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Device Determinations (October 2023)

This month’s Take 5 will cover medical devices. Specifically, the types of determinations that are routinely reviewed with the device studies that route to Committee.

An investigational device exemption (IDE) allows investigational devices to be used in a clinical study in order to collect safety and effectiveness data. Research that involves assessing the safety or effectiveness of a medical device must fit in ONE of the following categories and a completed Emory IRB Device Checklist is required for documenting the Board’s findings:

1. **Studies exempt from IDE requirements (“IDE Exempt”):** The Emory IRB Device Checklist in eIRB should indicate that the device, as used in this study, is “Exempt” from IDE requirements. If the IRB agrees that the study is exempt from IDE requirements, the IRB does not need to make a device risk determination and may proceed to evaluate study based on IRB approval criteria and informed consent regulations.
   - **Note:** The IRB always has the right to request that the PI consult with FDA to verify the study is exempt from IDE requirements.

If the study is NOT exempt from IDE Requirements, the convened IRB must make a device risk determination. The determination must be based on the proposed use of the device in the study, not just on the qualities of the device itself. The committee should use information such as the sponsor’s risk designation (if applicable), sponsor or PI’s justification for the risk, a description of the device, reports of prior investigations, proposed investigational plan, and subject selection criteria.

Note that OHRP and FDA do not allow studies with an IND or IDE to have expedited Continuing Review.

2. **Non-Significant Risk device research (“NSR device”):** These studies are also known as an “Abbreviated IDE.”
   - NSR device studies must return to full board for Continuing Review until they are in “long term follow-up only” stage. This is true even if the overall study is deemed no more than minimal risk.
   - **Note:** The IRB always has the right to request that the PI consult with FDA to see if a study is “Significant Risk” and needs an IDE.

3. **Significant Risk device research (“SR Device”):** This requires a formal IDE submission to FDA.
   - A Significant Risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) otherwise presents a potential for serious risk to a subject. The IRB should evaluate the device as used in the study.
   - **Note:** The study must be conducted under a valid FDA-approved IDE. The IRB staff validate the IDE number, and no further device determination is required.
**Ancillary Reviews (September 2023)**

This month’s *Take 5* will include a refresher on “Ancillary” Reviews. We reference these frequently during meetings and thought best to make sure everyone is clear on when they apply to a given project. As a reminder, Ancillary Reviews are required by groups outside of the Emory IRB; though, many provide valuable reassurance to the IRB about safety, feasibility, and scientific rigor.

**Common Ancillary Reviews:**

- **Departmental Review:** Required for all study submissions to ensure adequacy of the facilities and resources, eligibility, and qualifications of the investigators, and the scientific merit of the study. The PI’s primary department must provide the approval.
- **Conflict of Interest:** Required if an investigator or their immediate family member meets the threshold for financial interest and/or if there is any “institutional conflict of interest.”
- **CHOA Device Review:** Required if any investigational devices will be used at Children’s Healthcare of Atlanta.
• **EHSO Biosafety**: Required based on the Ancillary Review Information section of the eIRB SmartForm and location of the research. If the study teams indicate “yes” to either option under question #2 and the study includes non-VA sites, the review is required.
  - More information relating to human gene transfer studies (option #1) is covered in the Emory Biosafety Review Guidelines (PDF)
  - Option #2 should only be answered “yes” if the material is brought to an Emory research laboratory for further experimentation. Human blood, blood products or tissue that are shipped to non-Emory laboratories will not require Biosafety ancillary review.

• **EHSO Radiation Safety**: Required if the protocol includes any type of radiation—whether scans, radioactive drugs, or radiation therapy—and the study includes non-VA sites.

• **OIT Security Review**: Required for studies using PHI, IIHI, or sensitive information (e.g., drug use, alcoholism, sexual preferences) and storing data with identifiers in a “non-vetted” software or app.
  - Note that separate security reviews are required for each IRB submission as there are unique considerations for each project.

• **PRMC**: Required for all cancer-related research involving Emory faculty or students, regardless of Winship Cancer Institute involvement. This includes social and behavioral research, chart reviews, etc.

• **S-I Advisory**: Required for all studies for which an Emory researcher holds an IND or IDE.

### Less-common Ancillary Reviews:

• **Controlled Substance Consult**: Required if protocol includes the use of any controlled substances.

• **HESC (Human Embryonic Stem Cell Committee)**: Required for studies involving Human Embryonic Stem Cells or Inducted Pluripotential Stem Cells (iHPSCs) that may otherwise not require IRB review (e.g., research where cells are deidentified before being received by Emory).

• **REMS (Risk Evaluation and Mitigation Strategy) Consult**: Required for all protocols using a drug under a REMS, as imposed by the FDA.

### Post-Approval Ancillary Reviews:

These ancillary reviews occur after Emory IRB approval but should be selected by the analyst in eIRB during Pre-Review. This provides the reviewing Committee with view-only access to the study in eIRB.

• **Grady ROC (Research Oversight Committee)**: Required for studies conducted fully or partially at a Grady facility.

• **VA R&D (Research and Development Committee)**: Required for all studies which include the Atlanta VA.

When any Ancillary Reviews are pending at the time of IRB review, these will must remain pending issues with the Committee. In rare cases, if the pending review requires significant changes (i.e., beyond which a staff-Designated Reviewer or Vice-Chair can approve) the study may need to return to the Full Board.

**Template Modifications (August 2023)**
This month’s Take 5 will cover what can and can’t be modified within protocols and consent form templates.

When reviewing study documents, it’s important to remain focused on the approval criteria. If there is critical information missing, lack of clarity, overall high grade level, etc. it’s appropriate to request a revision. If it could be just a little bit better…probably best to just let it be or make the change a recommendation instead of a requirement.

A reminder of the information we should not modify:

- **Cost Option language**: this information has been vetted by our colleagues in the Office of Research based on budget negotiations. The language is intentionally vague on what may or may not be covered since it’s virtually impossible to predict all scenarios. Rare exception: if there is one “big ticket” item or procedure (e.g., study drug) that you believe it’s important to call out due to the expense, and we are certain whether the study will pay for it, then you could request it be added. The rest of the section should be left completely intact.

- **Injury Option language**: the option selected should line up with the terms of the contract. The language has been carefully crafted with input from legal and should only be modified if OSP notes incongruence with the contract.

- **Multi-site protocols**: Emory has little control over a protocol provided by a lead site or coordinating center. As a result, specific information about OUR site’s research activities can be included in that document.

**Note**: In general, be conservative when requiring changes to the consent form. Keep the approval criteria in mind…we don’t want perfect to be the enemy of the good! 😊

### Pending vs Deferred (July 2023)

It has been a while since we covered what types of revisions will meet approval criteria as opposed to deferral. So, now is the time!

As a reminder, if the IRB can’t easily suggest changes and/or seek concurrence with a proposed revision, it’s time to defer. The IRB must always make sure that approval criteria are met. If more information is needed from a team to make that call, it’s best to defer.

**Per OHRP guidance**, the IRB may require the following as conditions of approval of research:

1. **Confirmation of specific assumptions or understandings** on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children)

2. **Submission of additional documentation** (e.g., certificate of ethics training)

3. **Precise language changes** to protocol or informed consent documents

4. **Substantive changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy.**
Please to review the existing guidance on the website for more specific scenarios that the Board may encounter.

**Note**: the IRB staff will be looking for very clear wording for any pending issues. Taking the time to clarify during the meeting avoids confusion and the need for further follow up.

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**Reviewer Conflicts (June 2023)**

Any IRB member (or consultant) must disclose a conflicting interest in a project to the IRB Chair or Director before the project is reviewed by the Full Committee. The conflicted individual may not participate in the review of such project by any means. For studies reviewed by the Full Committee, the conflicted individual must leave the room during the discussion of and vote on such a project, *except when providing information at the IRB’s request*. In those cases, the conflicted individual will be present to provide the information but must leave the meeting for the remainder of the discussion and vote on the item.

A “conflicting interest” of an IRB member or consultant, generally includes the following:

1. **Participation of themself or their spouse or dependent children** in a project, including serving as an investigator on the project, a member of the research team or involvement in the design, conduct, or reporting of the research;

2. **Supervisory relationship** between themself and the Principal Investigator of the research.

3. **Financial interest**, defined as:
   
   a. **Receiving payments** of $5,000 or more including salary; consulting fees; honoraria; and/or gifts received within the past 12 months or anticipated for the next 12 months (excluding salary, grant support, and other payments for services received from Emory University)

   b. **Equity or ownership interest** (including stock options) valued at $5,000 or more as determined by reference to the entity’s publicly listed price (excluding mutual funds)

   c. Any equity or ownership interest in an entity if the entity’s value cannot be determined by reference to publicly listed prices (e.g., privately held companies, such as start-up companies)

   d. **A position** as director, officer, partner, trustee, employee, or any other position of management

   e. **Receipt of licensing fees or royalties** from intellectual property rights (patent, copyright, trademark, trade secrets, etc.) that are more than $5,000 annually from an entity or for a technology related to an Investigator’s teaching, research, administrative, or clinical duties at Emory

   f. **Any compensation** whose value could be affected by the outcome of the research.
4. **Personal relationship with investigator** (has an immediate family relationship or other close personal relationship with the investigator) NOTE: This does not mean a close *working relationship* (i.e., colleagues can review each other’s studies unless they for some reason do not feel they can be objective);

5. **Fiduciary relationship** to sponsor or the product or service being studied (serves as an executive to a company sponsoring the research or the product or service being studied or serves on such a company’s board of directors);

6. **Other non-financial interests** that may be conflicting interests, such as having an interest that they believe conflicts with the ability to review a project objectively;

7. Any other reason for which the individual believes they have a conflicting interest with the research.

*If you have any Conflict of Interest with research reviewed by your committee, the sooner you alert your IRB committee staff pod, the better! Staff will ensure that reviews are assigned appropriately, and quorum is maintained.*

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**Recruitment Methods (May 2023)**

Recruitment is the beginning of the informed consent process. As a result, IRBs are required to ensure that information given to subjects as part of informed consent meets the requirements specified in the regulations at 45 CFR 46.116. In addition, the FDA wants an additional assurance that the recruitment materials do not promise a certainty of cure beyond what is outlined in the consent and the protocol.

Below is a summary of the basic information to consider when reviewing the materials provide by the team. As a reminder, the materials can be found in the smart form under “Local Site Documents” question #2.

Here is a [link to additional guidance](#) on the IRB website.

**Recruitment Materials**

Recruitment materials *should*:

- Include name, address, and contact info of study site/study team.
- Detail the condition under study or purpose of the research.
- Cover basic eligibility criteria.
- Reference time or other commitment required.
- Mention participation benefits, if any (e.g., a no-cost health examination, participation in a nutrition program, etc.)

Recruitment materials *should not*:

- Emphasize compensation in any way. For example, no *bolding*, *italicizing*, underlining, or different colored text.
- Overstate benefits to participation.
- Keep the scope of the research question in mind.
- Gloss over risks
- Based on FDA guidance, no claims should be made that test article is safe or effective for the purposes under investigation- including by research subjects (if applicable)
- Should not use terms like “new treatment”, “new drug”, etc., without explaining the test article is investigational.
- Ads shouldn’t promise “free medical treatment” when the intent is to say subjects won’t be charged for taking part in investigation.

**Is the team proposing to review medical records for recruitment?**

Once the population is identified, teams should **not** be “Cold Calling”

- Team should find a treating physician willing to make contact. The provider can then ask patient’s permission to pass along contact info
- Passing along info about the study or providing a blank informed consent is not **engagement** in human subjects research thus no need to list treating physicians on the study if not engaged
- **Last resort:** researchers may obtain permission from physicians to contact their patients directly but must make it clear that physician was consulted in introduction

**Example of what NOT to approve:**

![Image of ad with corrected text]

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**Contact the Study Coordinator for more information:**

FDA.worstnightmare@example.edu
1. Reminder about expectations for both the **review** and **presentation** of continuing reviews (CRs). As a reminder, there is no need to complete a full review of the study. It’s ok to focus **only** on the below:

   **Where to focus your review**
   - Look at information **since the last CR**
     - any modifications with any **significant** updates to study design?
     - any withdrawals? If so, were there any concerning facts associated with the summary?
     - Check for any concerning reportable new information (RNI’s) that were not previously reported.
     - Discrepancies in enrollment data.
     - Any reports from data safety monitoring. Note: We ask analysts to request if missing. If there are any questions about what is provided, you may have to confirm intervals of review in the protocol.

   **What to present:**
   - Brief description of the study. Plan to hit on design, population, and any other important details related to review of progress.
   - Study status-enrolling, closed to enrollment?
   - Summary of feedback in DSMB reports e.g, statement about whether recommendations to proceed, concerns about progress, etc.
   - Determination of whether risk level is unchanged.

   ❖ The presentation generally takes a couple of minutes, assuming there are no concerns about progress in the last approval period.

2. When reviewing modifications to the study, it’s important for the committee to determine whether the risk/benefit ratio remains favorable. Please remember to be explicit about that finding when preparing to vote.

3. **Save the Date for the IRB Member Retreat! (It’s in person this year-yay!)**

   ❖ **When:** Friday, 8/18/2023 from 8-12
   ❖ **Where:** [Miller Ward Alumni House](#)

   We are planning to make it open to remote attendance, in case needed. There will be great topics and speakers. As a reminder, this is an opportunity to advance your knowledge as a member so please prioritize.

   **Added perk:** We will serve breakfast.

   A formal outlook invite will be coming your way soon!
Reviewing Modifications (March 2023)

This month’s Take 5 will revisit the process for reviewing modifications. Specifically, what Members should expect from study teams. We know this can be tricky, so let us know if we didn’t cover an area of confusion. As a reminder, study teams are instructed to clearly summarize what is included in a modification. Depending on what is being modified, teams may include tracked versions of documents or even a "summary of changes" document. The IRB is most concerned with changes that significantly impact risk or study design (e.g., IB updates, ICF risk updates, etc.).

- In the new system, we no longer require a “Tracked-change” version of a word document. Instead, study teams are directed to use the "Update" function to submit revisions to documents. The system can then automatically create a "compare" or "track-changes" version for the IRB.
- In cases where a PDF is uploaded, you should see either a stand-alone document summarizing changes or a page at the beginning of that details any updates. We generally only accept a PDF for IBs.
- In all cases, there should be some detail provided in the “Summarize the modification” section.

Below are some examples:

**Investigator Brochures:**

3. *Summarize the modifications:*

   CHANGES TO INVESTIGATOR BROCHURES
   - IDO IB v1 Addendum 01 (26-Sep-2016)
   - IDO IB v1 Addendum 02
   - IDO IB v5
   - IDO IB v8
   - NIVO IB v19 Addendum 01
   - NIVO IB v20 Addendum 01

In the example above, we would expect to see something in the actual IB that summarized what is being added/removed. We don’t necessarily expect any additional detail in this section.

**ICF and Protocol Revisions:**

If there were consent or protocol revisions, we would expect something like you see below:

3. *Summarize the modifications:*

   1) addition of language to the ICF regarding the possibility of a port—in discussing potential patients with Pediatric Research Unit at CAP, they brought up that a need for a port may become an issue for these very young patients. Even though the IV portion of the protocol is only 6 months and then IM injections become possible, the infusions are weekly. We would like to add language to the ICF that introduces this possibility at the time of consent, even though it may never become necessary. Also since the consent will be needed to be translated we would rather not wait to add this language. (the sponsor has agreed to pay the cost of a port if necessary and the patient’s choice)

   2) addition of the Spanish translation documents for travel services
Updated Subpart D Checklist (February 2023)

This month’s Take 5 will highlight recent improvements to the Subpart D checklist and assent template. As a reminder, the Subpart D checklist captures the following required regulatory findings during both expedited and Full Board review of studies involving minors:

- The appropriate risk-based category from Subpart D, and protocol specific findings justifying each determination
- The appropriate parental permission requirements
- The appropriate assent requirements

Subpart D form improvements include:

- More user-friendly formatting
• Guidance around when certain decisions need to be made by the Board
  o For example, when assent may not be necessary, and documenting the two-parent permission lines in the parent consent

Please see an excerpt from the revised form, below!

Assent form cover page:

- Clarification around when children who are unwilling/unable to assent may be enrolled
(i.e. when the study holds the prospect of direct benefit):

☐ In my opinion, this child is unable or unwilling to provide informed assent for non-age-related reasons and the study holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, and the PI for this study has been informed of this determination.

• Reason(s):

______________________________

______________________________

Signature of person soliciting assent (if above box is checked) Date Time
Meeting Agenda Process (January 2023)

First off, Happy New Year!! **THANK YOU** for all the wonderful work you’ve done throughout the year!

This is a quick recap of our new(ish) Meeting Agenda process, and gratitude for your support in using it.

1. IRB staff facilitators create an Agenda document based on what’s in eIRB. It includes:
   a. The reviewers for each item
   b. Known *administrative pending items* for each item
   c. *Special determinations* the members must make for each item
   d. Any other important notes
   e. Items are in the **order of review at the meeting** (not necessarily the order they appear in eIRB)

2. IRB staff send the Agenda document to you and the members twice:
   a. *First*, one week prior to meeting when review assignments go out
   b. *Second*, the morning of the meeting

3. **At the meeting, we use the latest and greatest Agenda document**
   a. Pending issues will be up to date
   b. *Order of items may be updated* based on members needing to arrive late or leave early, or items may have been added or removed from Agenda

This helps, as it allows our staff to accurately and efficiently record minutes at the meeting, remind you of pending items, and ensure the right order of reviews.
This month’s “Take 5” covers considerations around the “Study Scope” question for studies involving drugs and/or devices...

❓ Should the study team have completed the “Devices” and/or “Drugs” section of the smartform?
❓ What information does the IRB need about the drug/device, and where should it be?
❓ Is the study really FDA-regulated?

<table>
<thead>
<tr>
<th>Device</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?&quot;</td>
<td>&quot;Does the study specify the use of an approved or unapproved drug or biologic?&quot;</td>
</tr>
</tbody>
</table>

If the team answers “yes” - the device details and IRB Device Checklist will be in the Devices smartform section.

If the team answers “no” - the device should be described in the submission, but you will not see the Devices section.

- Information can be in the protocol and in uploaded manuals.
- The IRB should determine when it has enough information to assess the risks and benefits of the study.
- Also, FDA regulations may not apply.

Examples of when FDA regulations would generally not apply, and no Device section is required:

- An FDA-approved device is used to test a physiologic principle, and no data is collected about the device;
- An FDA-approved device is used to address a research question and no data is collected about the device; or
- An FDA-approved device is used for clinical purposes (e.g., to monitor a side effect, measure treatment progress in a study) with no intent to assess safety or effectiveness of

Note: FDA regulations generally always apply if a drug is being used as part of the research intervention, and the smartform answer should be “Yes.”

❖ Exception: If the study only involves collection of data from Standard of Care treatment, the study team should likely answer “No.” You should see the details outlined in the protocol as opposed to uploaded under the “Drug” section of the smart form.

❖ Caveat: if the study assigns participants to one or more “standard of care” treatments (i.e. a “comparative effectiveness” study), the Study Scope question should be answered “Yes”
<table>
<thead>
<tr>
<th><strong>Device</strong></th>
<th><strong>Drug</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>the device, nor to support a new indication for marketing</td>
<td></td>
</tr>
<tr>
<td>➢ A non-FDA-approved device is used for research data collection, with no intent to assess safety or effectiveness of the device (e.g. a research-use-only neural stimulator used to measure physiological reactions in healthy volunteers)</td>
<td></td>
</tr>
</tbody>
</table>

**Definition:**

The term *device* means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title.

**Definition:**

The FDA defines a drug, in part, as “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”

*If a study evaluates the effectiveness of a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition, it will likely qualify as a drug.*
Member Evaluation Process (November 2022)

For this month’s Take 5, we wanted to refresh everyone on how the IRB evaluates member Performance. As a reminder, the assessment is not meant to be punitive! It is a part of our accreditation, and we use the feedback to look for gaps in understanding, areas for training, etc.

To summarize the overall process:

The IRB Chair reviews each IRB member’s performance periodically in consultation with the IO and the IRB Director.

- The performance of each Vice-Chair, Chair, and IRB Director are reviewed on an annual basis by the IO.
- Members, Chairs, and Vice Chairs will be given formal feedback based on their performance evaluations.
  - The IRB Director will fulfill this function for the IRB members, Chairs, and Vice Chairs. With respect to the Chairs, the IO will also provide formal feedback based on their performance evaluations. Feedback is provided in writing and may also be provided in person.

The following categories are considered with the assessment:

- Preparedness for Meetings
- Contribution to IRB Meetings
- Quality of Reviews
- Knowledge of Organizational Policies and Procedures
- Knowledge of regulations and identification of areas for improvement
- Communication with Members, IRB Staff
- Comments
- Number of meetings attended out of total
- Timeliness of Reviews
- Number of Protocols Reviewed via Committee Review
- Number of Reviews Completed as Primary Reviewer
- Attended Member Retreat

If you ever have feedback to provide about your experience as a member, don’t hesitate! We appreciate both formal and informal feedback, as it helps us to improve.

As always, thank you all for your contributions to the IRB! We literally could not do it without you.
This month’s **Take 5** introduces new FDA guidance on “Clinical Decision Support Software”..

**Good news!**

The FDA just provided a helpful "infographic" we can use to determine when "Clinical Decision Support" software is a "medical device" per FDA rules.

**What is "Clinical Decision Support" software?**

It is **software** that is "intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of diseases or other conditions." Think of an app that guides doctors on how much of a certain medication to give based on certain lab results, based on standard guidelines. It can also refer to a specific function of a larger platform or app.

**Why is this FDA guidance useful?**

Because the IRB needs to know for sure when a study is an "FDA regulated clinical investigation" - for example, when the objective is to test a "drug" or "device."

**Why do we care about that?**

Because this impacts (1) the consent form language [FDA must be referenced in the Confidentiality or HIPAA section], (2) the need for continuing review, and (3) whether a study is subject to audit by the FDA.

**What does the guidance say?**

The guidance itself isn't really new - the infographic makes the very long text-based guidance easier to digest.

Per the guidance, a software function **must** meet all four criteria below to be considered a **Non-Device CDS**.

1. The software function does NOT acquire, process, or analyze medical images, signals, or patterns.
2. The software function displays, analyzes, or prints medical information normally communicated between health care professionals (HCPs).
3. The software function provides recommendations (information/options) to a HCP rather than provide a specific output or directive.
4. The software function provides the basis of the recommendations so that the HCP does not rely primarily on any recommendations to make a decision.
*If all four criteria are met, the software function may be non-device CDS. If a study includes software that does not meet the above criteria, we will apply typical device determinations (e.g. "non-significant risk device").

See the next page for a really helpful graphic:
Your Clinical Decision Support Software: Is It a Device?

The FDA issued a guidance, Clinical Decision Support Software, to describe the FDA’s regulatory approach to Clinical Decision Support (CDS) software functions. This graphic gives a general and summary overview of the guidance and is for illustrative purposes only. Consult the guidance for the complete discussion and examples. Other software functions that are not listed may also be device software functions.

Your software function must meet all four criteria to be Non-Device CDS.

1. Your software function does NOT acquire, process, or analyze medical images, signals, or patterns.

2. Your software function displays, analyzes, or prints medical information normally communicated between health care professionals (HCPs).

3. Your software function provides recommendations (information/options) to a HCP rather than provide a specific output or directive.

4. Your software function provides the basis of the recommendations so that the HCP does not rely primarily on any recommendations to make a decision.

Non-Device Examples display, analyze, or print the following examples of medical information, which may also not be images, signals, or patterns:

- Information whose reference to a clinical decision is well understood
- A single discrete test result that is clinically meaningful
- Report from imaging study

AND

Non-Device examples provide:

- Lists of preventive, diagnostic, or treatment options
- Clinical guidelines matched to patient-specific medical info
- Relevant reference information about a disease or condition

AND

Non-Device examples provide:

- Plan language descriptions of the software purpose, medical input, underlying algorithm
- Relevant patient-specific information and other known/unknowns for consideration

Device Examples acquire, process, or analyze:

- Signal acquisition systems
- In vitro diagnostics
- Magnetic resonance imaging (MRI)
- Next Generation Sequencing (NGS)
- Continuous Glucose Monitoring (CGM)
- Computer aided detection/diagnosis (CADs/CADx)

OR

Device examples display, analyze or print:

- Continuous signals/patterns
- Medical images
- Waveforms (ECG)
- More continuous sampling (aka – a signal or pattern)

OR

Device examples provide:

- Risk scores for disease or condition
- Probability of disease or condition
- Time-critical outputs

OR

Device examples:

- Basis of recommendations is not provided

Your software function is a device.

*Disclaimer: This graphic gives a general overview of Section IV of the guidance (“Interpretation of Criteria in Section 520(a)(11)(E) of the FD&C Act”), Consult the guidance for the complete discussion. The device examples identified in this graphic are illustrative only and are not an exhaustive list. Other software functions that are not listed may also be device software functions.*
Retreat Recap (September 2022)

Thanks to all that made it to IRB Member Retreat. We had some great speakers and thought-provoking topics! For those that could not make it, don’t stress! We have recordings. For this month’s Take 5, we are presenting the highlights from each presentation...

What’s on the horizon...Tribal Research & Community Engagement

Tribal Nations:

- Reminders that the tribal nations are sovereign governments and thus we need to ensure compliance with laws.
- It is crucial to understand necessary approvals (local context) – Rebecca reminded everyone that it’s not the Nation’s responsibility to teach us. We often loop in OGC and outside counsel since different entities within Nations may not know or not agree with requirements.
- IRB staff will do the necessary regulatory and local context research prior to your review. If you notice aspects of the study that are different than usual, it should be clear in eIRB when that is due to tribal requirements.

Community Engagement:

- Rebecca reviewed the following AAHRPP Elements:
  - Element I.4.B: The Organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement.
  - I.4.C: The Organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.

- To address these elements, the IRB has initiated a Community Participation Project, which is led by Carol Corkran.

Adults with Diminished Capacity:

- Reminders to Members that we have guidance on the topic: [https://www.irb.emory.edu/members/reviewer-checklists.html](https://www.irb.emory.edu/members/reviewer-checklists.html)
- What to look for in both protocol and consent process:
  - Are there tests or procedures to assess the participant's consent capacity?
  - Plans for documenting the assessment?
  - Has the team described procedures for reevaluating participants’ capacity to consent throughout the study?
  - Are participants asked to designate an individual to serve as a LAR, if necessary?
The team should describe plans for obtaining the consent of any participant who is initially judged incapable of providing consent but regains the capacity to consent, if that could occur.

The Appropriate Use of Race in Biomedical Research:

- The speaker touched on how biomedical research can “frame” the causes of racial inequity
- Race should be considered a social construct, and should not be directly tied to biological outcomes
- Teams need to clearly define the way they are using “Race” and/or “Ethnicity” in a study
- The IRB already has guidance about this built into our latest protocol templates, and we are working to clarify the IRB’s role in enforcing and educating about these concepts

Artificial Intelligence and Machine Learning in Research:

- Artificial intelligence and machine learning (AI/ML) continue to develop in the healthcare field while the FDA and other regulations attempt to catch up.
- AI/ML presents the potential for a level of precision care that could reduce cost, waste, improve quality and patient outcomes and transform the healthcare field.
- Dr. Madabhusi discussed the preliminary FDA considerations for studies that include AI. While not yet finalized as regulations, they provide a framework to review these types of studies.
  - For example, the FDA plans to require steps to increase robustness and decrease bias of data that is used to train and test the AI software.
  - Dr. Madabhusi highlighted the unique learning nature of AI systems that result in changes over time. As a result, FDA may require researchers/developers to identify potential changes and risk mitigation practices in AI software.
- More guidance to come, but we should be alert to protocols that involve reference to artificial intelligence, machine learning, algorithms, big data, etc.

Export Control and International Data Regulations:

Export Controls:

- U.S. federal regulations control export of certain items (hardware, technology, software) outside the U.S. or to foreign persons in the U.S.
- There are some individuals and entities that are on a "restricted parties list." As a result, it’s important that we verify whether any restrictions apply to human subjects research. Rose Ndegwa walked everyone through the process.
- There are considerations around International Collaborations, travel, shipping, etc.
- There are exceptions for research, which include “Research results that:
  - ordinarily are published and shared broadly within the research community, and
  - for which researchers have not accepted restrictions for proprietary or national security reasons

Data Regulations:
• **GDPR**: GDPR standardizes data privacy laws across Europe and puts in place more robust protections for individuals whose personal information is stored and maintained by any organizations like Emory. The IRB has GDPR consent language available. It's in a standalone form that should be used whenever someone is enrolling participants that are located in the European Economic Area at the time of data collection.

• **PIPL**: China's Personal Information Protection Law (PIPL) is a data privacy law in China, targeted at personal information protection. The law is applicable to organizations and individuals who process personally identifiable information (PII) in China as well as those who process data of China citizens outside of China. Emory is still in the process of gathering information around PIPL requirements and impact on research.

Lastly, **we would love feedback from those that were able to attend.** We have created a brief survey to capture your thoughts.
Process for Meeting Prep (August 2022)

We hope your summer is going well! It’s hard to believe it’s coming to an end here soon.... But we’re excited to see what this year holds!

This month’s “Take 5” will cover the basics for meeting prep, both from the IRB member and IRB staff "Pod" perspective. As a reminder, the "meeting Pod" is your meeting support team. They are managing all the moving parts of meeting facilitation from start to finish.

How you, the IRB Members, can assist with meeting prep:

RSVP, s’il vous plait!

- We really do need to hear from you promptly, even if you cannot attend.
- We need all RSVP's in order to finalize study assignments, especially for larger agendas or when certain expertise is crucial.
- This also allows your meeting Pod to prepare for any issues with quorum, lack of expertise, etc. The sooner we know your status, the better!
- If you cannot attend, please also let your meeting Pod know if you can still submit secondary reviews.

Keep those reviews coming...

- The Pod emails out review assignments about one week before the meeting. Assignments are based on expertise, availability, conflicts, etc.
- It is REALLY helpful if you complete your assigned reviews as soon as possible.
  - It's great to be able to pull off items that will definitely be deferred - shorter meetings! - or request information from study teams to avoid pending issues.
  - At the latest, we ask that you complete your reviews the day before the meeting.
- There really isn’t a right or wrong way to craft your review comments, but it helps to use our study review guidance on the IRB website and indicate whether you recommend to “approve,” “pend,” or “defer” the study.

Don’t let them peek behind the curtain, unless you really want them to

- Please use the “Add Review Comments” activity to document your review.
- REMEMBER: Definitely don’t use the simple “Add Comment” except when you want the study team to see your notes. The confidential "Add Review Comments" is the way to go!
- Minutes: The meeting Pod strives to provide the latest meeting minutes either in the Meeting Invitation or Reviewer Assignment emails.
- Please be sure to review them (if you were at the relevant meeting), and inform the meeting Pod of any needed changes within 7 business days
As always, don’t hesitate to reach out to your Pod with any questions.

Lastly, please make sure you have RSVP’d for the upcoming Annual IRB Member Retreat on 8/19/2022. An invite was sent to hold the time. If you did not receive it, let us know. We will be in touch closer to the event with details on speakers and timing of presentations. We really hope to see everyone there!
Reviewing Modifications (June 2022)

This month’s Take 5 will cover modifications. Specifically, what Members should expect from study teams.

- As a reminder, study teams are instructed to clearly summarize what is included in a modification. Depending on what is being modified, teams may include tracked versions of documents or even a "summary of changes" document. The IRB is most concerned with changes that significantly impact risk or study design (e.g., IB updates, ICF risk updates, etc.).
- In the new system, we no longer require a “Tracked-change” version of a word document. Instead, study teams are directed to use the "Update" function to submit revisions to documents. The system can then automatically create a "compare" or "track-changes" version for the IRB.
- In cases where a PDF is uploaded, you should see either a stand-alone document summarizing changes or a page at the beginning of that details any updates. We generally only accept a PDF for IBs.
- In all cases, there should be some detail provided in the “Summarize the modification” section.

Below are some examples:

**Investigator Brochures:**

3. *Summarize the modifications:*

CHANGES TO INVESTIGATOR BROCHURES
- IDO IB v1 Addendum 01 (26-Sep-2016)
- IDO IB v1 Addendum 02
- IDO IB v5
- IDO IB v8
- NIVO IB v19 Addendum 01
- NIVO IB v20 Addendum 01

In the example above, we would expect to see something in the actual IB that summarized what is being added/removed. We don’t necessarily expect any additional detail in this section.

**ICF and Protocol Revisions:**

If there were consent or protocol revisions, we would expect something like you see below:

3. *Summarize the modifications:*

1) addition of language to the ICF regarding the possibility of a port —in discussing potential patients with Pediatric Research Unit at CAP; they brought up that a need for a port may become an issue for these very young patients. Even though the IV portion of the protocol is only 6 months and then IM injections become possible, the infusions are weekly. We would like to add language to the ICF that introduces this possibility at the time of consent, even though it may never become necessary. Also since the consent will be needed to be translated we would rather not wait to add this language. (the sponsor has agreed to pay the cost of a port if necessary and the patient's choice)

2) addition of the Spanish translation documents for travel services

**Technical steps to review a modification in the system**
Review the Submission Pages

Review the submission and attached documents using the following tools:

1. Click Review Study and review each section. You can scroll through the submission or use the Left Navigator to jump to specific sections of the form.
2. To see what changed between this and a previous version, look in the Compare section of the Left Navigator.
3. After reviewing each section, select the check box at the bottom to indicate you have reviewed it.
4. The section turns green, and a green check mark appears in the Left Navigator.
5. If the submission is edited later, the green check mark is removed and a pencil icon is added, indicating to review that section again.

Note: This Review Tracker feature does not stop a submission from moving forward in the review process.

6. Click the Reviews tab to access reviews completed by other committee members or reviewers.
Hello Members! You may have noticed that the IRB website has been revamped. This is part of an ORA initiative to enhance the user experience and align among each office.

We want to highlight some key areas for Members, so we will plan do a quick demo as the “Take 5” for May.

Here is a link to the site so you can look around: https://www.irb.emory.edu

Please be prepared to share any feedback, good or bad!
Improving the Member Experience (March 2022)

Dear Members, this month’s “Take 5” is focused on keeping you informed about our quality improvement (QI) initiatives as they relate to the Member experience. You may recall that we surveyed Members prior to the most recent Member Retreat. We received valuable feedback regarding the desire to improve consistency and efficiency between panels. So, we felt it was a good idea to keep you all in the loop on progress.

Some examples of ongoing efforts related to QI:

- The IRB is conducting a multi-stage training with staff entitled “Meetingpalooza”. One of the primary goals is to provide a consistent experience for members. The workshop has allowed the opportunity for meeting pods to look at current differences, tools, and make improvements going forward.

  Topics explored:
  - Stressing importance of modifications summaries
  - Adopting one method for providing “huddle” information
  - Process for RSVPs and review assignments

- Additional ways that the IRB staff and leadership work to enhance knowledge:
  - New Member orientation
  - “Take 5” monthly trainings
  - Annual Member retreat
  - Member performance assessments
  - Vice Chair meetings

As always, let us know additional ways we can improve the experience.
Recent Updates to Protocol Templates (January 2022)

Dear IRB Members,

We have recently updated our Data safety Monitoring Plan requirements as well as our protocol templates. This information was pushed out to study teams in our recent webinar as well as via email “blast”

**Below are the highlights:**

**Updated Data and Safety Monitoring Plan Requirements**

There were recent updates to the Data and Safety Monitoring Plan (DSMP) requirements, which originally went into effect last year.

Specifically, it went from 3 high complexity categories to 2 (now just categories A and B). Category B comprises studies that are still high complexity (e.g. using drugs off label), but lower risk than Category A studies.

All studies in Category B will require your input re: whether self-monitoring is adequate (vs. external monitoring), and on the frequency of the monitoring. Researchers will provide rationale in their protocol to justify any requests for self-monitoring.

There are also a new monitoring questionnaire and monitoring tables to put the requirements into practice and document the details of the monitoring plan in the protocol.

**All more-than-minimal-risk studies that are a) investigator-initiated b) Emory-led multi-site studies, or c) other multi-site studies that are not monitored by a CRO will be required to use the questionnaire and monitoring tables:**

- The completed questionnaire will be uploaded as a separate document in the Basic Study Information section of eIRB for more than minimal risk studies (alongside the protocol)
- The completed monitoring table will be pasted into the protocol’s DSMP section, which should make it easier for you as a member to see the details provided.

*These requirements apply to all new more-than-minimal-risk study submissions as of 1/25/2022.

We have also updated the Protocol Templates:

- The protocol templates now include the checklists at the end instead of as a separate document.
- There is new guidance in some of the “population” sections:
  - 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.
  - Additional detail required for studies that address issues affecting a certain community or group

Let us know if you have any questions or feedback as you start seeing these protocols come through for review.