MEMORANDUM

To: Tulane Research Community
From: Roxanne R. Johnson, MSPH, CHRC
      Director of Human Research Protection Office
Date: December 4, 2017
Subject: Revisions to HRPP SOPs

An updated version of the Tulane University Human Research Protection Program (HRPP) Standard Operating Procedures (SOPs) has been posted (we need to include the appropriate link) as well as include in IRBManager for quick reference.

If you have any questions regarding the changes to the SOPs, contact the Tulane University Human Research Protection Office (HRPO) at irbmain@tulane.edu or 504-988-2665.

An overview of the changes to the SOPs is detailed below:

General Changes

1. Editorial and administrative updates have been made throughout.
2. Links to federal regulations and guidance are embedded throughout the entire document.
3. Glossary was updated to reflect new definitions.

Section 1

1. Definitions were added to Section 1.4.
2. Information regarding DoD regulations was added to Section 1.6.
3. Section 1.9 was extended to Engagement; the new title of this section is “Research under the Auspices of the Institution and Engagement.”
4. Section 1.13.1.1 was updated to include a new HRPO position; IRB Quality and Compliance Advisor.

Section 2 – “Quality Assurance/Quality Improvement Activities” was embedded throughout the last version of the SOPs. This is now a new section to clarify the establishment of quality assurance/quality improvement in the HRPP.
Section 3 – “Education and Training” was embedded throughout the last version of the SOPs. This is now a new section to clarify the establishment of education and training in the HRPP.

Section 4 – updated the following information:

1. Tulane also utilizes the services of off-site IRBs, including:

   - **National Cancer Institute (“NCI”) Adult Central IRB (“CIRB”)**: for applicable cooperative oncology group Protocols involving adult subjects.
   - **National Cancer Institute (“NCI”) Pediatric Central IRB (“CIRB”)**: for applicable cooperative oncology group Protocols involving Minor subjects.
   - **IRBchoice/SmartIRB**: for applicable national IRB reliance initiative studies.
   - **Independent (commercial) IRBs**: this option is available to Tulane investigators who conduct industry-initiated, industry-sponsored research activities, when use of independent IRB is required by the Sponsor of a particular proposed study or if such reliance benefits TU, its investigators, and/or the research participants. (see section 8.21) for more details.

2. Section 4.2.3 was revised to clarify the roles of IRB Members.
3. Section 4.2.4 was revised to clarify Alternate Members.
4. Section 4.5.3 was added for IRB Registration Updates.
5. Section 4.6 has been updated to clarify the Conflicts of Interest policy for IRB Members.

Section 5 was embedded throughout the last version of the SOPs. This is now a new section for the establishment of the new IRB Electronic System.

Section 6 has been updated to clarify “Human Subjects Research and Engagement Determination.”

Section 7 was embedded throughout the last version of the SOPs. This is now a new section for Exempt Studies.

Section 8

1. Section 8.2 has been updated to include definitions.
2. Section 8.3.2 has been updated to be consistent with the new application names in IRBManager.
3. Sections 8.4.7 and 8.4.7.1 have been updated to clarify IRB Meeting Procedures.
4. Section 8.5.1 has been updated to clarify the role of the IRB with regards to Risk-Benefit Assessment.

5. Section 8.5.6.1 has been updated to include a definition.

6. Section 8.6.5 has been added to include Investigator Qualifications.

7. Section 8.6.7 has been added to include Institutional Conflicts of Interests.

8. Section 8.7 has been added to include Social Media.

9. Section 8.9 has been added to include Non-Monetary Gifts and Incentives.

10. Section 8.11 the possible IRB actions has been updated to Conditions Required for Approval.

11. Section 8.11.2 Approval with Conditions has been changed to Conditions Required For Approval.

12. Section 8.13.2 has been update to clarify minor changes.

13. Section 8.14 was removed from the previous section and added to this section.

14. Section 8.17 was embedded throughout the last version of the SOPs. This is now a new section to clarify failure to submit a response to IRB requirements.

15. Section 8.18 has been updated to clarify the Investigator Appeal Process.

16. Section 8.19 has been added to clarify Research Previously approved by another IRB.

17. Section 8.20 was embedded throughout the last version of the SOPs. This is now a new section to clarify the Use of Centralized Institutional Review Board (CIRB).

18. Section 8.21 was embedded throughout the last version of the SOPs. This is now a new section to clarify the Use of External IRBs.

Section 9 was updated to clarify Study Suspension, Termination and Investigator Hold.

Section 10

1. Section 10.11.1 was updated to include FDA Access to Results of Quality Assurance Program Audits and Inspections.

Section 11

1. Section 11.2 was updated to include definitions.

2. Section 11.6 was added to include “Determining a potential adult subject’s ability to consent to Research.”
3. Section 11.9.2 was updated to include additional information on “Electronic Informed Consent.”
4. Section 11.10 was updated to include additional information on “Special Consent Circumstances.”
5. Section 11.16 was updated to include recent FDA changes.
6. Section 11.17 was updated to include recent FDA changes.

Section 12
1. Section 12.9.2 was updated to include specific FDA and OHRP regulations for the allowable categories for research that involves children.

Section 13
1. Section 13.2 was updated to include a definition.
2. Section 13.5 was revised to include additional information regarding “Investigator Responsibilities.”
3. Section 13.9.2 was updated to include a definition.
4. Section 13.9.5.1 was updated to include a definition.
5. Section 13.9.8 was updated to include additional information.

Section 14 was previously included in another section and is now a new section, entitled “Reportable Events”.

Section 15 was previously included in another section and is now a new section, entitled “Unanticipated Problems Involving Risks to Subjects or Others.”

Section 16 was previously included in another section and is now a new section, entitled “Non-Compliance with the Requirements of the HRPP.”

Section 17 was previously included in another section and is now a new section, entitled “Complaints.”

Section 18 title was changed to “Reporting to Regulatory Agencies and Organizational Officials.”

Section 19 was updated to clarify “Investigator Responsibilities.”

Section 21 was updated to clarify “Conflicts of Interest and Institutional Conflicts of Interest in Research.”
Section 23 was updated to clarify “Health Insurance Portability and Accountability Act (HIPAA).”

Section 24 was added to clarify “Off-Site Research, Collaborative Research, IRB Authorization Agreements, Local Context, International Research, and Research with Department of Defense (DOD).”

Section 26 was previously embedded in another section and is now a new section, entitled “Information Security.”

Section 27

1. Section 27.5 has been updated regarding Certificate of Confidentiality (CoC).
2. Section 27.11 has been added to clarify “Public Registration of Clinical Trials in www.ClinicalTrials.gov.”
3. Section 27.16 has been added for the “Establishment and Use of Research Repositories.”
4. Section 27.17 new section for “Compliance with the National Institutes of Health Genomic Data Sharing (GDS) Policy”.

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