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<tr>
<th>Policy Section</th>
<th>Type of Change</th>
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<tr>
<td>Title Page</td>
<td>Program and Policy Title Name Change</td>
<td>Human Research Protection Program (HRPP) July 2021</td>
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<tr>
<td>3.1 IRB Reliance Agreement with USC</td>
<td>Addition</td>
<td>SMART IRB will be used as the primary reliance agreement when USC IRB is serving as the IRB if record. If the relying institution is not associated with SMART IRB, the USC IRB Authorization Agreement form will be completed. (3.05.2021)</td>
<td>58</td>
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<tr>
<td>3.1 NIH Single IRB Mandate</td>
<td>Revision</td>
<td>USC IRB will act as the single IRB (sIRB) for full board multi-site studies of no more than 5 participating sites (including USC) due to limited resources. Maximum number of participating sites for expedited and exempt studies will be determined by the IRB on a case by case basis. (8.21.2020)</td>
<td>59</td>
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<td>5.3 Length of Service</td>
<td>Addition</td>
<td>Evaluations of IRB composition and <em>formal evaluation</em> of individual members are conducted at the end of the fiscal year at the time of IRB budget review/approval. (8.31.2020)</td>
<td>83</td>
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<td>5.3 Evaluation of IRB Members</td>
<td>Addition Clarification</td>
<td>This section has been revised to clarify the process of evaluation of IRB members (8.31.2020)</td>
<td>85</td>
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<td>5.6 IRB Chairperson – Duties</td>
<td>Addition</td>
<td>The Chair of the IRB convenes and runs the meetings of the IRB. <em>The Vice Chair, or the Director of OPRS will be assigned to Chair an IRB meeting when the Chair is unable to conduct the meeting.</em> (1.14.2021)</td>
<td>89</td>
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<tr>
<td>6.1 Human Subjects Research - Distinctions between biomedical and social behavioral research</td>
<td>Addition</td>
<td>This section has been added to provide direction for defining research and determining proper submission to the Biomedical IRB or the Social-behavioral IRB. (9.27.2020)</td>
<td>102</td>
</tr>
<tr>
<td>7.3 Criteria for IRB Approval of Research – Grant and Contract Submissions</td>
<td>Addition Revision</td>
<td>Grant and Contract Only submissions will be acknowledged when necessary to satisfy a funding sponsor. As these projects lack definite plans for involvement of human subjects, a new application must be submitted and approved by</td>
<td>134</td>
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<td>Section</td>
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<tr>
<td>9.1 The Process of Consent - Translation of Consent Forms into Languages Other than English</td>
<td>Revision</td>
<td>Translation of Consent Forms into Languages Other than English section was moved from 9.12 to 9.1. It is the responsibility of the investigator or study sponsor to provide translation of an IRB approved Informed Consent Form (ICF). For studies that are greater than minimal risk (Full Board), one of the following is required: a) A Certificate of Translation by a professional certified translator/translation company, or b) documentation that the translation has undergone quality review by an entity such as an NIH Regulatory Support Center or the NIH Translation Unit. The translated ICF and appropriate documentation must be sent to the IRB via “Send Message to IRB.” The translated consent form with IRB stamp will be uploaded into the iStar application. Investigators will receive email notification that the translated consent form is ready for use. A letter of IRB approval will not be issued for the translated consent document. Minimal risk studies (Exempt or Expedited) do not require a Certificate of Translation to be submitted. (11.18.2020) The USC IRB no longer provides translation services. (7.20.2021)</td>
<td></td>
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<td>9.5 Required Elements of Informed Consent</td>
<td>Addition</td>
<td>For studies with simple designs, the consent form itself may be just a few pages (less than 5 pages), meeting the requirements for being clear, concise and also containing key information in an appropriate format. (3.16.2021)</td>
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<td>9.11 Electronic Consent / Signatures</td>
<td>Additions, Clarification</td>
<td>Research that is deemed greater than minimal risk and is regulated by the FDA (if applicable)</td>
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<td>9.12 Use of the Short Form Consent</td>
<td>Addition</td>
<td>Short form consent process and addition of the following: <em>The short form process may be used twice for a particular language in a study. After the second use of the short form consent process, the informed consent document must be translated into that particular language as it can be anticipated you will encounter additional potential participants that understand that language.</em> (12.10.2020)</td>
<td></td>
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</table>
| 12.1 Who may be a Principal Investigator     | Revision   | At USC, the following may be listed as Principal Investigator in iStar:  
- Faculty that meet “Requirements of Principal Investigators for Grant Management”, as stated below, may serve as PI for studies receiving external funding, such as support from the Department of Health and Human Services (including NIH) and awards granted from federal agencies.  
- USC faculty and staff (excluding temporary personnel) may serve as PI for studies that are not funded, and do not require management of funds by the Department of Contracts Grants (DCG) or the Clinical Trials Office (CTO).  
- For studies that are of greater than minimal risk or require full board review – the PI must hold a full time faculty position. (8.17.2020)                                                                                     |
<p>| 12.3 Educational Requirements – Human Subjects Protection Training | Revision   | Requests to transfer GCP and/or Human Subjects training certifications from outside Institutions or vendors will be evaluated to determine that course content is equivalent to USC CITI course requirements prior to being accepted. (5.21.2021)                                                                                   |</p>
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<tr>
<td>12.3 Educational Requirements – Research HIPAA Course</td>
<td>Revision</td>
<td>USC researchers and study staff who use or access protected health information are required to complete the Research HIPAA course offered online through CITI. A refresher course is required every three years. (7.01.2021)</td>
<td>243</td>
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<td>12.7 Faculty Advisor’s Assurance for Student Investigators - Waiver of Full-Time Faculty Status to Serve as Advisor for Research</td>
<td>Revision</td>
<td><strong>Waivers of full-time faculty status to serve as advisor for research are limited to studies that are no greater than minimal risk; any studies that are greater than minimal risk, and require Full Board Review, will require a full-time academic appointment at USC.</strong> Guidance for IRB submission is provided. (7.14.2021)</td>
<td>250</td>
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<tr>
<td>14.1 Chart Reviews / Case Studies</td>
<td>Revision</td>
<td>Clarification and expansion of guidance is provided for determining the need for IRB review of chart reviews / case studies, and requests for waivers of consent and/or HIPAA authorization. (6.21.2021)</td>
<td>292</td>
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<tr>
<td>14.12 Considerations of Sexual Orientation and Gender Identity (SOGI)</td>
<td>Additions</td>
<td>This section includes references and guidance for research planning that incorporates attention to diverse sexual orientation and gender identity. (10.14.2021)</td>
<td>319</td>
</tr>
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<td>15.2 Student Research - Classroom Assignments Involving Human Research</td>
<td>Revision</td>
<td>Addition includes considerations for student research projects involving human subjects and clarification of IRB submission requirements. (7.21.2021)</td>
<td>321</td>
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<tr>
<td>15.4 Student Research - Waiver of Faculty Status to Serve as Advisor for Research</td>
<td>Revision</td>
<td>Reference to guidance in Chapter 12.7.</td>
<td>324</td>
</tr>
<tr>
<td>16.2 Right to Try Act</td>
<td>Revision</td>
<td>Addition and revision includes clarification and expansion on Right to Try law and required USC IRB submission. (6.17.2021)</td>
<td>332</td>
</tr>
<tr>
<td>16.13 FDA Inspection</td>
<td>Addition</td>
<td>Guidance provide regarding FDA inspection of FDA regulated clinical investigations. (12.07.2021)</td>
<td>359</td>
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