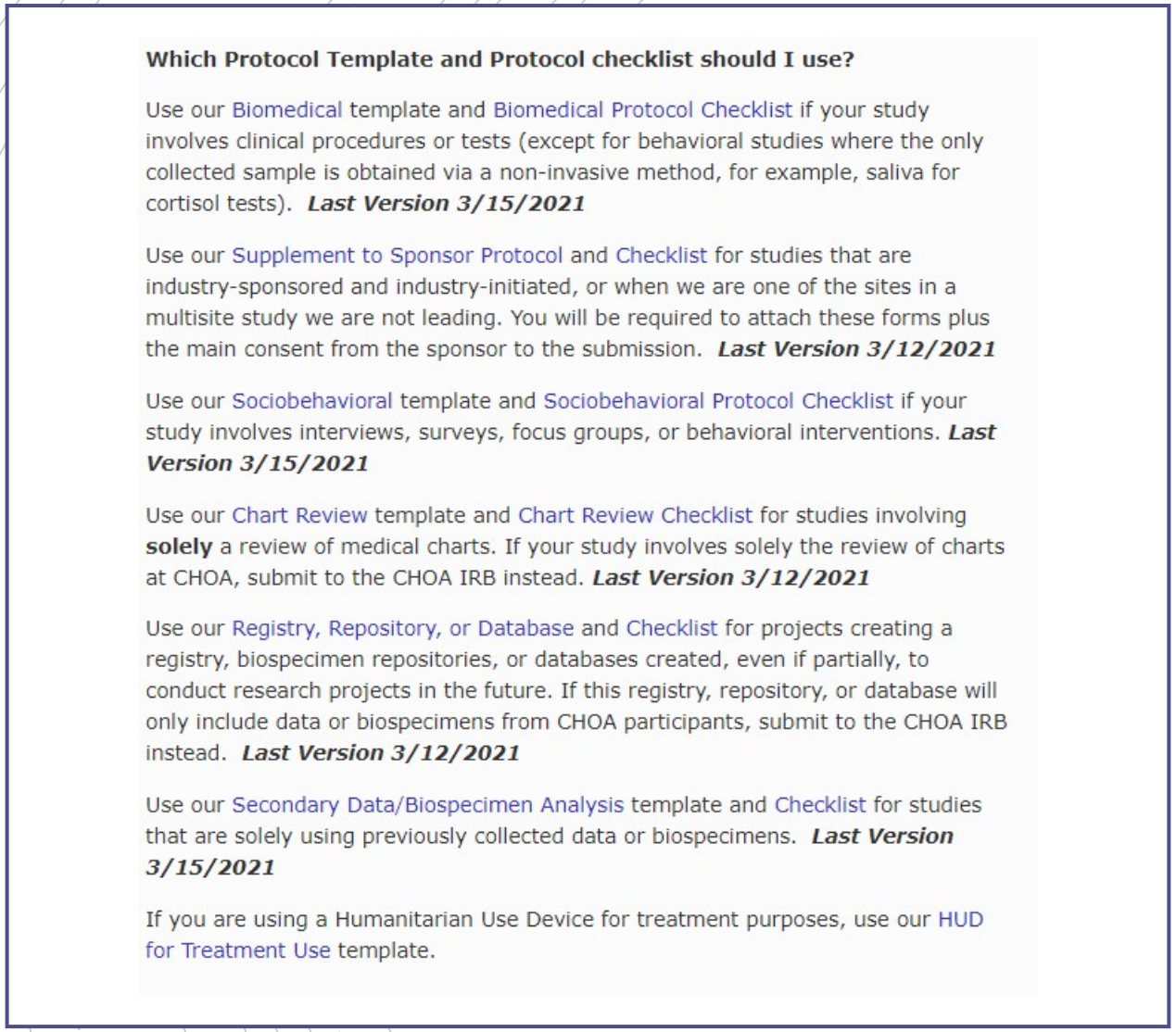
General IRB Updates

IRB Webinar- 4/15/2021

Today's Updates

- New Protocol Templates
- New DSMP Guidance
- Confidentiality and Emails
- LITS-approved List of Software/Apps
- HIPAA Guidance Revisions
- Hashtag and Research Recruitment
- DocuSign News
- Monitor Reports at CR time



Which Protocol Template and Protocol checklist should I use?

Use our Biomedical template and Biomedical Protocol Checklist if your study involves clinical procedures or tests (except for behavioral studies where the only collected sample is obtained via a non-invasive method, for example, saliva for cortisol tests). ***Last Version 3/15/2021***

Use our Supplement to Sponsor Protocol and Checklist for studies that are industry-sponsored and industry-initiated, or when we are one of the sites in a multisite study we are not leading. You will be required to attach these forms plus the main consent from the sponsor to the submission. ***Last Version 3/12/2021***

Use our Sociobehavioral template and Sociobehavioral Protocol Checklist if your study involves interviews, surveys, focus groups, or behavioral interventions. ***Last Version 3/15/2021***

Use our Chart Review template and Chart Review Checklist for studies involving **solely** a review of medical charts. If your study involves solely the review of charts at CHOA, submit to the CHOA IRB instead. ***Last Version 3/12/2021***

Use our Registry, Repository, or Database and Checklist for projects creating a registry, biospecimen repositories, or databases created, even if partially, to conduct research projects in the future. If this registry, repository, or database will only include data or biospecimens from CHOA participants, submit to the CHOA IRB instead. ***Last Version 3/12/2021***

Use our Secondary Data/Biospecimen Analysis template and Checklist for studies that are solely using previously collected data or biospecimens. ***Last Version 3/15/2021***

If you are using a Humanitarian Use Device for treatment purposes, use our HUD for Treatment Use template.

New Protocol Templates

- Posted on our Website
  - Added details for DSMP
  - Added recruitment requirements
  - New, clean template.
  - Removed comments and instructions are in green so they can be easily identified and removed
- These templates are required for new study submissions and do not affect already approved submissions.

DSMP Guidance

Posted on our website under “DSMP, Site Monitoring and DSMB Guidance”

New? No, just clearer information for research teams and IRB members

New definition for studies reviewed at Full Board

Medium Vs. High complexity

Studies require adequate site monitoring according to participants’ risk level.

Confidentiality and Emails

- Emails containing PHI or IIHI should be encrypted.
  - This may include sending a consent to a potential participant that enrolls people with a certain condition
  - Instructions here.
- Avoid sending mass emails when possible.
- If sending a mass email using BCC and verify before sending!
  - Errors in this area may require an RNI if confidentiality is negatively affected
- Have you identified an error? Contact our QA/QI staff for next steps or submit an RNI

LITS-approved List of Software/Apps

- We retired the IRB form and instead we are directing you to LITS page
- They will be updating this list moving forward and adding more apps/software as they become available
- Find the complete list here.

HIPAA Guidance Revisions

- Our guidance was recently updated to add additional information that may be of use when submitting your new study to our IRB
  - Emory Autism Center is now part of the covered entity (for information not covered by FERPA)
  - Further clarified that if a study includes activities that are not done because of the research, even if you these activities are done for billing or treatment, the study records will not be covered by HIPAA
    - All studies are covered by the IIHI Emory policy (5.23), so the participants' information is always protected
- Questions? Please email us at irb@emory.edu!

Hashtag and Research Recruitment

- Be aware of using a hashtag (#) when promoting research studies on social media!
- The FDA and the FTC find unlawful to advertise a product as if it can prevent, treat, or cure human disease before being FDA approved.
- The # cannot claim that this is #thebestproductever or say that the product #curesCOVID19.
- You will not be affected by participants misuse of hashtags but if you are aware, you should ask them to stop.

Reference: https://www.jdsupra.com/legalnews/can-hashtags-get-you-in-trouble-4092689/

DocuSign News

DocuSign (non-Part 11) is now free to use for all Emory University staff and faculty.

Emory Healthcare personnel can sign an envelope, but cannot send envelopes with the DocuSign enterprise agreement

Part 11 DocuSign is available at reduced price per envelope

Find more information here under “Electronic Signatures for electronic informed consent”

Monitor Reports at CR Time

You have been required to send your monitor reports to CTAC for studies conducted at our institution, even if not approved by our Emory IRB (WIRB, CIRB and other IRBs by agreement)

At ctcompliance@emory.edu.

To ensure compliance, the IRB staff will request confirmation that monitor and self-monitoring reports (as part of a DSMP) have been received by CTAC before the CR is reviewed.

Your Questions