Adjust your audio settings here.

Type all your questions in the Q&A space (not in the chat window). We will answer all your questions at the end of the webinar.
Upcoming Protocol Template Updates

JANUARY 13, 2022
Topics to be covered

- Protocol Checklists Moving to End of Protocol Templates
- Changes to Protocol’s Population Section
- Changes to Protocol’s DSMP Section
- New Protocol Template for Secondary Analysis of External Public Data Sets
- Other Updates: Recap October ‘21 ICF Updates and IRB Website Updates
Changes to Protocol Checklists

UPCOMING PROTOCOL TEMPLATE UPDATES
Protocol Checklist Moving to End of Protocol Templates

• Won’t need a separate document anymore!
• The protocol checklist will be embedded in your protocol template after the References section

Friendly reminder!
• You must always use a protocol template. We won’t begin IRB review until a protocol using one of our templates is uploaded in eIRB.
Changes to Protocol Population Section

UPCOMING PROTOCOL TEMPLATE UPDATES
Population Section Updates

The Emory IRB recognizes that race is a social category and not a biological one, so we have added some required detail for studies investigating race or ethnicity to the “Population” section of the Protocol Templates.

1. Describe the definition you are using for “Race” and/or “Ethnicity” in this study (examples here (link to JAMA, JHM, AHA, and Health Affairs guidance).
2. State whether you are using racial and ethnic classification of participants for descriptive statistics or within an explanatory model (as a covariate).
3. If you are using race and/or ethnicity as a variable to explain differences between participants (as a covariate), please describe the proposed mechanism of action (what is race being used as a proxy for?).
Population Section Updates

Additional detail required for studies that address issues affecting a certain community or group:

◦ How, if at all, will this study involve people from the target community in the design of the study?
◦ ..and in the conduct of the study?
◦ How will the results of the research be shared with the participants and/or the target community(ies)?
Changes to Data and Safety Monitoring Plan Section

UPCOMING PROTOCOL TEMPLATE UPDATES
The Data and Safety Monitoring Plan (DSMP) should be based on a *risk assessment* of critical data and processes that are necessary for human participant protection and the integrity of the investigation.

- **Monitoring** is an ongoing process of overseeing the progress of a study from start to finish.
- It is a quality control tool for determining whether study activities are being carried out as planned and whether there are any unexpected safety concerns.
- Monitoring enables study teams to identify and correct any deficiencies in study conduct, record keeping, or reporting.

All more-than-minimal risk studies require some degree of monitoring, based on study risk.

DATA AND SAFETY MONITORING PLAN REQUIREMENTS:
HTTP://IRB.EMORY.EDU/DOCUMENTS/DSMP_REQUIREMENTS_VER_2-21-2021.PDF
DSMP Requirements for More than Minimal Risk Studies

- Synthesis of guidance and regulations from various sources
- Meant to protect human research subjects per IRB’s mission
- Iterative process: the requirements and monitoring tables, like most of the IRB’s documents, are subject to continuous quality improvement. We will be making updates to enhance the review process over time! We will keep you updated as changes are made.

Requirements apply to:
- Investigator Initiated Studies, including multi-site led by Emory
- Multi-site studies where Emory is not the lead site and the study is not monitored by a CRO
DSMP Requirements Build As Study Risk and Complexity Increases

New DSMP Questionnaire in Biomedical and Site-Supplement templates (for multi-site studies where study is not monitored by CRO):

- Triages more-than-minimal risk studies into 3 categories based on complexity
  - Medium Complexity
  - High Complexity Category A (e.g. studies under IND/IDE)
  - High Complexity Category B (e.g. IND/IDE Exempt studies)

Each category has a corresponding Monitoring Table that lays out our minimum expectations for monitoring the different elements of the plan.

Tables make it easier to interpret our guidance, and to document compliance with IRB’s expectations for a faster review.

Additional requirements for FDA-regulated studies.
### Example Monitoring Table

<table>
<thead>
<tr>
<th>DSMP Requirement</th>
<th>How this Requirement is Met</th>
<th>Frequency</th>
<th>Responsible Party(ies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real-time review of participant data during initial data collection.</td>
<td><em>Expectation is that this happens every time you obtain information.</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Site Monitoring at pre-determined intervals: The Principal Investigator has a responsibility to ensure that the study is following all aspects of the protocol. | *There should be a standard operating procedure to review data (whether a sample or 100%) at pre-determined intervals to ensure that there is adequate documentation of critical elements such as eligibility criteria. Monitoring is required at the following timepoints (but may be done more frequently):*  
  - study initiation  
  - at least every six months while participants are receiving intervention and  
  - annually while participants are in follow-up | *Based on risk, a review is required annually when participants have been enrolled.*  
  *Self-assessment is acceptable*.  
  *Self-assessment:* a process for self-assessment of protocol compliance and data integrity which can be part of an overall DSMP. See CTAC’s self-assessment tool on their webpage. | *Delegate a responsible party for each requirement below.*  
  *Self-assessment is acceptable*.  
  *Self-assessment:* a process for self-assessment of protocol compliance and data integrity which can be part of an overall DSMP. See CTAC’s self-assessment tool on their webpage. |
| 100% review of consent forms                                                      |                                                                                                                                                            |                                                                           |                                                                                  |
| Review of credentials, training records, the delegation of responsibility logs (if applicable) |                                                                                                                                                            |                                                                           |                                                                                  |
| Comparison of case report forms (CRF) to source documentation for accuracy and completion |                                                                                                                                                            |                                                                           |                                                                                  |
| Review of documentation of all adverse events                                    |                                                                                                                                                            |                                                                           |                                                                                  |
| Monitoring of critical data points (eligibility, study endpoints, etc.)          |                                                                                                                                                            |                                                                           |                                                                                  |
New Submission DSMP Process

When Applicable

1. Complete the Monitoring Questionnaire and upload the questionnaire to the eIRB smartform alongside protocol

2. Complete the appropriate Monitoring Table and paste the completed table into your protocol’s “Plans for Monitoring Data” section

3. Check the corresponding box in the DSMP section of the protocol

<table>
<thead>
<tr>
<th>Select one of the following (do not delete this table; review the guidance document for definitions):</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Medium Complexity</td>
</tr>
<tr>
<td>☐ High Complexity Category A</td>
</tr>
<tr>
<td>☐ High Complexity Category B</td>
</tr>
</tbody>
</table>

*If choosing this category for a study under an IND or IDE because you believe the study intervention does not significantly impact morbidity or mortality, please provide your rationale:*
New Template Coming Soon!

UPCOMING PROTOCOL TEMPLATE UPDATES
Secondary Analysis of External/Public Data Sets-Protocol Template Coming Soon!

New template being drafted now

• Will cover secondary research of established data sets where a DUA or application is needed for access
  • Think SEER, CDC, AHRQ, etc.

• Very streamlined protocol template to facilitate a faster IRB submission and review
Other Updates
ICF Templates Updated 10/21

The informed consent templates were updated in October of last year:

**INSERT APPROPRIATE HIPAA OR CONFIDENTIALITY LANGUAGE HERE**

You should now insert the HIPAA language that applies to your study if needed
- HIPAA applies to research record (treating and billing for research)
- Obtaining PHI for research but not treating and billing ("IIHI")

Also included a QR code for our IRB research participant feedback survey to promote response
IRB Website Update- Sneak Peek

Our website is being updated to Emory’s new design!

We don’t have an exact go-live date yet, but most information and resources will be bucketed the same way they are currently to make the transition as easy as possible

- The mega menu will have sub-menus you will recognize
# Contact us

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shara Karlebach, WHNP-BC, CIP</strong></td>
<td>Associate Director, QA/Education Team</td>
<td>(404) 712-0727</td>
</tr>
<tr>
<td><strong>Jessica Blackburn, MPH, CIP</strong></td>
<td>QA and Education Lead Research Protocol Analyst</td>
<td>(404) 712-9698</td>
</tr>
<tr>
<td><strong>Jackson Parker, BA, CIP</strong></td>
<td>QA and Education Sr. Research Protocol Analyst</td>
<td>(404) 727-1674</td>
</tr>
<tr>
<td><strong>Briana Rotterman, MA, MS</strong></td>
<td>QA and Education Research Protocol Analyst</td>
<td>(404)-712-7624</td>
</tr>
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