|  |
| --- |
| **Checklist for :** **Initial Review of a Full Board or Expedited Study** |
| * This checklist will aid the IRB Member in completing a meaningful and substantive review.
* Please attach this completed form to reviewer note section in IRBNet or enter comments in IRBNet.
* For more information please refer to Policy IRB-01, IRB guidance, regulations, or contact the IRB at 718-613-8480or IRB@downstate.edu
 |

|  |
| --- |
| **GENERAL INFORMATION:** |
| **Reviewer Name:**  **IRBNet #:**  **If Full Board: indicate date:**  **Principal Investigator:**  **Study Title:****Comments:**  |
| **Funding/Support Source:**[ ]  Check if using only internal funds (e.g., Department/College funding)**Applicable Regulations for this study:**[ ]  [2018 Common Rule (45 CFR 46)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)[ ]  [PRE-2018 Common Rule (45 CFR 46)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) (for DOJ)[ ]  [HIPAA Privacy Rule (45 CFR Parts 160, 162, and 164)](https://www.hhs.gov/hipaa/for-professionals/privacy/index.html) [ ]  [FDA (21 CFR 11, 50, 56, 312, 320, 812, etc.)](https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm)[ ]  [Applicable Clinical Trial (ACT)](https://www.clinicaltrials.gov/)[ ]  [International Council for Harmonisation (ICH) Harmonized Guideline: Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2).](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf)[ ]  [NIH Single IRB Requirements](https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm)[ ]  [NIH Certificate of Confidentiality Requirements](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html)[ ]  [VA – VHA Handbook 1200.05](https://www.research.va.gov/resources/policies/human_research.cfm)[ ]  [Department of Defense](https://health.mil/Military-Health-Topics/Research-and-Innovation/Research-Oversight/Human-Research-Protection-Program)[ ]  [Department of Justice](https://www.nij.gov/funding/humansubjects/pages/human-subjects.aspx)[ ]  [EU General Data Protection Regulation (GDPR)](https://eugdpr.org/)[ ]  [FERPA](https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html) [ ]  [PPRA](https://www2.ed.gov/policy/gen/guid/fpco/ppra/parents.html) [ ]  [COPPA](https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/childrens-online-privacy-protection-rule) [ ]  [NYC DoE IRB](http://schools.nyc.gov/Accountability/data/DataRequests)Other. Specify:  | **Do you or any of your immediate family members have any conflicts of interests (COI)?** [ ]  Yes [ ]  No *Note: A conflict of interest may be real or perceived and may or may not be of a financial nature.* If “Yes” is checked, please contact the IRB Office to defer to another reviewer. An IRB Member with a COI can provide feedback, upon request from the IRB Chair/Vice-Chair, but cannot vote or approve a study.**Review Type(s) (check all applicable roles):** [ ]  **Consultant (non-IRB Member)**[ ]  **Expedited Reviewer**[ ]  **Other, list:** [ ]  **Full Board Reviewer, check type(s):**[ ]  Primary Reviewer [ ]  Secondary Reviewer[ ]  Clinical Reviewer [ ]  Informed Consent Reviewer [ ]  Scientific Design Reviewer [ ]  Statistical Reviewer[ ]  Prisoner Rep Member[ ]  Privacy Officer [ ]  Information Security Reviewer[ ]  Regulatory/Policy Reviewer[ ]  IRB Office Staff [ ]  Other, list:  |

|  |
| --- |
| **REVIEW:** |
| **Are the IRB application materials congruent with the federal grant?**[ ]  N/A (no federal grant or research reviewed under 2018 Common Rule) [ ]  Yes *Note: Congruency review required for research funded by DOJ or when following the PRE-2018 Common Rule.* [ ]  No, explain: 1) **Category of permissible research in children:** [ ]  N/A [ ]  404 [ ]  405 [ ]  406 [ ]  407**Category of permissible research in prisoners:**  [ ]  N/A [ ]  Category #1 [ ]  Category #2 [ ]  Category #3 [ ]  Category #4 [ ]  Epidemiological Waiver**Overall risk assessment? (Choose one):**[ ]  No greater than minimal [ ]  Greater than minimal risk (>MR)**If >MR and the research involves children, check below:**[ ]  N/A (No Children involved)[ ]  Minor increase over minimal risk for children (research is approvable under Category 406).[ ]  Greater than just a minor increase over minimal risk for children (research is NOT approvable under Category 406).**Medical device study** [**risk assessment**](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf)**, if applicable:**[ ]  N/A [ ]  Non-Significant Risk (NSR) [ ]  Significant Risk (SR); IDE required.**All risks to research participants reasonable in relation to anticipated benefit:**[ ]  N/A or No anticipated benefit [ ]  Yes [ ]  No, explain: 1) If no is checked, please request changes below.**Check the eligible** [**expedited review category/categories**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html)**:** [ ]  N/A [ ]  #1A [ ]  #1B [ ]  #2A [ ]  #2B [ ]  #3 [ ]  #4 [ ]  #5 [ ]  #6 [ ]  #7 **Check if any of the following are missing, when required:**[ ]  N/A [ ]  IRBNet Registration Form[ ]  IRB Application[ ]  Protocol[ ]  Informed Consent Form (with HIPAA Authorization)Note: Please confirm use of version date of 12.26.2018 (or later) for any NEW research approval on or after 1.21.2019. Be sure to require additional modifications based on regulatory requirements if using prior version for NEW studies.[ ]  Information Sheet (no PHI/no signatures)[ ]  Information Sheet/HIPAA Authorization [ ]  Pregnancy Follow-Up Consent Form[ ]  Consent Addendum for SUNY RF Payment[ ]  Consent Form Addendum for NCI CIRB Approved Clinical Trials[ ]  Assent Form (generally required for 7-12 y/o participants)[ ]  Subject Recruitment Authorization - Internal Authorization for Recruitment Contact [ ]  Subject Recruitment Authorization - Internal Verbal Authorization for Recruitment Contact [ ]  Subject Recruitment Authorization - External Authorization for Recruitment Contact [ ]  Short Form(s) (version 11.14.2018) Specify language below.[ ]  Short Form(s) (version 05.18.2016) Specify language below.[ ]  Telephone script[ ]  Verbal recruitment script[ ]  HIPAA Preparatory to Research Certification[ ]  Data Use Agreement (DUA) – Require for activities involving limited data sets. [ ]  Business Use Agreement (BAA) –Require for activities involving business associates.[ ]  Waiver of the entire informed consent process[ ]  Waiver of documentation (signatures) of informed consent *(NOTE: an information sheet or telephone script will most likely be required for the study)*[ ]  Waiver of an element of informed consent[ ]  Information for [Exception form informed consent (EFIC) requirements for emergency research](https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm249673.pdf). Specify below.[ ]  Health Insurance Portability and Accountability Act (HIPAA) Waiver[ ]  Partial HIPAA Waiver (e.g., for recruitment purposes, with follow-up authorization)[ ]  HIPAA Alteration (e.g., removal of signature or other required element)[ ]  Honest Broker Agreement[ ]  Recruitment Materials Specify below.[ ]  Questionnaires or Surveys[ ]  Data Collection Tools[ ]  FDA Form 1572[ ]  IND Letter[ ]  Investigator Brochure[ ]  IDE Letter or SR/NSR determination, as applicable[ ]  Package Insert for medical device, if available[ ]  Scientific Review Committee Worksheet[ ]  CV or Biosketch of PI: [ ]  Credentials of PI or other study staff. [ ]  Sponsor contract. Specify reason required below.[ ]  Other. Specify below.**Indicate type(s) of waivers requested for this submission:**[ ]  N/A [ ]  Waiver of the entire informed consent process[ ]  Waiver of documentation (signatures) of informed consent *(NOTE: an information sheet or telephone script will most likely be required for the study)*[ ]  Waiver of an element of informed consent[ ]  [Exception form informed consent (EFIC) requirements for emergency research](https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm249673.pdf)[ ]  Health Insurance Portability and Accountability Act (HIPAA) Waiver[ ]  Partial HIPAA Waiver (e.g., for recruitment purposes, with follow-up authorization)[ ]  HIPAA Alteration (e.g., removal of signature or other required element)**Criteria are met to grant a waiver of informed consent and/or HIPAA Waiver:***Note: The criteria to approve the waivers are included on the request forms.*[ ] N/A [ ]  Yes [ ]  NO: Changes requested below.[ ]  Wavier(s) missing, specify: 1) **Check if the research involve any of the following:** [ ]  Diagnostic genetic tests [ ]  Future use of specimens or information **Informed consent and/or HIPAA Research Authorization requirements met (except as otherwise waived above):**[ ]  N/A [ ]  Yes [ ]  NO: Changes requested below.**To enroll participants with Limited English Proficiency, the following translated forms can be used:**[ ]  N/A [ ]  Short Form(s) (version 11.14.2018) [ ]  Short Form(s) (version 05.18.2016) [ ]  Long Form(s) *Note: Requires future amendment for certified written translation of consent document, information sheet, etc.***All IRB application materials are congruent with one another:**[ ]  N/A [ ]  Yes [ ]  NO: Changes requested below.**Marked-up copy of the consent document/information sheet attached:**[ ]  N/A [ ]  Yes [ ]  NO: Changes requested below.**Criteria met for IRB approval:**[ ]  N/A [ ]  Yes [ ]  NO: Changes requested below.**Ancillary reviews required to grant riteria met for IRB approval:**[ ]  N/A or all complete[ ]  Can be completed after IRB approval [ ]  Required prior to granting IRB approval (e.g., research protection concern) Specify below.**CHANGES REQUESTED:****Specific Changes needed for Conditional Approval**:(PLEASE BE AS SPECIFIC AS POSSIBLE)1)2)**General Modifications Required:**1)2)**Recommendations (optional/not required):** 1)2)**Comments:** 1)2)**Approval Decision:****For Expedited Reviews:**[ ]  **Approval.** Approval as submitted, no changes required.[ ]  **Conditional Approval or** **Modifications Required.** The revised submission returned for review by an expedited reviewer.[ ]  **Refer for additional review by IRB member with the following area of expertise:**[ ]  **Refer to IRB Chair.** IRB Chair to resolve controverted issue(s) with PI.[ ]  **Refer to Full Board.** PI not willing or not able to make requested changes.**For Full Board Reviews:**[ ]  **Approval.** Approval as submitted, no changes required.[ ]  **Conditional Approval.** Approval is subject to verification of **specific** requested revisions required to meet all approval criteria. Revisions submitted back to an expedited reviewer before final approval granted.[ ]  **Modifications Required.**  **General** changes submitted back to the full board).[ ]  **Disapproval** (the submission is not approvable).**Approval Period:****Based on the assessed degree of risk, regulatory requirements, or** [**Policy IRB-01**](http://research.downstate.edu/irb/irb-policies.html)**, specify the approval or check-in period for this study:**[ ]  12-month approval period. If less than 12 months, list the number of months for approval (not to exceed 12): If less than 12 months, please explain: 1) [ ]  36-months check-in. If less than 36 months, list the number of months before check-in (not to exceed 36): If less than 36 months, please explain: 1)  |