IRB Documents- Initial Checklist

Date: _____ **Protocol #:** _____

Title: _____

Principal Investigator: _____

Project: ☐ **CCC** ☐ **Industry** ☐ **Other** _____

- ☐ **Biosafety Approval Letter or evidence of submission:**
- ☐ **Protocol**
- ☐ **IRB Application**
- ☐ **Consents Forms**
  - Informed consent
    - ____ Spanish
    - ____ English
  - Assent
    - ____ Spanish
    - ____ English
  - Letter for request waiver to consent
- ☐ **Instruments**
  - ☐ Surveys/ Questionnaires
    - ____ Spanish
    - ____ English
  - ☐ Data Sheets
  - ☐ Guide questions for focus groups or interview
  - ☐ Flyers
  - ☐ Script
  - ☐ Educational materials or brochures
  - ☐ Other: _____
- ☐ **Conflict of interest**

- ☐ **Bio sketch of the researchers**

- ☐ **Letter of collaboration**
  - ☐ for recruitment
  - ☐ utilization of facilities
  - ☐ utilization of data

For IRB Use only: Decision

IRB: □ Complete Board □ Expedited

□ Exempt

Waiver accepted: □ **Yes** □ **No**

Decision:

☐ Not approved

☐ Approved contingent to changes

Date: _____

☐ Final Approval

Date: _____

Next progress:_____

IRB Members present:

Members inhibited:

Note: Each PI, Co-Pi, Investigator, researcher, key person/staff of the study must have to be certified in HS, HIPAA, GCP. The certificates must not have more than three years of issued.

- ☐ **Protection of Human subjects Certificate**
- ☐ **HIPAA Certificate (HIPS)**
- ☐ **Good Clinical Practices Certificate (all NIH Funding study)**