Summary of Changes to the UMC IRB Policies and Procedures

1. Section 3 MEMBERSHIP:
    a. change members recommendations for appointment by the IRB Chair - remove majority vote of the IRB members
    b. changed UMC administration can be appointed as voting members - remove ex-officio, non-voiting members
2. Section 4 SIGNATORY AUTHORITY:
    a. added electronic signatures
    b. added designated reviewers
3. Section 11 EXPEDITED REVIEW
    a. added designated reviewer can approve expedited reviews
    b. Removed that a research protocol that has been intially approved by full-borard may not be reviewed by the expedited review procedure
4. Section 12 NCI CIRB INDEPENDENT MODEL
    a. Added the following language that the UMC IRB will defer to the NCI CIRB:

    " In such cases where University Medical Center of Southern Nevada has a Consortium Agreement with an independent signatory of the NCI CIRB the independent signatory will add the University Medical Center of Southern Nevada to their NCI CIRB Affiliate Agreement. NCI CIRB will serve as the IRB of record for the University Medical Center of Southern Nevada for NCI-sponsored Cooperative Group Human Subjects Research under that Affiliation Agreement. The CIRB does not approve the HIPAA Authorization language as it does not function as a Privacy Board, as such, the UMC IRB will provide separate approved HIPAA Authorization language.

    In cases where University Medical Center of Southern Nevada does ***not*** have a Consortium Agreement with an independent signatory of the NCI CIRB the following will apply:"

5. Section 14 EXEMPT FROM IRB REVIEW - added designated reviewer to be able to make determination
6. Section 15 COOPERATIVE APPROVAL - is this section necessary? Why does the IRB have to authorize anything? We are not engaged in research. Can we change to notifiy?
7. Section 18 VULNERABLE POPULATIONS; Research involving: Children
    a. added Subpart D
    b. added the specific regulation and updated OHRP language
8. Section 30 INVESTIGATOR RESPONSIBILITIES
    a. Remove unessecary language regarding exempt research
    b. Addeded Resident to Student section and moved requirement that they can only serve as a Co-I
    c. Added language for research team member requirements
9. Section 35 - updated Education for CITI requirements

10. All references to University of Nevada School of Medicine (UNSOM) have been replaced with University of Nevada, Las Vegas School of Medicine (UNLV SOM)
11. New Process for NIC CIRB deferred studies:
    a) Research that falls under a Consortium Agreement with an independent signatory of the NCI CIRB where the NCI CIRB will serve as the IRB for the University Medical Center of Southern Nevada for NCI-sponsored Cooperative Group Human Subjects Research.
    b) When the first subject is put on protocol at UMC the signatory PI will submit the following to the Clinical Trials Office at UMC:
        a. A copy of the NIC CIRB approval letter
        b. A signed copy of the Informed Consent Form(s), including any assents and HIPAA Authorization form(s)
        c. A detailed list of any items and services that are to be billed to the research study
    c) For additional subjects enrolled on an existing study at UMC the signatory PI will submit the following to the Clinical Trials Office at UMC:
        d. A signed copy of the Informed Consent Form(s), including any assents and HIPAA Authorization form(s)
        e. A detailed list of any items and services that are to be billed to the research study