# For Best Practice in record keeping when conducting human research, keep the following documentation collected, filed, and easily accessible: (All documentation listed below may not be relevant to your specific research protocol).

## Protocol and Amendments

* IRB approved protocol, previous and current versions.
* IRB-approved recruitment materials, previous and current versions.
* All other IRB-approved information provided to subjects, previous and current versions.
* Copies and examples of all data collection instruments (survey’s, interview scripts, observation protocols, etc.)

## Training Documents

* CITI Training Certifications (Social Behavioral or Biomedical depending on your type of human research) for all key personnel listed on the protocol.

## Informed Consent Documents

* IRB-approved Informed Consent document, previous and current versions.
* Signed and Dated Consent forms for every subject participating in the research.

## IRB Approvals and Correspondence

 IRB approval letters (e.g., protocol, protocol amendments, consent/assent documents, continuing review, etc.)

 Original IRB application/submission

 Correspondence related to contingent approvals or stipulations

* New Information reports to the IRB
* Any other miscellaneous correspondence with the IRB (i.e. Email correspondence)

## Investigator Qualification Documentation

 Updated Principal Investigator CVs

 A clinical (dental, medical, etc.) license for the PI and co-investigators, if licensed

## FDA Documents (if applicable)

 FDA Forms 1571 and 1572

 Sample of labels attached to investigational product containers

 Regulatory approval or authorization

 FDA Correspondence Log

## Financial Conflicts of Interest/DEPA Documentation

 Current DEPA and any other Financial Conflicts of Interest Disclosure Forms or Memorandums of Understanding for the PI and co-investigators (if applicable)

## Screening/Enrollment Log (if applicable)

 Screening/Enrollment Log

 A log without identifying information that lists all screened subjects

 Subject Identification Code list (which should be kept separately)

## Serious Adverse Events (SAE)/Unanticipated Problem Documents

 AE Report Forms

 Unanticipated Problem Forms

 IND Safety Reports