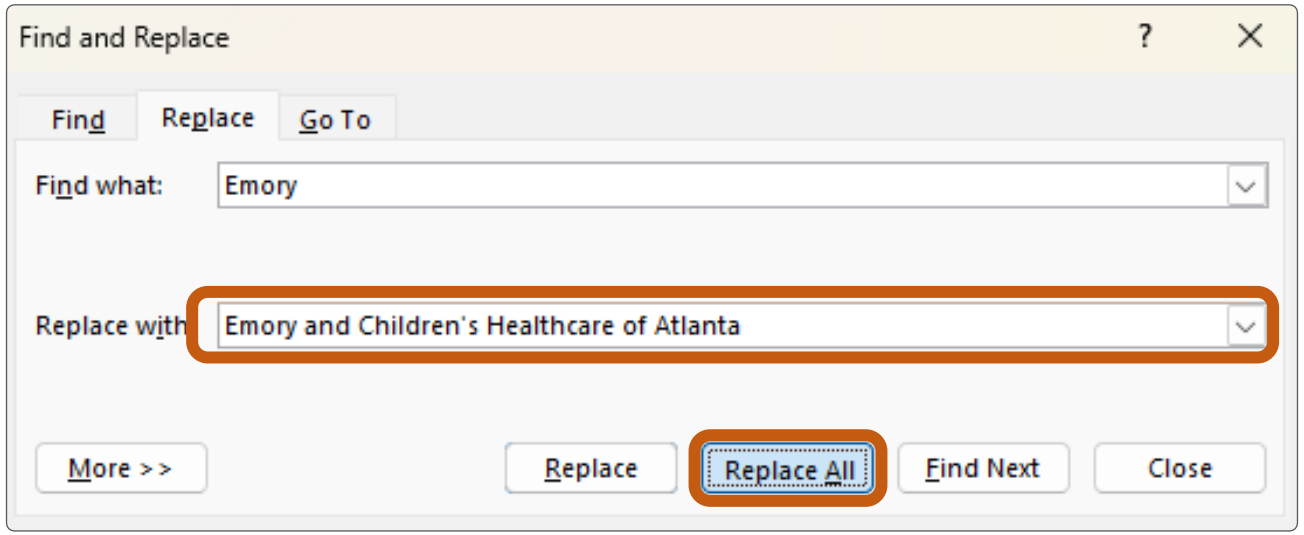
Pro Tip: Find + Replace in the Navigation Pane



To replace:

- Select the drop-down carrot and select “Replace”

Pro Tip: Find + Replace in the Navigation Pane



To replace:

- Select the drop-down carrot and select “Replace”
- Enter the word you want to find and the phrase you want to replace the word with
- Select “Replace All”

Important changes and reminders

- **Injury Language**
  - Consolidated into two options
  - Selection now based on the funding sources
- **Cost Language**
  - Now limited to options 2 and 3
  - “No cost” language only applies when no billables and research is limited to survey/interview procedures or services outside of the clinical space
- *Reminder: Do not modify the language in these sections!*

What’s next?

Requirements, changes, and things in the pipeline

Looking forward…

Biomedical studies

- Template adoption date: **October 1, 2024**
- Studies *created in eIRB* before Oct 1 may be approved with the most recent template
  - Protocol: 01/2023
  - Consent: 10/2022
- Ideally, all studies in progress should use the updated templates

Future changes are coming

- Iterative changes based on feedback, early experiences
  - Example: Sub-study guidance
  - Email irb@emory.edu with the subject "Template Feedback"
- Other templates to be released soon!
  - IRB Email Blast notification
  - Always check the IRB website

Questions? Comments?

Please let us know what you think of this webinar!