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# 🗹 before & during study: do’s

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|  | Ensure that your iRIS application mentions all of your research procedures, all of the information/data that you will be collecting during the study, and all the locations where the research will be taking place. |
|  | Submit all of your data collection forms and spreadsheets that you will be using prior to their implementation (Investigator-initiated studies and any site-created forms or forms that will be given to subjects). |
|  | Submit all informed consent and document translations within 30 days of receiving IRB approval for your study. |
|  | Obtain and submit all other approval letters to the IRB for review during initial submission to the IRB. |
|  | Collect and submit all Sponsor Monitoring Reports and external audit reports for IRB review. |
|  | Review your protocol and create a calendar of events or a subject road map for your study prior to enrolling the first subject. |
|  | Always print the most up-to-date version of the informed consent directly from iRIS on the day of consent. |
|  | Ensure that all electronic storage and data capture systems are IRB approved for this study prior to use. |
|  | Be sure to document all procedures and situations on research notes to abide by Good Documentation Practices and ALCOA. |
|  | Observe as each subject signs their informed consent/HIPAA and review each consent during and just after the consent process to ensure that the form is complete and correct. |
|  | Make sure research personnel line through, initial and date any mistakes or corrections that they may make during the study. |
|  | Submit all Serious Adverse Events and deviations to the IRB within 10 days of their discovery. |
|  | Ensure that all the research personnel update their CITI trainings and financial disclosures before they expire. |

# 🗷 before & during study: don’ts

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|  | Do not collect any private health information or other information without prior IRB approval to do so. |
|  | Do not implement the use of any surveys, questionnaires, data collection forms, etc. prior to obtaining IRB approval. |
|  | Do not allow subjects to scribble out mistakes on consent forms. Ensure that they line through, initial and date their mistakes. |
|  | Do not add subject PHI or contact information to the informed consent/HIPAA. |
|  | Do not add time or date to the informed consent/HIPAA on behalf of the subject. |
|  | Do not add any additional information to the informed consent/HIPAA after an exact copy of the informed consent/HIPAA has been provided to the subject. |
|  | Do not sign the consent before the subject signs or sign the consent a significant amount of time after the subject has signed. |
|  | Do not enroll more subjects than you were approved to enroll by the IRB. |
|  | Do not allow anyone who does not have prior IRB approval for your study to work on that study. |
|  | Do not enroll non-English speaking subjects without the IRB approved translated documents. |

*\*This checklist is not meant to be an exhaustive list and is meant to be used as a supplemental aid for your toolkit. For more information, refer to the* [*Human Research Protection Program Manual.*](http://elpaso.ttuhsc.edu/research/committees/irb/resources/_documents/HRPP%20Manual%20El%20Paso%20October%2024%202016.pdf)