1. PURPOSE

1.1. This guidance provides information regarding changes to IRB protocol and consent templates effective January 30, 2019.

2. BACKGROUND

2.1. Changes to the Common Rule, the primary rule regulating human subjects research, are effective January 21, 2019.

2.2. As a result of the Common Rule changes, combined with our brand name change and other minor updates, our templates have been revised. The AdventHealth IRB Orlando 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 February 11, 2019.**

3. GUIDANCE

3.1. Protocol templates

3.1.1. Documents affected:

3.1.1.1. HRP-504 TEMPLATE Protocol – Prospective & Retrospective
3.1.1.2. HRP-504 A TEMPLATE Protocol Supplement

3.1.2. Important revisions:

3.1.2.1. Improved sections with clarifications and/or new instructions:

3.1.2.1.1. “Research Intervention Description”
3.1.2.1.2. “Non-English Speaking Subjects”
3.1.2.1.3. “Data Confidentiality, Storage, and Retention”

3.2. Consent templates

3.2.1. Documents affected:

3.2.1.1. HRP-500 TEMPLATE Consent
3.2.1.2. HRP-501 TEMPLATE Consent for Minimal Risk Research

3.2.2. Important revisions:

3.2.2.1. New branding name change and contact information.
3.2.2.2. New consent elements:

3.2.2.2.1. A concise summary in advance of the body of the consent document required for federally funded studies.
3.2.2.2.2. A statement whether information or biospecimens collected as part of the research, with identifiers removed, will be used for future research studies.
3.2.2.2.3. When appropriate, 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.
3.2.2.2.4. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
3.2.2.2.5. 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)

3.2.2.3. New statement to include for research that involves questionnaires which ask about physical/emotional wellbeing.
3.2.2.4. Suggested language when the study involves genetic research (GINA)
3.2.2.5. Suggested language concerning NIH Certificates of Confidentiality
3.2.2.6. Additional language to “Are there any costs in this study?” section.
3.2.2.7. New section “Will I be paid for taking part in this research?”
3.2.2.8. Improved signature pages regarding witness signature.

4. REFERENCES

4.1. HRP-828 INVESTIGATOR GUIDANCE: Common Rule 2019