**APPLICATION CHECKLIST FOR INITIAL OR CONTINUING REVIEW BY THE FULL BOARD**

This checklist is to be used in conjunction with electronic full board application or requests for full board continuation. The checklist should be the first document attached in the Study Document Section of the On-Line Application. To avoid delays in the review and approval process investigators must ensure that all required elements are included in the on-line submission. Investigators should check off those elements that are applicable to their study and attach those items to the submission. If an element is Not Applicable, indicate NA. Investigators are encouraged to add clarifying comments.

NOTE:  If applicable to your studies translated documents are required to be approved by the IRB prior to use.  The IRB encourages translated documents to be submitted as a request for modification after the English versions are approved, but investigators may submit at the time of initial review if they prefer.   Documents may be translated by a certified translating service or by back translation.  See the Translation Policy (2011-013.0) at <http://research.uchc.edu/rcs/hspp/policies/>.

**Legend**: I = Initial Review C = Continuation NA = Not Applicable

| **Study Title:**  |
| --- |
| **IRB # (if known):**  |

 **For IRB Use Only**

| **When Needed** | **Check** **or NA** | **Element of Application** | **PI** **Comments** | **IRB Stamped** |
| --- | --- | --- | --- | --- |
|  |  | **General Documentation** |  |  |
| I / C |  | This Checklist  |  |  |
| I **(See note)** |  | Complete on-line application (**Note**: electronic application must be routed for sign-off by principal investigator and individuals noted in sections 3.2 of the on-line application form) |  |  |
| C **(See note)** |  | Continuing Review Request Form created within IRIS and signed by the PI. (**Note:** Only the PI is required to sign.) |  |  |
| I / C  |  | Complete protocol – apart from any grant application. (For investigator-initiated studies use the Protocol template. Template available from the [HSPP web site](http://research.uchc.edu/rcs/hspp/irb/irb-instructions-forms-and-samples/)) |  | **Y**  |
| I **(See note)** |  | The initial entire grant application / proposal as submitted to the external funding agency **in a single word or pdf file**. (**Note -** **Do not submit only cover pages that contain hyperlinks to various portions of the grant proposal**. In most cases the IRB only reviews funded grant proposals. The grant proposal is distinct from the IRB protocol. If external funding is obtained after initial IRB approval, the entire grant proposal must be submitted to the IRB as a modification to the funding source of the study. The initial grant application need only be submitted once, followed by progress reports or competitive renewals.) |  |  |
| **I** **(See note)** |  | For proposals submitted to National Institute of Justice, submit the Privacy Certificate that was submitted to NIJ with the proposal. (Note: if funding is obtained after initial approval proposal and certificate are to be submitted as addendum / modification) |  |  |
| I **(See note)** |  | The signed ORSP Grant Routing Sheet. (**Note**: same note as prior section)  |  |  |
| C**(See note)** |  | The grant competitive renewal application, or any revised new or renewal application, as applicable (distinct from the IRB protocol) (**Note**: Any change during a non-competitive period, including supplemental applications, requires the submission of the progress report/application. If the grant cycle does not coincide with the IRB continuing review cycle submit the material as a modification and use the PI Comments section to note the date the modification was approved and describe exactly what was submitted.)  |  |  |
| I/ C**(See note)** |  | If applicable, Investigator’s Brochure (**Note**: most common for pharmaceutical sponsored studies)  |  | **Y** |
| I/C |  | If applicable, package insert for marketed drugs used in study in accordance with label |  |  |
| I / C  |  | Standardized assessment tools or questionnaires that are commercially available |  | **Y** |
| I / C |  | Any survey instruments, interview questions, screening forms, or assessment tools (including health history questionnaires) that are not commercially available |  | **Y** |
| I **(See note)** |  | Pink sheets from grant reviewers (e.g., NIH, Donaghue). (**Note**: Pink sheets are only required at continuing review if not previously provided as part of the initial IRB application or as a study modification, e.g. provide them at continuation if new funding is obtained and the continuation includes a request for modification to indicate the new funding source) |  |  |
| I |  | Results of any scientific review already conducted (e.g. reviews by CRC, NIH, or foundations) |  |  |
| I / C**(See note)** |  | Data Safety Monitoring Plan / Data Safety Monitoring Board information when done external to UConn Health. (**Note:** if incorporated into protocol please reference page numbers)  |  | **Y** |
| I / C**(See note)** |  | Charter for Data Safety Monitoring Board when external to UConn Health (**Note:** if incorporated into protocol please reference page numbers)  |  | **Y** |
| I / C |  | Findings from DSMB meetings that have occurred prior to IRB approval at this site or since the previous IRB review (for multi-site trials if findings are already available based on other site activity they should be included at the time of initial application.) |  |  |
| I / C |  | For investigator-initiated studies, all data collection forms and/or case report forms. |  | **Y** |
| I / C**(See note)** |  | For NIH-funded research, the Data Management & Sharing plan (**Note:** If the plan is included in the grant, provide page reference. If the funding entity requires that the IRB review this plan annually, add a comment to request that the form be stamped which will trigger resubmission at continuation. Links to sample plans are available from the [HSPP web site](http://research.uchc.edu/rcs/hspp/irb/irb-instructions-forms-and-samples/))  Continued on next pageFor genomic data sharing, including GWAS studies, also include Appendix E.If no Data Management and Sharing plan, provide comment to explain.  |  | **Y**(Only if requested) |
| I / C**(See note)** |  | Form B 204, 205, 206 or 207 for verification that additional protections for pregnant women are addressed (**Note:** applicable to federally funded research and to non-federally funded research when a pregnant woman will be recipient of a drug or device or biologic. Form B is not required for research that is not federally supported to collect follow-up data on a woman who becomes pregnant while on study providing the intervention is stopped.) |  | **Y** |
| I / C**(See note)** |  | Form C for verification that additional protections for prisoners are addressed. (**Note:** applicable to federally funded research involving prisoners, and to non-federally funded research that is intended to involve an interaction or intervention with prisoners.) |  | **Y** |
| I / C**(See note)** |  | Form D for verification that additional protections for children are addressed. (**Note:** applicable regardless of funding source when the research is intended to involve an interaction or intervention with children) |  | **Y** |
| I / C**(See note)** |  | Form S for verification that additional protections for other vulnerable groups are addressed. (**Note:** applicable regardless of funding source to research targeting recruitment of educationally or economically disadvantaged, students or employees when considered vulnerable, decisionally impaired or terminally ill.) |  | **Y** |
|  |  | **APPLICATION APPENDICES / ADDENDUMS** |  |  |
| I  |  | Appendix A – GCRC Resource Request |  |  |
| I / C |  | Appendix B – Internal Data Safety Monitoring Plan / Charter  |  | **Y** |
| I / C |  | Appendix C – UConn Health as statistical, coordinating or lead institution |  | **Y** |
| I / **C** **(See note)** |  | Appendix E – NIH Genomic Data Sharing Certification (**Note:** When initially submitted the IRB staff will obtain signatures for the certification and return the signed form through Submission Correspondence. If the funding entity requires that the IRB provide annual certification, add a comment to request that the signed form also be added as a submission component and stamped which will trigger resubmission at continuation. If no changes have been made, new signatures are not required. Links to sample plans are available from the [HSPP web site](http://research.uchc.edu/rcs/hspp/irb/irb-instructions-forms-and-samples/)) |  | **Y**(Only if requested) |
| I /C**(See note)** |  | Appendix F – Department of Defense Addendum (Note: required when DoD or any of its components fund or supports the research in any way.) |  | **Y** |
| I / C |  | Appendix G – Community Based Participatory Research |  | **Y** |
| I / C |  | Appendix H – National Institute of Justice Addendum |  | **Y** |
| I / C |  | Appendix I –Dept. of Energy Checklist – required when research is funded/supported by DOE |  |  |
| I / C |  | Appendix J – Federal Bureau of Prisons – required when research is conducted within the FBP  |  |  |
| I / C |  | Appendix K - - Department of Education (required when research is funded by US Dept. of Education or research is conducted in a school that receives such funding).  |  |  |
|  |  | **Informed Consent**(Section not required if study is no longer enrolling and there have been no changes to the document.)  |
| I / C**(See note)** |  | Form to request a waiver of the requirement to document consent (Note: this waives documentation only; the consent process still occurs and a consent form may still be required.)  |  |  |
| I / C**(See note)** |  | Informed consent form for IRB approval. (**Note** for continuations the form should include the IRB # in the header area) |  | **Y** |
| I  |  | Informed Consent Checklist and, as applicable, relevant consent checklist addendums  |  |  |
| I / C**(See note)** |  | Form to request a waiver of the requirement to obtain informed consent (**Note**: request may apply to duration of project, or portion of project.) |  | **Y** |
| I / C**(See note)** |  | Form to request an alteration to required element(s) of consent or to waive certain elements of consent (Note: for example, if conducting deception research, you may request approval to alter the description of the research) |  |  |
| I / C**(See note)** |  | A written summary of the research that will be provided to subjects if a waiver of documentation is requested (**Note**: Most often a consent form is used for this purpose. If requesting that the consent form serve this purpose indicate so) |  | **Y** |
| I / C**(See note)** |  | If enrolling children, the separate assent statement to be signed by the children (**Note**: In general children between the ages of 7 – 12 sign a separate assent statement, children between 13-17 sign the consent form on a separate line designated as assent, children under age 7 are generally considered too young to provide written assent. The IRB makes the final determination and may impose other requirements. ) |  | **Y** |
| I / C**(See note)** |  | If enrolling decisionally impaired adults who may be providing consent; the tool/plan to assess capacity prior to obtaining consent (**Note**: the consent comprehension feedback form available with the template consent documents, or other similar tool is required)  |  | **Y** |
| I  |  | For NIH supported multi-site studies – the sample NIH consent form and/or the sample DHHS consent if one exists |  |  |
| I / C |  | If applicable, for planned emergency research, the form to request a waiver or alteration of consent. |  | **Y** |
| I |  | If applicable, for planned emergency research which is DoD-supported, attach documentation of approval from the DOHRP on behalf of the Secretary of Defense for a waiver of the advance informed consent provision of 10 USC 980. |  |  |
| I/C |  | When proposing eIC (electronic consent process without a consenter present) and/or electronic documentation of consent in FDA regulated research, confirmation that the system to obtain consent and signature meet regulatory requirements at 21 CFR part 11. (\*Note: eIC is not approvable for all research; PI should consult IRB to ensure eIC can be used for the specific project.) |  |  |
| I/C |  |  When proposing eIC (electronic consent process without a consenter present), hard copy of all informational materials, videos, web-based documents/links the subject may receive/view during the eIC process. (Note: the content appearing on any hyperlinks must be provided)  |  |  |
| I/C |  | When proposing eIC (electronic consent process without a consenter present), access to the eIC platform for IRB review and approval. |  |  |
|  |  | **HIPAA****(Section not required if study does not involve seeing, using or disclosing PHI or is no longer enrolling)** |
| I / C |  | Authorization to Use and Disclose PHI  |  | **Y** |
| I / C**(See note)** |  | Application for Waiver or Alteration of Authorization (**Note**: generally used 1) when identifiers from a retrospective chart review must be maintained, or 2) to collect PHI during a screening phase prior to obtaining authorization, for example phone screening in response to a print ad) |  | **Y** |
| I / C**(See note)** |  | Certification of De-identified Data(**Note:** all persons who will be doing the abstraction must sign the form) |  | **Y** |
| I / C**(See note)** |  | Certification of Limited Data Set and Data Use Agreement (Note: used to disclose indirectly identifiable information outside of the UCHC)  |  | **Y** |
|  |  | **RECRUITMENT MATERIAL****(Does not pertain if study is no longer enrolling)** |  |  |
| I/C |  | The IRB recommends completion and submission of the Recruitment material checklist |  |  |
| I / C |  | Recruitment material to be approved (e.g., advertisements, letters, radio or t.v. scripts, final taped ads, broadcast message text, etc.) Include the text of any link that once clicked will go to the full advertisement. The text associated with the link should not reference payment or reference the need for subjects |  | **Y** |
| I / C |  | Telephone scripts/screeners to be approved, including those for receipt of calls in response to general advertisements (e.g. receptionist scripts) or for calls initiated by the study team. *Template available from the* [*HSPP web site*](http://research.uchc.edu/rcs/hspp/irb/irb-instructions-forms-and-samples/) |  | **Y** |
|  |  | **OTHER ATTACHMENTS** |  |  |
| I  |  | Proof those individuals external to UConn Health have completed human subjects training. (**Note**: IRB staff will verify training of UCHC personnel via IRB records therefore training documents for UCHC personnel are not generally required) |  |  |
| I**(See note)** |  | Final contract if available at time of IRB submission (**Note:** If being negotiated concurrent with this submission please indicate and provide a copy of the intended subject injury language for preliminary review by the IRB. Contract language may be obtained from the Clinical Trials Unit. Final approval will not be granted until a fully executed CTA is received and subject injury language is consistent with the consent) |  |  |
| I**(See note)** |  | For investigational drugs, or investigational devices, if the IND/IDE # is not provided, a letter from the sponsor confirming IND, IDE approval. (**Note:** if only the # is provided in the application the # must correspond to the sponsor’s protocol. If the PI is the sponsor of the IND/IDE there must be communication with the FDA that documents the IND/IDE #)  |  |  |
| I |  | Biosketch of PI if qualifications are not summarized on application or within IRIS.  |  |  |
| I / C (See note) |  | Significant Financial Interest (SFI) of Study Personnel form. (Note: only required if in response to solicitation about SFI status an individual responds YES a SFI related to the research does exist) (**Contact** Gus Fernandez-Wolff (x8125) for guidance on COI plans/determinations / Reminder: keep backup correspondence in study binder).  |  | **Y** |
| I / C**(See note)** |  | For SFI forms with SFI disclosures - the corresponding Conflict of Interest Management Plan or determination by the Conflict of Interest Committee that the conflict is not a significant financial interest that needs management. (**Note**: Final IRB approval cannot be granted until the IRB reviews and approves the management plan or determination.  |  | **Y** |
| I **(See note)** |  | As applicable, for federally funded or supported research or research involving greater than minimal, risk signed Individual Investigator Agreements for those individuals external to UConn Health. (**Note**: The IIA form describes the types of investigators to whom this applies) |  |  |
| I / C |  | Any other relevant document not addressed in this form that will be used within the conduct of the study |  |  |
| C **(See note)** |  | Any relevant multi-center trial reports (**Note**: submit only those that have not previously been submitted to the IRB by the PI.) |  |  |
| C **(See note)** |  | Audit or inspection reports (including internal audits) or findings issued by regulatory agencies, cooperative research groups, contract research organizations, the sponsor or the funding agency (**Note**: submit only those that have not previously been submitted to the IRB by the PI.) |  |  |
| C |  | Annual report to FDA when UConn Health PI is sponsor of IND/IDE |  |  |
|  |  | **Proof of Additional Approvals** |  |  |
| I |  | Written confirmation from UConn Health I.T. that mobile apps and/or web based systems (exclusive of industry sponsored web based systems for electronic case report forms) used to collect identifiable protected health information are HIPAA compliant (**Contact** itsecurity@uchc.edu) |  |  |
| I |  | If Institutional policies and standards for data security, inclusive of standards for use of data encryption, are not being used on all devices (e.g. desktop, laptop, thumb-drive, other mobile devices) used to store/transfer data, approval from I.T. must be obtained for use of alternate data security plans. Contact itsecurity@uchc.edu. |  |  |
| I  |  | Budget Workbook Memo required for all full board submissions – (**Contact** OCTR octrclinicaltrial@uchc.edu).  |  |  |
| I |  | Pharmacy Approval (for drug dosage, frequency, duration and method of administration and drug storage if outside of pharmacy) (Contact Jennifer Czerwinski x 2085) |  |  |
| I |  | For research involving UConn Health resources (including, but not limited to, inpatient stays), the signed Confirmation of Available Resources Form |  |  |
| I / C |  | Institutional Biosafety Committee Approval for gene therapy studies (**Contact** **IBC@uchc.edu**) |  |  |
| I |  | Research Safety Approval (**Contact** Steve Jacobs x2723)  |  |  |
| I |  | Approval from the Protocol Review Committee for studies utilizing the resources of the Clinical Trials Office within the Neag Comprehensive Cancer Center |  |  |
| I |  | Review and approval for conduct of study in foreign location from foreign IRB or equivalent review body on letterhead to include the title and contact information for that site |  |  |
| I |  | For studies conducted off-site, a letter of permission to conduct the research at the site. The approval, preferably on the letter head of the site at which the research will be conducted, should contain the title and contact information of the individual granting permission and that individual must have the proper authority to grant permission for the conduct of the study. If permission is granted by email the email address is to be from the specific institution at which the research is to be conducted or the official email associated with that individual’s position |  |  |
| I |  | For studies that will focus recruitment on UConn Health medical, dental or graduate students and record identifiable information, and/or make use of the official academic record, documentation confirming permission from the applicable Dean of Student Affairs of the School (or other designee by the Dean) to conduct the research. |  |  |
| I |  | FERPA Verification form for research studies conducted in other schools (e.g. surveys of elementary school children) If FERPA verification is obtained by email, the form content must be included in the email thread as evidence the school official reviewed the form. The email message must indicate whether the school is FERPA compliant or does not receive Dept. Of Ed support and the email from the school official should include the name and title of the official responding and be sent from that person’s official school email account. |  |  |
| I |  | For studies conducted outside of CT that involve Guardians and/or Legally Authorized Representatives and/or Children; and for which review and approval of the local IRB or its equivalent is not required (e.g. the external site is not engaged in research) documentation from legal counsel, or other qualified individual, as to who can act as a guardian and/or LAR or who is considered a child in the jurisdiction in which the research is to be conducted.  |  |  |
| I |  | Pre-application audit if UCHC PI is sponsor for IND or IDE study (**contact** the Research Compliance Monitor at x3054 to schedule) |  |  |
| I |  | Approval from AVP for Research Administration (Julie Schwager or Michael Glasgow) and Finance to have checks made payable to cash or proof that the check service of the Clinical Research Center will be utilized. |  |  |
|  |  | **Verifications**  |  |  |
|  |  | The IRB # is the correct number for the listed study title.  |  |  |
|  |  | If utilized, the correct consent and protocol versions are noted on documents (e.g. in the footer or on the face page, and if applicable have been revised appropriately when modifications are made) |  |  |
|  |  | Title on Consent, HIPAA, Protocol, and DSMP/Bs Correspond |  |  |
|  |  | PI, Co-PIs, Coordinators and those authorized to obtain consent have completed human subjects protection training (within past 3 years for UConn Health )  |  |  |
|  |  | Professional license types and #s have been provided for personnel performing clinical functions within the study. (via comments, attached cv, or IRIS profile)  |  |  |
|  |  | **IRB USE ONLY** |  |  |
| **(See note)** |  | IND/IDE # in application is validated to sponsor protocol or correspondence from the sponsor or from the FDA. (**Note**: Correspondence from FDA is required for validation when the PI is also the sponsor.)  |  |  |