Rebecca Gibson

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Monday, September 21, 2020 5:13 PM
To: Mercedes Livingston; Kandy Downs; Brook Jackson; William Jones
Subject: Common findings/Action Plan- all sites

This is really rough- I had so many distractions trying to type this up, but hopefully, it's a helpful start:

Finding of Concern:	Details of Findings:	Solution (QUICK FIX):	Comments:
HIPAA Violations	Sites not consistent with protecting PHI- PHI left on desks (FW front desk example); patient schedule with patient names left on counter faced up; patient folders out on counters in the clinic and faced up with names visible; emails with patient names in the subject line.	1. RDs to observe and correct at sites when onsite- discuss/re-educated with employees at the site as concerns are found. 2. "Audit Readiness" training- I think we still need this for sites quickly, and we HIPAA can be included.	Where are we with HIPS training?
Outdated Protocol Pages in Patient Folders	Sites are not keeping the Schedule of Events pages in the patient folders current and some copies are so poorly printed that they are completely illegible, defeating the purpose of them being placed in the chart.	1. Pull all protocol pages out of all charts. 2. Reassess the process for future studies.	
AEs Not Reported	AEs from diary entries are not being reported correctly or at all- 1. Protocol is unclear; 2. Conflicting information received from Pfizer	1. We need to get an official direction from Pfizer. Email from ICON received but the email was not clear as well and not an official "Clarification" or "Addendum" or even a "Memo". 2. For now, we should follow the protocol as to how we read it and record any AEs ASAP- may need to split the patients up for staff to verify. 3. Anyone doing QC should be looking for potential AEs not caught during study visits and flag them for correction.	Email from ICON dated 8/17/20. FUTURE: revise AE log

		4. Once we have clarification- train all staff.	
Injection Wait Time Discrepancy (<30 mins)	Injection wait times have been found to be less than 30 mins without any explanation.	1. Site staff needs to correct ASAP- add a note to explain why the time was less than 30 mins and submit deviations accordingly. 2. We need an NTF to explain that we caught the errors and implemented an action to prevent this moving forward, for example, FW implemented the use of timers.	Long term- need to conduct re-training on why this is so critical
IP Storage	IP rooms are disorganized, drug/placebo and saline are not being kept locked- no double lock in place at Keller or FW? Not sure about Houston. Keller had kit #s that were transcribed incorrectly and a CAPA was written.	1. RDs and staff at site to get these rooms cleaned up and organized; drug locked up and keys place in a separate place than the IP room and secured- need to have documentation of this process as well- who has keys, etc. 2. Keller- quick fix for a double lock is to place all loose drug currently in the refrigerator in locked boxes as well- the freezer is already a double-lock system.	Long term- get locks placed on doors to IP room.
Informed Consent Errors	1. Consent being done during the protocol-required "5 mins of wait time". 2. Paper consents used were not being scanned into eConsent. 3. Several of the paper consents that were used, as opposed to electronic, were printed with a large number of artifacts on the copies and appeared to have wording present that truly wasn't present. 4. Some consents were printed or copied with the footers missing. 5. Consent process page- inconsistently being filed with visit and sometimes with consent.	1. NEED CLARIFICATION IF THIS IS OKAY OR NOT (#1). If not, we need staff to explain the atmosphere and patient status during the consent process and complete deviations if warranted. 2. Need to scan in all paper consents to eConsent ASAP, if not done already. 3. Correct consent issues and note changes being made in progress notes where needed. NTF for	Long term- re-training as stated above, on documentation practices. Change process for process page of consent- consider adding this as page 1 of ALL consents, versus the visit source.

	6. Amendment #6- I'm told some patients are not being re-consented, but it sounds like it's required?	errors and corrective action?? 4. Confirm if re-consent is needed for Amend #6. 5. Document re-training	
Progress Notes	1. Inconsistencies in its use and doesn't always match what's being documented in the source. 2. Progress Note form requires a "time" in the header but time is not being recorded.	1. Flag corrections needed to notes 2. Remove "time" and state "N/A"?	Future- suggest creating a progress note page specific to each visit, as opposed to one running log.
Source Errors	1. Contraception Check: "NA" checked for menopausal/hysterectomy patients but the signature at the bottom of this section is also signed, which states a "subject agrees to maintain birth control, etc."	1. V2 Source: For patients who are confirmed to be post-menopausal or have had a hysterectomy- cross through signature and write "error- the patient is confirmed to be post-menopausal, etc.. or "error- the patient has had a hysterectomy". 2. V1 Source: same section but also has investigator signature- handle in the same manner.	Long Term- re-create source templates
Other Findings	2. Sticky notes on top of the patient charts not being consistently completed. 3. Deviations- not sure they are getting completed or not- need to verify all items above mentioned. 4. Visit 2s- some are out of window due to staff following CC which hadn't been updated until 9/18/20.	3. Charts are being flagged to complete sticky notes- reeducating staff as well to always complete this. 4. CC has been updated, need to verify upcoming V2s are in window- if many deviations, may need to do a NTF to explain why they were out of window?	Overall training needed- Research 101 training, in particular documentation practices.

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