

**Institutional Review Board (IRB)**

2700 Bay Area Boulevard

Houston, Texas 77058-1098

Telephone: (281) 283-3015 Fax: (281) 283-2143 Email: sponsoredprograms@uhcl.edu Website: uhcl.edu/research

**Protocol Submission Checklist**

|  |  |
| --- | --- |
|  | **Required Training**:* Include current CITI Social-Behavioral-Educational training completion certificate with application submission.
 |
|  | **IRB Application:*** All of Sections A, B and C, items 1 – 10 have been fully explained.
 |
|  | **Instrument(s):*** Instruments are attached: educational tests, questionnaires, psychological tests, educational materials, or interview/phone scripts. (Sections C, Item 4)
 |
|  | **Informed Consent Form:*** Informed Consent form is attached. Language understandable to the subject is used. (Section C, Item 6)

OR**Waiver of Documentation of Informed Consent:*** Waiver for Documentation of Informed Consent is requested and justification is provided, if applicable. [Section C, Item 6; §46.117(c)(2)]
 |
|  | **Assent and Parental Permission:*** Assent and Parental Permission forms are attached, if children between the ages of 7 and 17 are recruited. Language understandable to the child’s age and maturity is used. (Section C, Item 6)
 |
|  | **Site Permission:*** Signed, written approval from site’s appropriate official is provided when human subjects are recruited outside UHCL. (Section C, Item 10)
 |

**After IRB Approval of Protocol**

|  |  |
| --- | --- |
|  | **Modifications to Protocol:*** Additions or changes to protocol will be submitted to IRB for review prior to implementing into research study.
 |
|  | **Report Problems with Human Subjects During Research:*** Immediately report any unanticipated problems or injuries (Adverse Event) connected with an approved protocol to OSP at 281.283.3015. Written document of the Adverse Event must be received by IRB via OSP within 5 working days.
 |
|  | **Data Safeguarding and Maintenance:*** All research data and signed informed consent forms will be safeguarded by principal investigator or faculty sponsor for 3 years after completion of research study. Internal and external audits may occur.
 |
|  | **Continuing Review:*** Exempt studies do not require continuing review
* Expedited studies may require continuing review; see your notification letter for details
* Approval by full board review expires one year after the approval date and must be submitted for continuing review. Submit early to prevent a gap in compliance.
 |