1. PURPOSE

1.1. This guidance provides information regarding change to the Common Rule effective January 21, 2019.

2. BACKGROUND

2.1. Changes to the Common Rule, the primary rule regulating human subjects research, are effective January 21, 2019. This document and FAQs will be updated as new information and guidance becomes available. Please note that, at AdventHealth Orlando, only federally funded/conducted studies initially submitted on or after 1/21/19 will be governed by the new rule at this time.

2.2. As a result of the Common Rule changes, combined with our brand name change and other minor updates, a number of AdventHealth Orlando IRB policies, procedures, and documents have been updated. Investigators will see a number of changes required as follows below. These changes are reflected in our revised documents i.e. consent templates. The AdventHealth Orlando IRB protocol and consent form templates will be uploaded into IRBNet soon and may be used immediately. **These revised templates must be used for any new studies submitted on/after 2/11/2019.**

3. GUIDANCE

New	Studies Utilizing External IRBs	Federally funded Studies <u>initially</u> submitted on/after 1/21/2019	Non-Federally Funded Studies <u>initially</u> submitted on/after 1/21/2019	Existing Studies on/after 1/21/2019*
Brand Name Change AdventHealth Orlando replacing Florida Hospital	Required	Required	Required	Recommended when submitting informed consent or other participant facing documents for revisions.
AdventHealth Memo in IRBNet	Refer to External IRB Policies	n/a	n/a	Use recommended up until which time the consent form is submitted with revisions to the IRB.
New Consent Element: A concise summary of study activities, risks, and benefits presented to research participants in advance of the body of the consent document.	Refer to External IRB Policies	Required	Not Required	Not Required

New Consent Element: **<u>One</u>** of the following: a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility **-OR-** b) The subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.	Refer to External IRB Policies	Required	Required	Recommended.
New Consent Elements: Additional Disclosures to be included <u>when appropriate</u>: • For research involving biospecimens, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. • A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions	Refer to External IRB Policies	Required	Required	Recommended

• For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)				
AdventHealth IC Template Employee Language HIPAA Language (refer to HRP-507)	Required	Required	Required	Required

*** The IRB will not require re-consent, except when other significant changes are made.**

4. REFERENCES

4.1. 45 CFR §46.116