

## **Take 5 – Table of Contents**

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## Reviewer Expertise (May 2024)

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We want to take an opportunity to remind members to **alert your pod if there are review assignments that fall outside the scope of your expertise.**

Per regulatory guidance, we rely on IRB Members who are qualified by education and/or professional experience and expertise (professional competence) to serve in their particular IRB role (physician scientist, non-physician scientist, etc.)

As a reminder, analysts utilize our [IRB Member Roster](#) to reference reviewer's expertise. Of course, there are situations that warrant multiple perspectives but generally we default to one reviewer.

**As part of ongoing QA processes, we hope to conduct an IRB Member survey to get updated details. This is meant to ensure that we have any updated professional details.**

### Per our P&Ps, IRB Members shall:

- Have knowledge of applicable law and HHS, FDA and VA Regulations
- Have knowledge of Emory University commitments and policies
- Be sufficiently qualified through their experience and expertise; their diversity, including considerations of race, gender, and cultural backgrounds; as well as their sensitivity to such issues as community attitudes; to promote respect of its advice and counsel on safeguarding the rights and welfare of Human Subjects

The IRB membership overall will possess the professional competence necessary to review specific Research activities and will include persons knowledgeable in a variety of areas such that the IRB will be able to ascertain the acceptability of proposed Research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice.

## Investigator Conflicts of Interest (April 2024)

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This month's Take 5 will provide an overview of the process for managing *investigator* Conflict of Interest (COI).

### Some key COI terms:

**Financial Conflict of Interest (FCOI)** refers to situations in which Emory determines that a Covered Individual or Covered Family Member's **SFI** is related to the Research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of the Research.

**Significant Financial Interests (SFI)** requiring disclosure are interests held individually by the investigator, their spouse or same-sex domestic partner, and dependent children. They must be added together, and the aggregate value used to determine limits set forth as one or more of the following financial interests held by an Investigator/Key Personnel, their spouse, or dependent children:

1. Remuneration or honoraria over \$5,000 from an entity within a 12-month period
2. Ownership interests valued over \$5,000 in a publicly traded entity
3. Any ownership interests in a privately held entity (e.g., start-up companies, LLCs)
4. Any intellectual property fees and/or royalties
5. Holding any management positions in a non-Emory entity (director, officer, trustee, management employee)
6. Sponsored travel over \$5,000 (except from Emory, U.S. government, higher ed, academic medical centers)

The **COI management plan** is a key component of this process. It is a document that outlines and implements measures to actively reduce, mitigate, or eliminate an actual, potential, or perceived conflict of interest held by an employee.

#### About the collaborative COI review process:

The [Conflict of Interest and Conflict of Commitment \(COI and COC\) Office](#) is the group tasked with managing individual and institutional financial interests that could impact research and scholarly activities. The Emory IRB is responsible for reviewing the proposed management plans for investigators conducting research under a local IRB approval.

When the Emory COI Review Committee identifies a **Significant Financial Interest Requiring Disclosure (SFI)**, the COI Review Committee provides the IRB with documentation establishing the Committee's decision regarding the Significant Financial Interest, as well as a copy of any management plan. The Compliance Review (CoRe) team will review any management plan to determine if the SFI will adversely affect the protection of Human Subjects and if the management plan is adequate.

Based on the significance of the SFI and potential for adverse effects on the protection of subjects, management plans may include:

- disclosure to subjects through the consent process,
- modifications in the research plan,
- monitoring by independent reviewers,
- divestiture of financial interests,
- appointment of a non-interested PI,
- or prohibition of the conduct of the research at the University.

The IRB analyst works with the study team to ensure that any of the required updates to study documents are implemented before releasing final approval. It's important to note that an SFI can develop during a study. If a new conflict is reported with a modification or CR, the team will have to go back through the above process, as applicable.

*Referral to Full Committee Review:* If the CoRe team requests additions to the plan that the PI does not agree with, the recommended additions are referred to a convened meeting and the Board's decision will apply.

**Note about externally reviewed studies:** In cases where the Emory IRB has ceded review to an external IRB, the COI Review Committee still conducts their review to determine if there is a SFI and if so, will develop a management plan. Once the investigator accepts the COI management plan, the investigator is responsible for ensuring it is submitted to the external IRB reviewing the research. The external IRB may impose additional restrictions based on the nature of the SFI if they determine that is necessary.

## Reviewing and Presenting Modifications (March 2024)

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This month's Take 5 will briefly cover the process for reviewing modifications. Specifically, the **expectations for both the review and presentation of modifications.**

When reviewing modifications, the **IRB is *most* concerned with changes that significantly impact risk or study design** (e.g., IB updates, ICF risk updates, etc.).

As a reminder, **there is no need to complete a full re-review** of the study. It's ok to focus only on the below:

### Where to focus your review:

- Review information provided in the modification summary
- Do the proposed changes impact the risk/benefit ratio for subjects?
- Do the revisions include a new population; addition of a device; or changes in drug dosing, route, etc.?
- Are the requested changes incorporated into all relevant study materials?
- Could the proposed changes affect an active participant's decision to continue participation in the study?
- If the consent form is revised, are there appropriate plans to either re-consent or notify?

### What to present:

- **Brief description of the study.** Plan to hit on design, population, and any other important details. The presentation generally takes a couple of minutes.
- **Study status.** Is the study enrolling or closed to enrollment? This will impact the decision to require re-consent.
- **Determination of risk level has changed.** Please remember to be explicit about the impact to risk/benefit ratio when preparing to vote.

### eIRB review tips:

Finally, don't forget that our [Member Guidance webpage](#) includes technical steps and tips to review modifications in eIRB. Some quick tips include:

- **Changes to word documents:** Teams don't have to provide "tracked change" versions of word documents. 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 change" version for the IRB.
- **Changes to PDF documents:** 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.
- **Modification Summary:** In all cases, there should be some detail provided in the "summarize the modification" section.

For more insights on reviewing modifications, also check out our earlier Take 5's covering modification reviews and the technical processes from [March 2023](#) and [June 2022](#).

## **Quality Assurance Process Pilot (February 2024)**

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This month's Take 5 covers the new **pilot QA process** for reviewing studies that rolled out in January.

The purpose of the Emory University IRB QA and Compliance Program is to assist the IRB in achieving its mission of protecting human subjects participating in research while maintaining compliance with all associated laws and regulations. To facilitate that mission, we have processes that assess compliance internally. The internal review process includes assessment of study screening procedures, ancillary review selections, and regulatory determinations among other things to ensure compliance.

### **Please keep in mind:**

- We will not be able to review every study but will attempt to hit most, as outlined below.
- Because this is a pilot, ***we want your feedback on this process!***
- And, with this feedback, the QA review process will change over time.

### **QA Review Process for Full Board Studies:**

1. Analysts alert the QA review team when a new Full Board study pre-review is complete and assigned to a meeting agenda.
2. The QA review team looks for any missing information, regulatory forms, etc.
3. The QA team alerts the analyst if there are findings that need to be addressed prior to the committee review.
  - *If there are potentially deferrable issues:* the study team will be instructed to provide a response by a specific deadline; if not met, the study will most likely be removed from the agenda.
  - *If all items can be considered as "pending":* the study team will be instructed to provide a response prior to the meeting date if possible, and the IRB Pod will ensure that the items are included in the "huddle" document shared with Members.

*Note:* The requested documents and clarifications will come in as a logged comment since the study team can't edit the submission once on the agenda. Members should refer to the details in the submission as well as the history to ensure a thorough review.

### QA Review Process for Expedited and Exempt Studies:

A selection of studies with one or more of the following features will be reviewed at the time of initial request for clarification:

- Vulnerable populations included
- Federally funded
- AI/ML/Big Data included
- External team members in the submission or in protocol or the grant
- International research submissions
- Tribal research

As with Full Board studies, the study team will be asked to resolve issues prior to assigning for Designated Review. If there are any outstanding items, the analyst should include a note to the IRB reviewer.

## Expanded Access (January 2024)

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This month's Take 5 will cover [expanded access](#), sometimes referred to as "compassionate use." Expanded access is an alternative option for patients with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment **outside of clinical trials when no comparable or satisfactory alternative therapy options are available**. Products used under expanded access have not yet been approved or cleared by FDA and FDA has not found these products to be safe and effective for their specific use.

The preference is to have patients enroll in available clinical trials. However, the FDA is aware that it's not always possible. For example, if they don't meet eligibility, there are no available trials, or distance to a trial precludes access.

### Key Stakeholders:

**Licensed Physician:** Agrees to oversee the patient's treatment and works with industry (e.g., medical product developer), files paperwork with FDA and IRB (for many expanded access request types), and is responsible for patient care and reporting.

**Company:** Willing to provide the investigational medical product and either sponsors the expanded access, allows the FDA to cross-reference to their industry IND (for drugs and biologics) or IDE (medical devices) on behalf of the expanded access [sponsor-investigator](#) through the use of a [letter of authorization](#), or provides the necessary investigational medical product information for the sponsor-investigator to submit to support an expanded access request.

**IRB:** Reviews expanded access protocol and consent to ensure that the patient is informed about the nature of the treatment. Except for emergency expanded access use when there is not sufficient time to secure prospective IRB review, an investigator treating a patient with an investigational drug under expanded access is responsible for obtaining IRB review and approval consistent with 21 CFR part 56 before treatment with the investigational drug may begin, regardless of whether the protocol is submitted in a new IND or to an existing IND (21 CFR 312.305(c)(4)).

**FDA:** Reviews the expanded access request and determines if the treatment may proceed.

*Note:* A physician submitting an individual patient expanded access IND using Form FDA 3926 may select a request to waive the requirements in § 56.108(c), which allows for IRB chair concurrence in lieu of review by the convened IRB.

### IRB Review Procedures:

While this is NOT research, the IRB will need to review according to 21 CFR parts 50 and 56, unless one of the exceptions found in part 50 applies. There are no special determinations required for expanded access, just typical drug or device study review documentation.

These protocols and consent forms will look a bit different since they do not (generally) involve research. For example, the protocol may consist of a description of patient's disease/condition, medical history, and previous treatment for along with a description of the clinical procedures, laboratory tests or other monitoring necessary to evaluate the effects for the drug and minimize its side effects. The consent form should include a statement that the patient is being offered treatment with a drug/device that has not been approved by the FDA. The SmartForm will have the supporting documentation for the drug or device. You may encounter older expanded access consent documents that include the term “research” or “study” throughout. We are in the process of revising the expanded access template to make it clearer that it doesn't involve research.

### An overview of the different types of expanded access:

Expanded Access for <u>Drugs</u>	Brief Definition
<b>Expanded access for individual patients</b>	Expanded access to an investigational drug for <b>treatment use by a single patient submitted under a new IND</b> . There is a 30-day waiting period before treatment with the drug may begin, unless the treating physician receives clearance from FDA. If the treatment protocol is submitted to an existing IND by the sponsor of the existing IND, there is no 30- day waiting period before treatment with the product may begin. FDA just needs to have received and IRB approval has to be in place before treatment may begin.
<b>Expanded access for individual patients, for emergency use</b>	Use by a <b>single patient in an emergency situation (i.e., a situation that requires a patient to be treated before a written submission can be made) submitted as a protocol under a new IND or as a new protocol to an existing IND by the sponsor of the existing IND</b> . Treatment is initially requested and authorized by

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telephone or other rapid means of electronic communication, and may start immediately upon FDA authorization. The written submission (i.e., the individual patient expanded access IND) must be submitted within 15 business days of the telephone authorization.

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<b>Expanded access for intermediate-size patient groups</b>	Access to an investigational drug for <b>use by more than one patient, but generally fewer patients than are treated under a typical treatment IND or protocol</b> , submitted as a protocol under a new IND. Unless FDA notifies the sponsor that treatment may begin earlier, there is a 30-day waiting period before treatment may begin.
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<b>Expanded access for widespread treatment use</b>	Access to an <b>investigational drug for treatment use by a large (widespread) population, can be submitted as a protocol under a new IND</b> . The investigational product must be under active development for marketing. Unless FDA notifies the sponsor that treatment may begin earlier, there is a 30-day waiting period before treatment may begin.
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<b>Expanded Access for <u>Devices</u></b>	<b>Brief Definition</b>
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<b>Emergency use</b>	Use of an investigational device when an <b>individual patient is in a life-threatening situation and needs immediate treatment</b> (there are no alternative options and no time to use existing procedures to get FDA approval for the use)
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<b>Compassionate use</b>	Use of an investigational device to <b>treat or diagnose an individual patient or a small group of patients</b> with a serious disease or condition when there are no available alternative options
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<b>Treatment Investigational Device Exemption</b>	Use of an investigational device to <b>treat or diagnose a group of patients</b> with a serious or immediately life-threatening disease or condition when the device is also being studied for the same use under an approved Investigational Device Exemption.
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## **Artificial Intelligence, Machine Learning, and Big Data (December 2023)**

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This month's Take 5 will cover the IRB's progress developing guidance and tools related to review of Artificial Intelligence (AI), Machine Learning (ML), and Big Data in Human Subjects Research.

As we noted during the IRB Member retreat, the IRB has an AI/ML/Big Data Working Group. **The goal of the working group is to develop useful guidance and reasonable requirements which maximize participant safety, rights, and welfare while facilitating research.**

**Here are some specific areas of focus for the AI/ML/Big Data working group:**

**Data:** Data quality, bias, security, monitoring in secondary use, development, training, testing, deploying in research

**Blackbox Considerations:** transparency, explainability

**Identifiability:** ease/risk of reidentification, best practices to avoid reidentification, transparency to participants

**The working group is also collaborating with the following experts and key stakeholders:**

1. Data science experts
2. IRB Members
3. Emory and External Researchers who are working with and have expertise in AI/ML/Big Data
4. Internal Emory Offices working on institutional, compliance, and ethical guidance and best practices in this space
5. A Nationwide IRB Working Group comprised of members from peer institutions

**What this means for You as an IRB Member:**

1. Training is forthcoming on policies and guidance around the use of AI/ML/Big Data in research
2. Protocol templates will be revised to capture critical details
3. New IRB Members to be added with related expertise

Here is a link to [this month's IRB webinar](#) on the topic, which is also located on the [IRB website](#).

## **IRB Member Performance Evaluations (November 2023)**

For this month's Take 5, we wanted to provide an annual refresher on how the IRB evaluates member performance. As a reminder, assessments are not meant to be punitive! It is a part of our accreditation, and we use the feedback to look for gaps in understanding, opportunities for training, and so on.

**The evaluation process:**

**Who reviews performance?**

## **Member Recruitment**

**We need your help in recruiting new IRB members with expertise in:**

- Anthropology
- Cardiology
- Infectious Diseases
- Neurology
- Peds Oncology
- Pulmonology
- Sociology
- Solid Organ Transplant

Please [email Rebecca Rousselle](#) with your member recommendations!

- **IRB Member reviews are conducted periodically by the IRB Chair**, in consultation with the Institutional Official (IO) and the IRB Director.
- **Vice-Chair, Chair, and IRB Director reviews are conducted annually by the IO.**

**Performance feedback:**

- Feedback is provided in writing and may also be provided in person.
- Members, Vice-Chairs, and Chairs will be given formal feedback based on their performance evaluations; the IRB Director will provide this feedback.
- Additional, formal feedback to the Chairs will also come from the IO.

**The following categories are considered with the assessment:**

**Meeting contributions and attendance:**

- Preparedness for meetings
- Contribution to meetings
- Meeting attendance

**Reviews:**

- Quality of Reviews
- Timeliness of Reviews
- Number of Protocols Reviewed as a Committee Reviewer
- Number of Reviews Completed as Primary Reviewer

**Knowledge:**

- Knowledge of Organizational Policies and Procedures
- Knowledge of regulations and identification of areas for improvement

**Communication and engagement:**

- Communication with other members and IRB Staff
- Member Retreat attendance

**There are two key ways that IRB Members improve contributions to the IRB and their Committees:**

1. **Complete all assigned reviews in eIRB as soon as possible.** This allows for staff to get in front of any issues that may arise.
2. **RSVP to IRB Committee Meeting invites invite as soon as possible.** In some cases, we may need to find expertise and the more time, the better.

If you ever have feedback to provide about your experience as a member, let us know! 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.

**Device Determinations (October 2023)**

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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:

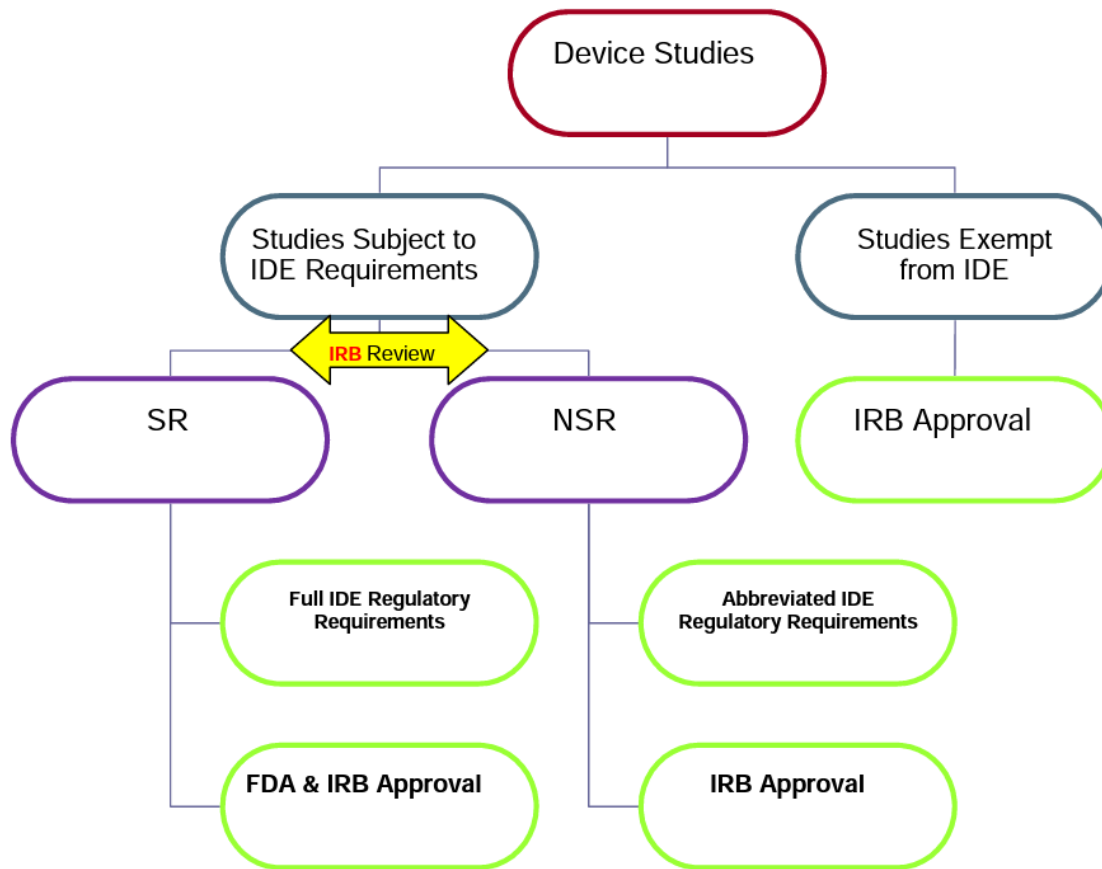
1. **Studies exempt from IDE requirements ("IDE Exempt"):** The Emory IRB Device Checklist in eIRB should indicate that the device, as used in this study, is "Exempt" from IDE requirements. If the IRB agrees that the study is exempt from IDE requirements, the IRB does **not** need to make a device risk 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.**

A helpful flowchart:




## 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, IHI, 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 Induced 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)

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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)

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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.

## **Reviewer Conflicts (June 2023)**

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**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 themselves 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 themselves 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.*

## Recruitment Methods (May 2023)

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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:

**TROUBLE SLEEPING? Try a new drug for insomnia!**

**So far, in patients we have studied, we believe Exonopin™ can reverse damage caused by lack of sleep.**

**Exonopin™**

**PARTICIPANTS RECEIVE A FREE SLEEP STUDY!!**

Contact the Study ~~Coordinator~~ for more information:  
 FDA.worstnightmare@example.edu

## Reviewing Continuing Reviews (April 2023)

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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)

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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

## Technical steps to review a modification in the system

The screenshot displays the IRB review system interface. At the top, a 'Next Steps' section includes a 'Review Study' button (marked with a blue arrow '1') and a 'Printer Version' button. A flowchart shows the process: Pre-Submission → Pre-Review → IRB Review, with 'Clarification Requested' loops between Pre-Submission and Pre-Review, and between Pre-Review and IRB Review. Below this, a 'Study Related Documents' section shows a 'Draft' document titled 'Tobacco Sales Laws and Teen Smoking Protocol.docx'. A 'Compare' dialog box is open, showing a comparison between the current state (0.3 Changes submitted to IRB) and a previous version (0.2 Submit to IRB, dated 4/19/2019 2:33:13 PM). The dialog indicates 'Changes found on 1 step:' and is marked with a blue arrow '2'. Below the dialog, a table lists documents, including 'Tobacco Sales Laws and Teen Smoking Protocol.docx(0.01)' with a 'View' link and a 'History' link (marked with a blue arrow '3'). A checkbox labeled 'Above section has been reviewed:' is present. At the bottom, a 'Changes found on 1 step:' section shows 'Basic Study Information' (marked with a blue arrow '5') and 'Study Funding Sources' (marked with a blue arrow '4').

### 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.

## 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
  - 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!

<p><input type="checkbox"/> <b>Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research (45 CFR 46.405 and 21 CFR 50.52).</b></p> <p>To approve research in this category, the IRB must make <b>all</b> of the following determinations:</p> <p><input type="checkbox"/> The research presents greater than minimal risk to the <u>children</u>; <i>Provide protocol specific findings to justify determination:</i></p> <p><input type="checkbox"/> The research presents the prospect of direct benefit to the individual subjects. <i>Provide protocol specific findings to justify determination:</i></p> <p>At least one of the following is true. (Check box that is true)</p> <p><input type="checkbox"/> The risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject.</p> <p><input type="checkbox"/> The risk to children is presented by a monitoring procedure that is likely to contribute to the subject's well-being. <i>Provide protocol specific findings justifying this determination:</i></p> <p><input type="checkbox"/> The risk is justified by the anticipated benefits to the <u>subjects</u>; <i>Provide protocol specific findings to justify determination:</i></p> <p><input type="checkbox"/> The relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative <u>approaches</u>; <i>Provide protocol specific findings to justify determination:</i></p> <p><input type="checkbox"/> Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408 or FDA regulations at 21 CFR 50.55. <b>[check even if waived]</b> <i>Provide protocol specific findings to justify determination:</i></p>	<p><input type="checkbox"/> Permission of <b>one parent</b> is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.</p> <p><input type="checkbox"/> Permission is to be obtained from <b>both parents</b> unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. <b>[If checked, make sure consent reflects this.]</b></p> <p><input type="checkbox"/> Parental permission is waived <b>[complete waiver of parental permission section below]</b></p>	<p><b>Check all that apply</b></p> <p><input type="checkbox"/> Assent will be obtained from some or all children and documented according to <a href="#">Emory's age-based guidelines or all children are younger than 6.</a></p> <p><input type="checkbox"/> The capability of some or all these children (<u>taking into account the ages, maturity, and psychological state of the children involved</u>) is so limited that they cannot reasonably be consulted.</p> <p><input type="checkbox"/> The intervention or procedure involved in the research 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. Thus, assent is not a necessary condition for proceeding with the research, but assent should be obtained when possible. <b>[For rare studies where this isn't granted, ensure <u>assent form cover page</u> is revised accordingly.]</b></p>
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**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):

<p><input type="checkbox"/> In my opinion, this child is unable or unwilling to provide informed assent for non-age-related reasons <b>and</b> 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.</p> <ul style="list-style-type: none"><li>• Reason(s): _____</li></ul> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Signature of person soliciting assent (if above box is <u>checked</u>)    Date    Time</p>
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## Meeting Agenda Process (January 2023)

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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.

## "Study Scope" for Drugs and Devices (December 2022)

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?

Device	Drug
<p><i>"Does the study evaluate <b>the safety or effectiveness</b> of a device or use a humanitarian use device (HUD)?"</i></p>	<p><i>"Does the study <b>specify the use of an approved or unapproved drug or biologic</b>?"</i></p>
<p>If the team answers "yes" - the device details and <a href="#">IRB Device Checklist</a> will be in the <i>Devices</i> smartform section.</p> <p>If the team answers "no" - the device should be described in the submission, but you will not see the <i>Devices</i> section.</p> <ul style="list-style-type: none"> <li>• Information can be in the protocol and in uploaded manuals.</li> <li>• The IRB should determine when it has enough information to assess the risks and benefits of the study.</li> <li>• Also, FDA regulations <b>may not</b> apply.</li> </ul> <p>Examples of when FDA regulations would generally <b>not</b> apply, and no Device section is required:</p> <ul style="list-style-type: none"> <li>➤ An FDA-approved device is used to test a physiologic principle, and no data is collected <i>about</i> the device;</li> <li>➤ An FDA-approved device is used to address a research question and no data is collected <i>about</i> the device; or</li> <li>➤ 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</li> </ul>	<p><b>Note:</b> FDA regulations generally always apply if a drug is being used as part of the research intervention, and the smartform answer should be "Yes."</p> <ul style="list-style-type: none"> <li>❖ <b>Exception:</b> If the study only involves collection of data from <b>Standard of Care treatment</b>, 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.</li> <li>❖ <b>Caveat:</b> if the study <i>assigns</i> participants to one or more "standard of care" treatments (i.e. a "comparative effectiveness" study), <i>the Study Scope question should be answered "Yes"</i></li> </ul>



Device	Drug
<p>the device, nor to support a new indication for marketing</p> <ul style="list-style-type: none"> <li>➤ 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)</li> </ul>	
<p><b>Definition:</b></p> <p>The term "<b>device</b>" 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:</p> <ul style="list-style-type: none"> <li>(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,</li> <li>(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</li> <li>(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.</li> </ul>	<p><b>Definition:</b></p> <p>The FDA defines a <b>drug</b>, 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.”</p> <p>*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.</p>

## Member Evaluation Process (November 2022)

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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.

## Clinical Decision Support Software (October 2022)

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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.

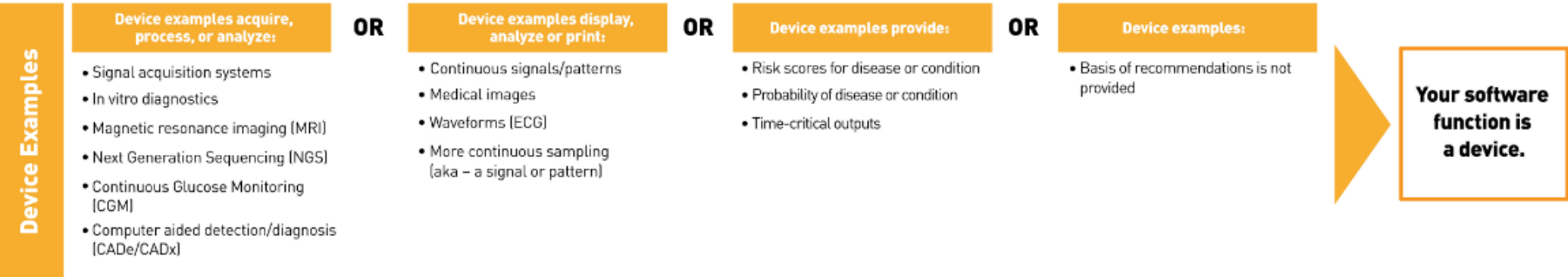
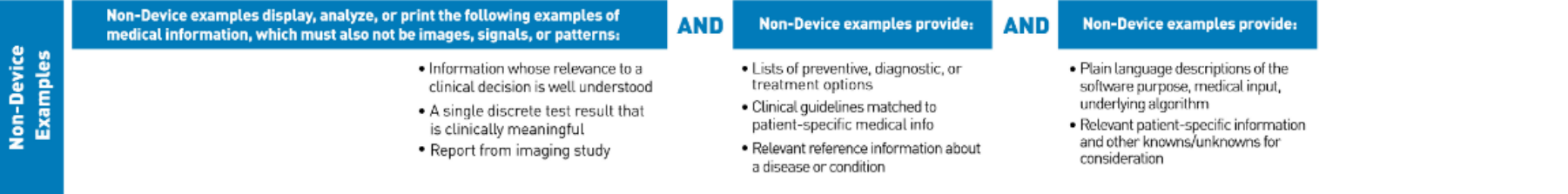
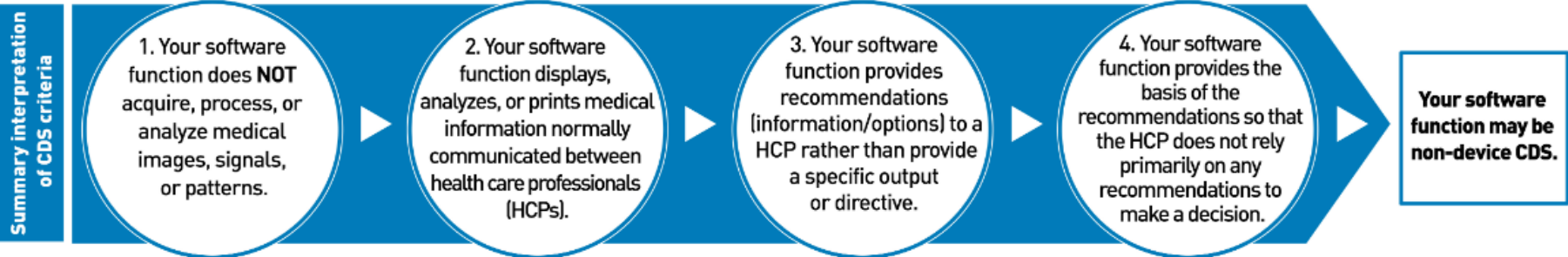
\*If all **four criteria are** met, the software function may be **non-device CDS**. If a study includes software that **does not meet the above criteria**, we will apply typical device determinations (e.g. "non-significant risk device").

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.



\*Disclaimer: This graphic gives a general overview of Section IV of the guidance (“Interpretation of Criteria in Section 520(o)(1)(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)

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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 a bit 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>
- 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)

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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)

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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

**Next Steps**

Review Study (1)

Printer Version

Submit Committee Review

Request Clarification by Committee Member

Assign to Non-Committee Review

Edit Pre-Review

Pre-Submission → Pre-Review → IRB Review

Clarification Requested

History Funding Contacts Documents IRB Assign

**Study Related Documents**

Draft

Tobacco Sales Laws and Teen Smoking Protocol.docx

Compare current state of version:

0.3 Changes submitted to IRB  
with  
0.2 Submit to IRB  
4/19/2019 2:33:13 PM

Changes found on 1 step:

**9. \* Attach the protocol:**

Document	Category	Date Modified	Document History
<a href="#">View</a> Tobacco Sales Laws and Teen Smoking Protocol.docx(0.01)	IRB Protocol	3/19/2019	History (3)

Above section has been reviewed:

Changes found on 1 step:

Basic Study Information (5)

Study Funding Sources (4)

## 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.

## **New Website Highlights (May 2022)**

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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)

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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)

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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.