NEW COMMON RULE IMPLEMENTATION @ EMORY

PART 2 OF 2

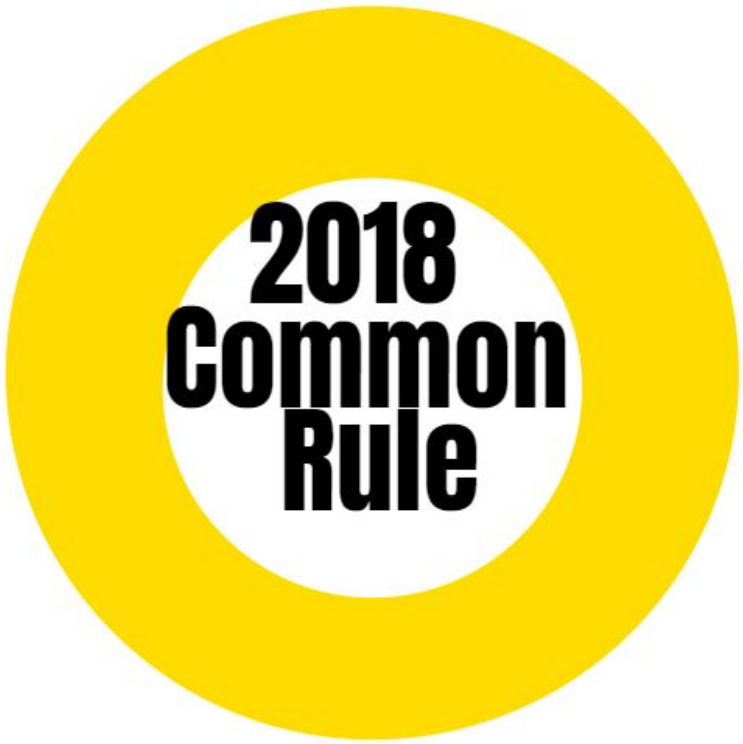
BEFORE WE START…

Disclaimer: we have a plan based on available information from OHRP and FDA. New information from these agencies may alter our plan. If so, we will promptly inform the community.

FDA release guidance we will go on detail in this presentation.

FDA guidance: Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations

TOPICS WE WILL COVER TODAY



- Background information
- High level details from past webinar
- Exempt research changes
- FDA alignment with Common Rule
- More information about IRB implementation
- Questions?

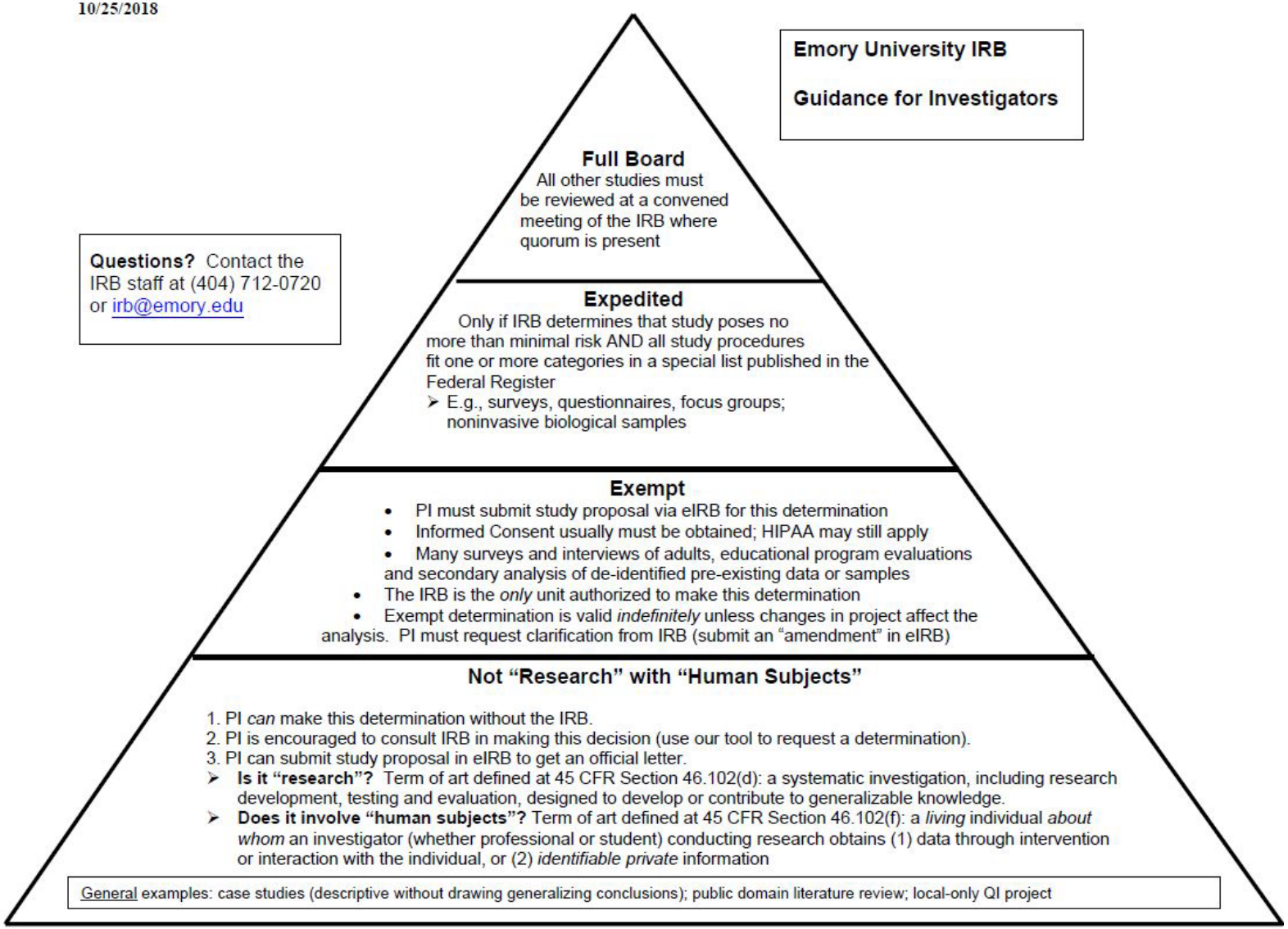
BACKGROUND INFORMATION- RECAP

- The 2018 Common Rule is effective on **January 21, 2019**
- Some of the changes will <u>not</u> impact investigators
  - E.g., pregnant women are no longer considered a "vulnerable population." This will not affect how you submit a study, but may change the way we document our IRB review
- What <u>will</u> affect investigators:
  1. New information required to be in the informed consent
  2. Continuing review of studies considered "minimal risk," and
  3. Expansion and changes in expedited and exempt categories.
- This webinar covers item #3 along with implementation plan
- We covered item #1 and #2 in last month's webinar, that can be found under at http://www.irb.emory.edu/Training/webinars.html

HIGH LEVEL DETAILS FROM PAST WEBINAR

- Consent will have new basic and additional sections, plus a more robust cover letter (key information section)
- Broad consent- subjects consent (or not) for a storage, maintenance, and secondary research on data and/or specimens will not be implemented at Emory for the time being!
- Screen prior to consent, collecting PHI: will not require consent but should be part of IRB approved research plan
- Requirement to post ICF in clinical trials.gov after clinical trial is closed for recruitment (no later than 60 days after the last study visit was completed)
- No more continuing review for studies considered minimal risk (**not applicable to FDA regulated studies**)

10/25/2018



EXEMPT CATEGORIES

Before we start, let's quickly review the research categories

EXEMPT CATEGORIES - CHANGES

- In case you notice a different Exemption naming convention (some IRB nerd information for you…)
  - The exempt categories were named after their section in the regulations , e.g., the exempt categories were under section B, and each category was named B1, B2, etc.
  - Now, the categories are under section D, so you will see these categories now be named as D1, D2, etc.
- In the following slides, we will use the new naming convention for each exempt category
  - New additions in **Green** (credit to Verrill Dana's redline unofficial final revised common rule doc)
- Interpretations may evolve after more guidance from OHRP

APPLICABILITY OF THESE CATEGORIES

- Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:
  - (1) Subpart B (fetuses and neonate research): Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.
  - (2) Subpart C (prisoner research): The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
  - (3) Subpart D (research with children): The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

EXEMPT CATEGORIES - CHANGES

D(1): Education-related research

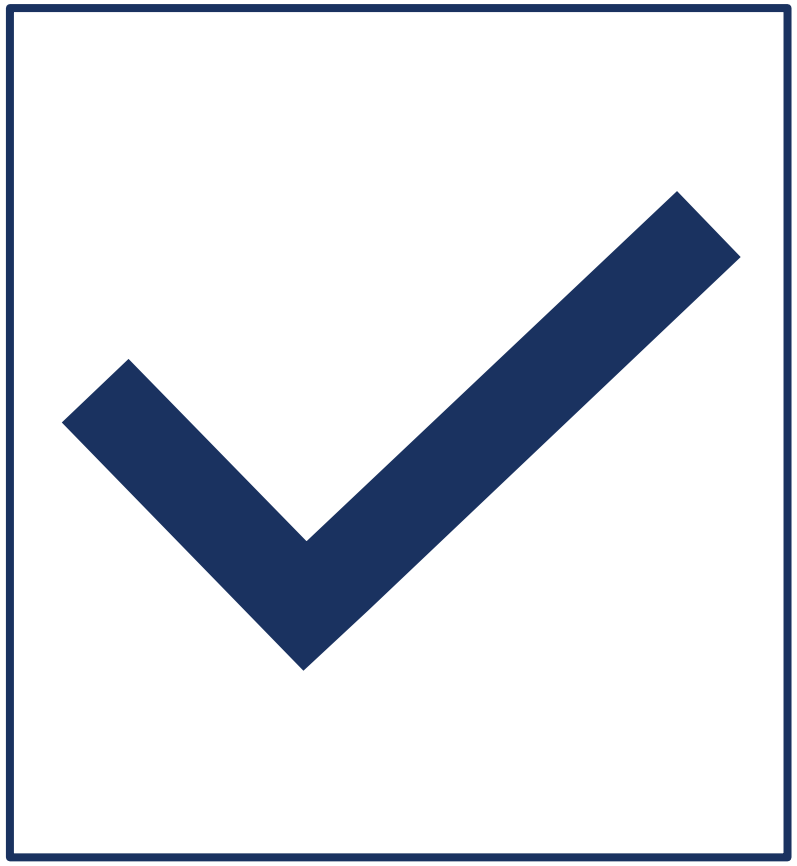
- Research, conducted in established or commonly accepted educational settings, **that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most** research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
  - How does this affect you?
    - Investigators will need to show that the proposed research will not impact students' ability to learn. Emory IRB interprets this as "substantive" impact.
    - Example: you are conducting a battery of tests that take the student out of the classroom for extended periods, which may impact student's learning time. Investigators would have to speak to that in protocol.

EXEMPT CATEGORIES - CHANGES

D(2): Surveys/interviews

- Research **that only includes interactions involving** educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public **behavior (including visual or auditory recording) if at least one of the following criteria is met:**
  - (i) The information obtained is recorded **by the investigator** in such a manner that **the identity of the** human subjects **cannot readily be ascertained**, directly or through identifiers linked to the subjects; *(Can be applied to research with children when the investigator(s) do not participate in the activities being observed)*
  - (ii) Any disclosure of the human subjects' responses outside the research **would not** reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or *(Can be applied to research with children when the investigator(s) do not participate in the activities being observed)*
  - **(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).** ***Cannot*** *be applied to research with children*

EXEMPT CATEGORIES-CHANGES



- **D(2)'s new criterion (iii):** allows the Exempt review of ***sensitive, identifiable*** data collection (via survey, e.g.) that previously required Expedited review
  - What does this mean for you? Not much – eIRB submission still required, and now no Continuing Review regardless of exempt vs. expedited for non-FDA studies
  - What is "Limited IRB review?
    - A review of confidentiality and privacy protections which must be done by an IRB member (could be IRB staff person who is also a member) – awaiting further guidance

EXEMPT CATEGORIES-CHANGES

New Category D(3)– a lot to unpack!

- **D(3)(i):** Research involving **benign behavioral interventions** in conjunction with the collection of information from an adult subject through **verbal or written responses** (including data entry) **or audiovisual recording** if the subject prospectively agrees to the intervention and information collection and **at least one** of the following criteria is met:
  - "no identifiers recorded" - (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
  - "identifiable but not sensitive" - (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
  - "identifiable ***and*** sensitive" - (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

EXEMPT CATEGORIES-CHANGES

D(3)(ii) – what are "benign behavioral interventions?"

(ii) For the purpose of this provision, **benign behavioral interventions** are:

- brief in duration
- harmless, painless
- not physically invasive
- not likely to have a significant adverse lasting impact on the subjects,
- and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Examples from the Regulations:

Having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

EXEMPT CATEGORIES-CHANGES

D(3)(iii) - Deception

- (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

EXEMPT CATEGORIES-CHANGES

D(4): Secondary research

- **Secondary research uses of identifiable private information or identifiable biospecimens for which *consent is not required* (though HIPAA may apply)…**

… if **at least one** of the following criteria is met:

- "identifiable but publicly available" - (i) The identifiable private information or identifiable biospecimens are publicly available;
- "no recorded identifiers" - (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects **cannot readily be ascertained** directly or through identifiers linked to the subjects, the investigator does **not contact** the subjects, and the investigator **will not re-identify** subjects;
- ***NEW*** "identifiable but covered by HIPAA" - (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [i.e. HIPAA] , for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
- "almost never happens" - (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information…

EXEMPT CATEGORIES-CHANGES

D(4)(iii) – secondary use that is covered by HIPAA

- **New** sub-category
- Previously required expedited review if identifiable data or specimens
- BIG CAVEAT: Emory's current HIPAA policy does **not** cover data or specimens once pulled into the research record, *unless* the research involves **treatment and billing,** so we would not be able to use this exempt category.
  - May be able to use if doing research within CHOA or Grady, depending on their HIPAA structure
- How this affects researchers: not really. Exempt or expedited studies require IRB approval and would not require continuing review.

EXEMPT CATEGORIES-CHANGES

D(5) and D(6) - did not change

D(7) and D(8) - involve the use of secondary data for which **broad consent** was obtained

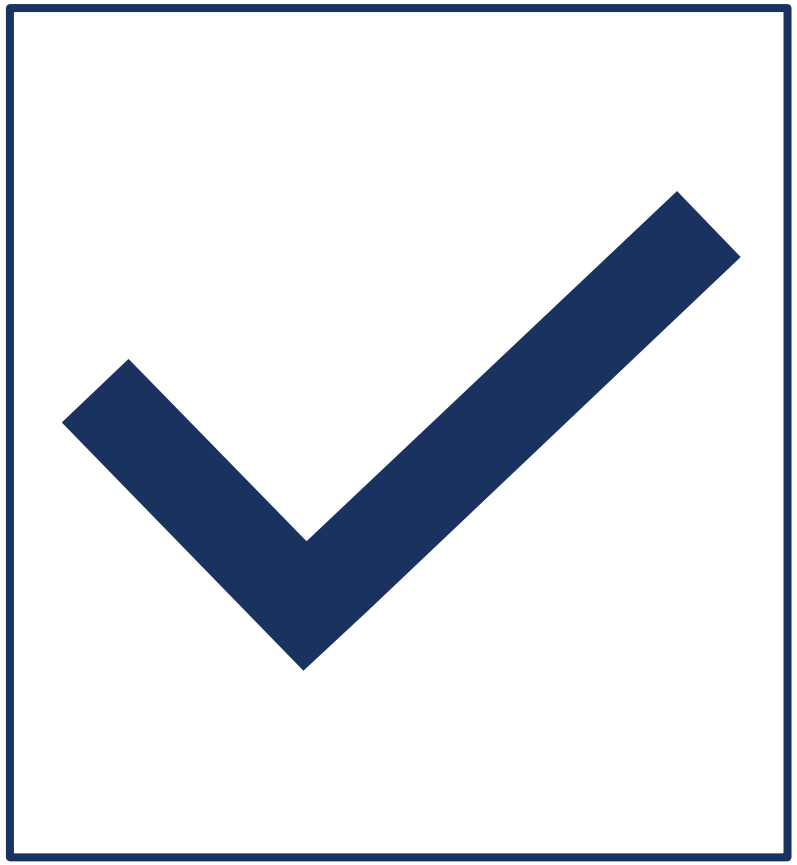
Emory is not yet implementing IT changes that would allow us to implement Broad Consent, or therefore these categories

FDA HARMONIZATION WITH THE COMMON RULE?

- The FDA released guidance dated October 2018, explaining their compliance plan
- FDA expected to propose changes within the next year
- In the meantime:
  - **Informed Consent Forms**: Common Rule changes are *not inconsistent* with the FDA regs – so you can use one set of consent templates for all studies
  - **Expedited review**: IRB still must find study to be "minimal risk" (new Common Rule just requires that study fits into at least one Expedited Review category)
  - **Continuing review**: IRB must review at least annually until study closes

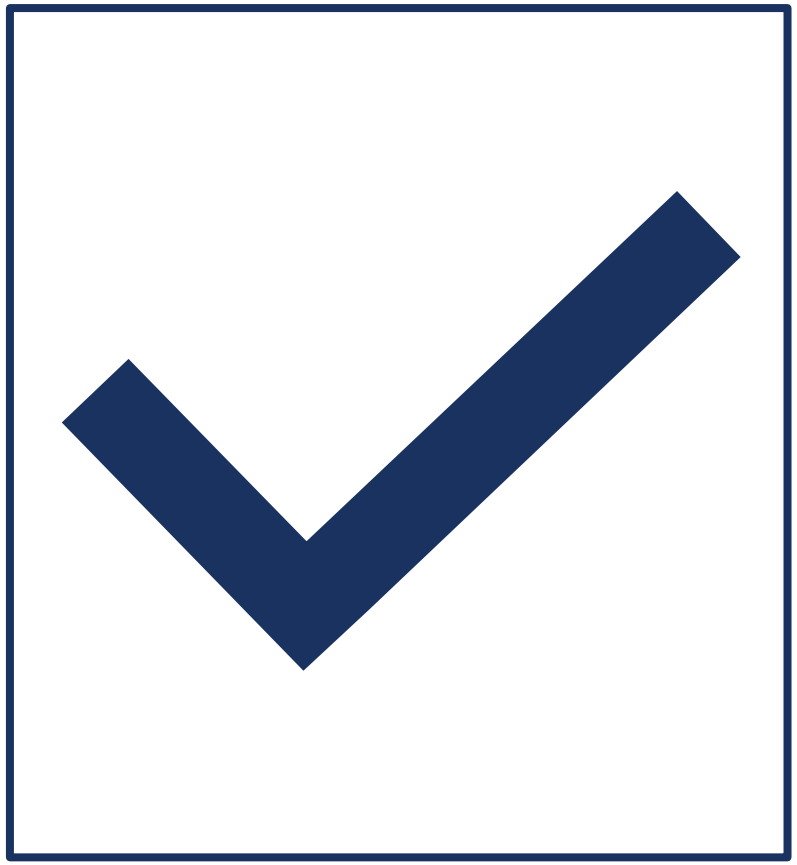
Fogler, E; Rusczek, A: Tag, You're It: FDA Issues Guidance Ahead of Revisions to its Human Subjects Protection Regulations

EMORY IRB IMPLEMENTATION: CURRENT PLAN



- For studies approved before 1/21/19:
  - IRB will eventually ***require*** transition of studies to new Rule if:
    - Not obtaining consent (or no longer obtaining consent) – e.g. chart reviews, or in data analysis or Long-Term Follow Up only, **and**
    - NOT FDA REGULATED
  - Other study teams can ***request*** transition via amendment, and update consent form(s)…
    - …not FDA-regulated, and
    - …study will continue for multiple years, and
    - …eliminating Continuing Review would thus be worth the effort
    - *Consider cost/benefit to transitioning*

EMORY IRB IMPLEMENTATION: CURRENT PLAN



- IRB is posting a new template for all of our consents in December (stay tune!). We are awaiting OHRP guidance.
- Our eIRB system is ready to go! If you have a study submitted by January 1, you will be asked to complete the new eIRB version.

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QUESTIONS?