IRB Quick Checklist

Please note: This is a brief checklist only. For additional explanation, please see full document below.

- ☐ Complete TTUHSC-required/approved CITI training.
- ☐ Request iRIS access (if you do not already have a username and password).
- ☐ On iRIS, provide the following (as applicable) for initial review:
  - ☐ Completed iRIS application (must be electronically signed/approved by a Departmental signatory authority)
  - ☐ CVs on all investigators *(Please see document below for additional information on how to upload into iRIS)*
  - ☐ Protocol (required; must be uploaded as a separate "Study Document")
  - ☐ Consent form(s)
  - ☐ HIPAA form (authorization OR request for a waiver; *please see additional information below)*
  - ☐ Research instruments (e.g. questionnaires, data collection sheets, etc.)
  - ☐ Committee/Department/Board approval letters
    Examples: approval letters from other, external IRBs & approvals from other TTUHSC bodies (*please see document below for additional information and links to these committees/boards*).
  - ☐ Letters of support from external entities
  - ☐ Grant(s)
  - ☐ Contract(s) with investigator(s)
  - ☐ IND/IDE number(s) (this refers to experimental uses of drugs or devices)
  - ☐ Investigator's Brochure (if the study involves an investigational drug/device)
- ☐ On iRIS, respond to all IRB requests for clarifications and/or revisions.
- ☐ Conduct study in accordance with the approved protocol and Good Clinical Practice guidelines.
  - ☐ Report unanticipated/adverse events to the IRB, federal agencies, and sponsor.
  - ☐ File IND safety reports (if applicable) individually on iRIS.
  - ☐ Notify the IRB of any changes in the study PRIOR to implementation.
- ☐ On iRIS, submit study for IRB continuing review by the established deadline to keep it open.
- ☐ On iRIS, submit study's final report for permanent closure.

Table of Contents for Remainder of Document

Section **Page**

Initial Concerns – Study Planning

This list is not exhaustive but will hopefully provide a starting point and will address commonly-overlooked aspects of submitting human studies for review. Please see the IRB's website for additional, more specific information: http://www.ttuhsc.edu/research/hrpo/irb

1. The **Principal Investigator (PI)** of a study must be a faculty member at TTUHSC or an approved affiliate. **A resident cannot serve as the PI.**

   For additional information, please see the TTUHSC Institutional Review Board (IRB) Policies and Procedures Manual, section 3.0, http://www.ttuhsc.edu/research/hrpo/files/IRB_P&P.pdf

   NOTE: Collaborative efforts with principal investigators at other institutions require special considerations. Please consult with the appropriate (depending on location) TTUHSC IRB office for additional information: http://www.ttuhsc.edu/research/hrpo/irb

2. **TTUHSC prohibits payment to the PI or study personnel** considered to be "finder's fees" or "incentive payments", an issue which might need to be addressed with externally-funded studies.

   TTUHSC Institutional Review Board (IRB) Policies and Procedures Manual, section 8.2, http://www.ttuhsc.edu/research/hrpo/files/IRB_P&P.pdf

3. If **any TTUHSC employee** (faculty member, student, resident, staff, etc.) plans to conduct/assist in a research study (even if it is not a TTUHSC-sponsored study and even if the role will be limited) he/she **must submit the study for TTUHSC IRB review**.

   NOTE: Even if a different institution (with a non-TTUHSC PI and its own IRB review) is sponsoring the study, for the purposes of the TTUHSC IRB submission, the TTUHSC investigator may list his/her name as the PI. For the IRB's consideration, the PI is the primary contact person. In the application to the IRB, the TTUHSC investigator should focus on his/her involvement in the study; essentially, he/she will be viewed as the PI for those aspects of the overall study.

   For additional information, please see the TTUHSC Institutional Review Board (IRB) Policies and Procedures Manual, section 3.2, http://www.ttuhsc.edu/research/hrpo/files/IRB_P&P.pdf *and contact the appropriate (depending on location) TTUHSC IRB office for guidance:* http://www.ttuhsc.edu/research/hrpo/irb

4. All research study personnel associated with a study must have completed/maintained their **TTUHSC-required** "**CITI training," which includes a TTUHSC-approved HIPAA research component**.

Please see information pertaining to such training on the IRB website:
http://www.ttuhsc.edu/research/hrpo/irb/edurequirements.aspx

NOTE: While many researchers complete similar training programs at other institutions, the TTUHSC-approved training programs for research are the only accepted programs, unless the researcher obtains special approval from Victoria Rivera, TTUHSC Research Compliance Officer, (806) 743-4754 / fax: (806) 743-4746, Victoria.Rivera@ttuhsc.edu

5. When planning the study, researchers should **review the exempt criteria** and structure their study appropriately.

   Often, there are no easy, definitive strategies for structuring studies that will be granted exempt status. Regardless of the PI's best intentions or his/her opinion of whether or not a study qualifies as an exempt study, only the IRB can make this determination. IRBs are responsible for making such judgments on a case-by-case basis; however, studies that probably *could have* been exempt are often not structured in such a way that would easily allow for the IRB to grant that exemption. For example, retrospective chart reviews could often be exempt studies; however, if patient names or other protected health information (PHI) are recorded on data collection sheets, such studies *typically* cannot be granted exempt status. Simply by reevaluating the data elements to be collected, the researcher could plan a study that might better meet the exemption criteria.

   When evaluating individual criterion to be gathered, consider that the IRB weighs the information collectively. For example, when looked at together, can the data collected lead back to the identity of an individual (e.g., age + time of admission + date of admission)? Typically, such a study would *not* be eligible for exempt status.

   NOTE: A common myth shared among researchers is that exempt studies fly through IRB reviews more quickly and with less work on the part of the investigator. This is not always the case, and in fact, the IRB sometimes reviews exempt studies with even more scrutiny, simply because they will not be able to continue to follow the study's future progress in the same way as they follow non-exempt studies. Granting a study exempt status does not mean that the study (as submitted by the investigator) will be "rubber stamped."

   For additional information on exemption criteria, please see the TTUHSC Institutional Review Board (IRB) Policies and Procedures Manual, section 4.3,
   http://www.ttuhsc.edu/research/hrpo/files/IRB_P&P.pdf

   For additional information on Protected Health Information PHI, please refer to the Code of Federal Regulations: 45 CFR 164.514 (b) (2) & 45 CFR 164.514 (e) (2);
   http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1 (select the most recent version of Title 45, and then continue selecting appropriate sections, as listed in the above citation).

6. The flowcharts prepared by the federal Office for Human Research Protections (OHRP) are excellent starting points when **planning research studies**. The second flowchart, for example, prompts researchers through questions aimed at determining whether or not the study qualifies for exemption. The 11 helpful charts often answer many of the questions investigators frequently ask IRB personnel and may be found at: http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm

7. A document very similar to this guide, but much more in-depth, may also be useful to investigators designing new studies. The **Investigator's Guide** may be found at: http://www.ttuhsc.edu/research/hrpo/irb/files/InvestigatorsGuide.doc.

8. All **research personnel will have to be identified and their roles explained clearly** *prior* to submission to review boards like the IRB.

   While the IRB can later be notified (by way of an amendment) of any changes in research personnel, when *initially* submitting a study, all individuals involved in the study must be identified specifically and their roles explained in detail. Particularly important is explaining exactly **who/which members of the study team will be obtaining consent** from subjects.

9. **Where** each aspect of the study will take place (i.e. recruitment of subjects, consent of subjects, data collection, data analysis, storage of data (such as PHI/consent forms), etc.) must be clearly outlined.

   NOTE: Principal Investigators are required to keep study documents/records for a minimum of five (5) years after completion of the study for audit by the IRB or authorized officials from the granting agency, FDA, DHHS, etc. **All such study-related documents are considered institutional/departmental records and should not be transferred to another institution with a principal investigator leaving TTUHSC.**

   Specific note regarding consent forms: In a confidential manner, PIs are also required to maintain either the original/signed consent forms OR copies of the signed consent forms in their departmental files. Depending on the location of recruited subjects, it will vary whether the originals or copies are kept by the PI.

   At every TTUHSC office/clinic/hospital, PIs are required to keep the originals and can place copies in the subjects' medical charts. Other institutions may have different requirements (i.e. they may keep the originals on site, and PIs will need to make copies for their study files).

   It is the responsibility of the PI to determine what is appropriate. Additional copies of consents will likely be made over the course of the study (i.e. to give to each subject after he/she consents to the study, etc.). But because the PI is ultimately responsible for the study, he/she must keep records of the consents, keeping either the originals or copies (again, depending on institutional policies) with the other study documentation.

10. If any portion of the study will take place at another facility/institution, prior to final approval, the IRB will require:
    - **Letter(s) of support from a research administrative official at the other institution(s)** [Such letters should simply acknowledge that the institution knows about the planned research and deems it acceptable for the study (under the direction of the named PI) to take place on their premises/with their patient population, etc.]
    - **HIPAA forms** (if required by the study) from the other institution(s) (the TTUHSC template/form is *not* acceptable). Other institutions' HIPAA forms should be attached in iRIS in "Study Documents."
      (For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS Submissions*** *at:*
      http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf)
    - **committee approvals (and, if applicable, IRB approvals) from the other institution(s)**
    - **TTUHSC template consent form** (provided a consent form is required by the study). NOTE: The IRB must approve the use of external entities' consent forms. *(Please contact the appropriate IRB office for additional information:* http://www.ttuhsc.edu/research/hrpo/irb)

11. Performing a **power analysis** is particularly important if the subject population is small.

    The IRB is charged with evaluating the benefits to risks ratio. Justifying to the IRB that the study is viable and worth doing is important. If an appropriate number of subjects (according to a power analysis) cannot practically be recruited, explain why they cannot be enrolled and why you would still like to conduct the study. Why would the data still be valuable? If applicable, argue that this would be a valuable pilot study to guide future research.

12. On **data collection sheets,** make sure to clearly enumerate ALL information to be recorded from patient medical charts.

    When considering what elements to record, please respect patient confidentiality (i.e., if you do not *need* information, do not record it!) In addition, consider your own time. Recording numerous data elements from medical charts can be time-consuming, particularly in those institutions in which charts are not computerized.

13. Investigators often misunderstand questions pertaining to **whether or not individual subjects can be identified**.

    Even if you do not intend to associate individuals' data to their personal identifiers, if you keep a key (after coding patients' information to allow for later follow-up or data-gathering verification), you *can* track information back to individual subjects, and you can identify those subjects.

Further, when evaluating the data to be collected, the IRB considers the information collectively. For example, when looked at together, can the data collected lead back to the identity of an individual (e.g., age + time of admission + date of admission)? Typically, such a study would *not* be eligible for exempt status, because it does allow identification of individual subjects.

14. With very few exceptions, prospectively-conducted studies submitted to a TTUHSC IRB must have a **TTUHSC template consent form** (if a consent form is required by the study).

    NOTE: The IRB must approve the use of external entities' consent forms. *Please contact the local IRB office for additional information:* http://www.ttuhsc.edu/research/hrpo/irb

15. If a **corporate sponsor** (such as a pharmaceutical company) will be providing funding for the study, the TTUHSC PI must *first* go through the **Office of Research** (School of Pharmacy, Amarillo) and one of the following two Lubbock offices: the **Office of Sponsored Programs** (non-human subjects) OR the **Division of Clinical Research Office** (human subjects).

    For assistance with external grant applications and procedural information, please see http://www.ttuhsc.edu/sop/research/links/ExternalGrants.aspx.

    Please contact the appropriate Lubbock office directly for specific information regarding their requirements/procedures. The OSP's website is at http://www.ttuhsc.edu/sponsoredprograms/ *and the Division of Clinical Research contact information may be found at* http://www.ttuhsc.edu/research/office/dcr.aspx

    Investigators are also required to provide copies of ALL grants, contracts, and other materials regarding their funding (both applied for and funded) to the Office of Research (School of Pharmacy, Amarillo) AND, for those studies overseen by the IRB, to the IRB office.

16. **All industry-sponsored studies** will be assessed an **IRB fee**, according to TTUHSC policy.

    Please refer to the TTUHSC Institutional Review Board (IRB) Policies and Procedures Manual, section 4.4, http://www.ttuhsc.edu/research/hrpo/files/IRB_P&P.pdf

17. Prior to submitting a study for IRB review (and prior to beginning any aspect of the study), the **study must first receive approval from all appropriate committees/departments**.

    The time required to complete all of the necessary committee/departmental reviews should be taken into consideration when planning a study.

- **Prior to submitting *any* IRB project for review, the SOP Research Administrator (Office of Research, Amarillo SOP) must review it in its entirety in order to offer suggested changes.**
  NOTE: Because the iRIS system does not allow changes to be made after an application is signed and the initial review form is completed, investigators may prefer to prepare all documents, attach them in iRIS, and then complete the application *only up to* the point prompting that the application be signed (electronically) and submitted. *Prior to signing/submitting*, the investigator can then notify the Research Administrator that the project is ready for review in iRIS. After receiving the Administrator's comments, the investigator can then decide which recommended changes to incorporate into the submission. When the investigator finally submits the project, he/she should list the Research Administrator as one of the first reviewers. That way, the Department Chair and any other reviewers can see that the Administrator approved and signed off on the study (an SOP requirement).
  The other option for researchers is to list the Research Administrator as a reviewer from the very beginning. The iRIS process is automated – iRIS notifies all reviewers of the need to evaluate the submission. However, if the Administrator suggests needed changes, the PI will be obligated to withdraw the study, make the changes, and then resubmit. All reviewers will then *again* be asked to review the resubmitted project.
- **The Departmental Signatory Authority or Department Chair** must sign off on all new research studies submitted to the IRB. The Chair's approval (or the approval of the Chair's Designee) is required *prior* to submission to some review boards/committees/offices (such as the IRB, the Office of Sponsored Programs, or to any/all external entities).
  - For **Dallas** projects, Dr. Leff is the authorized "Department Chair"
  - In **Lubbock,** Dr. Seifert signs off on all IRB projects
  - In **Amarillo,** Dr. Akins is the designated signatory.
- Prior to submitting to any formal review, **TTUHSC residents** may also be required to submit to an **internal review** by a committee of faculty members. Specifics/deadlines vary, depending on the resident's project and faculty members involved.
- TTUHSC studies in which **radioactive materials** will solely be used for *research* purposes (excluding routine diagnostic tests/clinical treatments such as x-rays, bone scans etc.) must first be approved by the **Radiation Safety Committee**. The PI will be required to complete safety training and may be required to have a license to handle radioactive materials. *(Please see the Safety Services webpage for additional information:* http://www.ttuhsc.edu/Admin/safety/rad.htm.)
- TTUHSC recombinant DNA studies require approval by the **Recombinant DNA Biosafety Committee (RDBC)**. *(Additional information on this committee may be found at:* http://www.ttuhsc.edu/sponsoredPrograms/rdbc/)
- In some cases, approval will be required from the **Institutional Biohazards Committee (IBC)** prior to IBC submission. *(Additional information on this committee may be found at: http://www.ttuhsc.edu/sponsoredPrograms/ibc/)*

- In certain cases, individual investigators may also be required to submit to **internal peer reviews** or to receive approval from **other TTUHSC committees** prior to submitting to specific committees/boards (such as the IRB) and/or prior to submission to any external entity.
- As appropriate, the **Office of Sponsored Programs** and **Division of Clinical Research Office** must give financial approval for studies, prior to submitting to the IRB. *(Please see number 15 above.)*
- Prior to submitting grant applications outside of TTUHSC, the materials must first be routed through and approved by the **Office of Sponsored Programs.** The **Office of Research** should also at least receive copies of all such materials, even if investigators do not need assistance in preparing the documents.

NOTE: Committee reviews/approvals must be scanned into the computer and attached in iRIS to be reviewed by the IRB. All such additional documents should be attached as "Study Documents" in iRIS. *(For additional iRIS guidance, please log into your iRIS account. These Operating Procedures can be found under My Assistant)*

18. When appropriate, researchers will need to submit **IND (Investigational New Drug) or IDE (Investigational Device Exemption) numbers and Investigator's Brochures** with IRB submissions.

    NOTE: Even drugs approved by the FDA are considered to be "investigational drugs" if they're going to be used in new ways that are not listed on the label. The same "new use/off-label" rule of thumb applies to devices as well.

    For more information on IND/IDE applications, please see the TTUHSC Institutional Review Board (IRB) Policies and Procedures Manual, section 13.1, http://www.ttuhsc.edu/research/hrpo/files/IRB_P&P.pdf

19. **Special recommendations for *TTUHSC RESIDENTS:***
    - Get guidance on your project from individuals like the SOP Research Administrator early on, before you've invested too much time in organizing your study.
    - Allow approximately **8 weeks to get IRB approval**.
    - Due to the time limitations of resident projects, **retrospective studies** are often easier to accomplish than prospective studies.
    - **Multi-site studies are often hard to accomplish** within the project timeline, since multiple IRB approvals are often required.
    - Planning not only enough **time** to obtain all required committee/board approvals but also to **collect and evaluate all of the data** is essential.
    - **Strictly limit the amount of Protected Health Information gathered**, particularly on data collection sheets (i.e., if possible, do not record patient names, record numbers, dates, or any identifying information). *(For additional explanation of PHI, please refer to the Code of Federal Regulations: 45 CFR 164.514 (b) (2) & 45 CFR 164.514 (e) (2);* http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1 – select the most

recent version of Title 45, and then continue selecting appropriate sections, as listed in the above citation).

- **Double-check dates** given for the study. If conducting a retrospective chart review for a set span of months, no dates in the future should be listed, unless there is also a prospective element to the study. Typically, studies are either retrospective OR prospective, but not both.

20. **All IRB submissions must be sent electronically, via the iRIS system.**
iRIS Website: **http://www.ttuhsc.edu/research/iRIS/**

*For step-by-step guidance in using the iRIS system, please consult the **Investigator's Guide to iRIS Submissions** at: http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf)*

While the online user manual is very helpful and takes you through each step of the iRIS process, to **schedule an in-person iRIS training**, please contact the SOP Research Administrator at (806)356-4000, 326 and/or Kathy Thomas in the TTUHSC Amarillo IRB, (806)354-5419.

Before using the iRIS system, investigators must have completed **CITI training** *(for more information on the training requirements, please see number 4 above)* and must have an iRIS username and password.

To **request iRIS access** and obtain a username/password, please submit the form located at: http://www.ttuhsc.edu/research/iris/forms.aspx

NOTE: Because the iRIS system is the primary tracking system for all IRB activity, all investigators are asked to maintain their current contact information in the system. After logging in to iRIS, select:

to make any necessary changes. The IRB will use this information to contact you (as the researcher) with any questions. Providing current contact information might also increase the likelihood that your studies will pass through the IRB more quickly – if you can easily be reached, IRB questions to you will be answered more quickly.

Initial IRB Review – What to Submit to the IRB

This list is not exhaustive but will hopefully provide a starting point and will address commonly-overlooked aspects of submitting human studies for review. Please see the IRB's website for additional, more specific information: http://www.ttuhsc.edu/research/hrpo/irb

*NOTE: All TTUHSC IRB submissions must go through the online iRIS system. (For additional iRIS guidance, please consult the **Investigator's Guide to iRIS Submissions** at: http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf)*

1. **Application**

   *(For additional iRIS guidance, please consult the **Investigator's Guide to iRIS Submissions** at: http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf)*

   Additional Notes Regarding the iRIS IRB Application *[This information is supplemental to the **Investigator's Guide to iRIS** (please see website directly above). These points address commonly-overlooked elements or common mistakes made by investigators]:*

   - *All* individuals listed on the application must have completed the **TTUHSC-required/approved CITI training**. *(For more information about these requirements, consult the IRB's website at:* http://www.ttuhsc.edu/research/hrpo/irb/edurequirements.aspx.)
   - Only those **individuals selected in the application will have access to the study** and will be eligible for IRB approval for involvement in the study; however, research personnel may be added later (by amendment). *(For more information regarding the selection of individuals not already listed in the iRIS drop-down menus, please contact the appropriate (depending on location) IRB office:* http://www.ttuhsc.edu/research/hrpo/irb/
     Also, please note: Appropriate *departments* must first be identified in section 2 of the application before you can select personnel. If pertinent personnel do not appear in section 3, revisit section 2 for accuracy.
   - In the **Research Procedures** section, investigators often fail to note the following instructions given in the first question: **Describe in list or outline fashion**. The IRB would like to see a simple, yet detailed, explanation of what will happen, in wording understandable to a lay person.
   - In the **Protocol Sponsor** section of the application, please indicate the site(s) where each aspect of the research will take place. Even if there is no *external* sponsor – there will still be an *internal*, departmental sponsor, which should be listed. Before the IRB will provide final approval of a project, it will require a letter of support from all non-TTUHSC entities (e.g. Northwest Texas Hospital, BSA, the VA, Harris

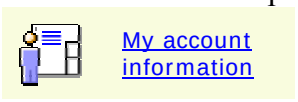
Methodist, etc.).
NOTE: These non-TTUHSC study sites can be listed on the iRIS application under "Other."

- In the **Subject Recruitment** section, some of the questions require that answers be given one at a time, in a list: ***(Add each criteria 1 by 1, using the add button on the next screen as many times as the number of criteria)***
- Information regarding potential risks/benefits, duration of subject involvement, total amount of subject personal time, and the approximate time required for each subject visit (sections 17 and 18) must be stated **using the exact wording** as on the consent form.

2. **Information on the PI and co-investigators**

If the IRB has not previously received it, or if it has been updated substantially, upload a current CV for the PI and each of the co-investigators in iRIS.

From his/her iRIS homepage, each study member can select



and then click on the tab "Profile" to add/maintain a current CV.

To add additional CVs for personnel who do not have/require iRIS access (e.g. technicians, external collaborators, etc.), uploading CVs into "Study Documents" under the pertinent study is acceptable; however, whenever possible, keeping CVs current under each iRIS user's individual profile is preferred.

For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS Submissions*** *at:*
http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf.

3. **Verification of very recent or imminent completion of CITI training**

Notification of completion of this required training is automatically conveyed to the IRB online; however, in some cases, lag time in this reporting procedure may require PIs to communicate training completion directly to the IRB. If training has not yet been finished, the IRB should be informed of when to expect notification of completion.

NOTE: Investigators should always keep in their own files all certificates or notifications of training completion that they receive, as part of their overall responsibility to maintain complete records for the study.

Should the IRB need verification of training completion, attach certificates, etc. as "Study Documents." *(For additional iRIS guidance, please consult the* ***Investigator's Guide to iRIS Submissions*** *at:*
*http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_*

14_2005.pdf)

4. **Protocol**

   Federal guidelines require a protocol to be submitted with each submission. Much of the information requested on the IRB application may be redundant (repeated in the protocol), but *both* the application and the protocol must be completed and submitted, as separate documents. Where appropriate, the IRB expects and encourages copying and pasting information into the IRB application directly from the protocol.

   *Please see the section below on the **Protocol Template**, to use when creating a new protocol, and for additional iRIS guidance, please consult the **Investigator's Guide to iRIS Submissions** at:*
   http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf.

5. **Letters of support or letters of approval from subcommittees**

   Before granting final approval to a project, the IRB will need to receive copies of all approvals from other entities. Examples: A letter of support from a hospital research setting, the Dallas VA's Research Committee/IRB approval letter, approval from the Institutional Biohazards Committee, or Radiation Safety Committee reports.

   *For additional iRIS guidance, please consult the **Investigator's Guide to iRIS Submissions** at:*
   http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf

6. If consent of subjects is required, the **TTUHSC informed consent** template OR a request to waive consent must be used.

   NOTE: The IRB must approve the use of external entities' consent forms. *Please contact the local IRB office for additional information:*
   http://www.ttuhsc.edu/research/hrpo/irb

   For additional information about waiving consent, please see the TTUHSC Institutional Review Board (IRB) Policies and Procedures Manual, section 7.2,
   http://www.ttuhsc.edu/research/hrpo/files/IRB_P&P.pdf

   *For additional iRIS guidance, please consult the **Investigator's Guide to iRIS Submissions** at:*
   http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf

   Additional Notes Regarding Informed Consent on iRIS *[This information is supplemental to the **Investigator's Guide to iRIS Submissions** (please see website*

directly above). These points address commonly-overlooked elements or common mistakes made by investigators]:

- When creating or adding an informed consent in iRIS, a helpful box with **Instructions** appears on the right side of the screen. This box will walk you through the process; you might consider copying and pasting this information into another document that you can easily refer to while going through the process.
- Because the TTUHSC consent form template is routinely updated, it's recommended that investigators **download the template** before creating a consent for a new study.
- After the current consent form template has been downloaded from iRIS and saved onto your computer, you can make changes directly to that file on your computer as much/often as necessary. When all changes are made, you'll simply "**Check-in"** the revised consent in iRIS, as often as needed.
- **Please remove all blue-colored instructions** to you (the investigator) from the consent form before submitting. The IRB provides this information as additional instructions to you, but they should be deleted from the final copy.
- Before viewing the checked-in consent, you may need to **refresh your screen back on iRIS**. (This is only necessary if you worked on the consent form while iRIS was left open in your browser.) Click on the refresh icon  along the browser's toolbar OR hit the F5 button on your keyboard to refresh.
- When creating the informed consent document, please remember that it should be **no higher than a 7th-grade reading level**.
- If you are using a consent form that has already been created or one from a non-Tech entity (e.g. the VA), it **MUST be an .rtf file.** Many VA consents come in .pdf formats, but these must be saved as files with .rtf file extensions before they can be uploaded into iRIS (in "Study Documents"). NOTE: Only non-Tech consent forms must be loaded into "Study Documents;" **Tech templates must be attached in the consent form area of the submission.** *For additional iRIS guidance, please consult the **Investigator's Guide to iRIS Submissions** at: http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf.*

7. If applicable, one of the two appropriate TTUSHC **HIPAA forms** (Authorization to Disclose PHI for Research Study *OR* PI's Request to Disclose PHI) *OR*, if research is taking place at a non-TTUHSC facility, *that* institution's HIPAA form

   *For additional iRIS guidance, please consult the **Investigator's Guide to iRIS Submissions** at: http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf.*

8. **Research instruments (study documents)**

   Examples: Questionnaires, subject recruitment notices, patient education materials, follow-up interview questions, scripts used by study personnel in interacting with subjects, anything the subjects will see/be given, data collection forms, etc.

For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS Submissions*** *at:*
http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf.

9. **When applicable, grant applications, approval letters, and other documentation from funding entities**

   For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS Submissions*** *at:*
   http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf.

10. **General rule of thumb when submitting to the IRB:** When in doubt, submit it. The IRB always appreciates receiving adequate, thorough documentation, which only serves to make their jobs easier.

During the Study – While Conducting

This list is not exhaustive but will hopefully provide a starting point and will address commonly-overlooked aspects of reporting on human studies. Please see the IRB's website for additional, more specific information: http://www.ttuhsc.edu/research/hrpo/irb

NOTE: All IRB submissions are now on the online iRIS system. All four of the reports outlined below are submitted through iRIS. (For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS Submissions*** *at: http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf)*

1. **Adverse Event Reports**

   The Principal Investigator must submit a report to the IRB on each and every unanticipated adverse event or problem (serious and non-serious) involving risks to subjects that occur at TTUHSC or an affiliated entity. Reports must be submitted for all adverse events that are known to be related, or may possibly be related, to the research activities, within two (2) business days after becoming aware of the event. **NOTE: Even if you do not think that the drug/study caused the adverse event, you still must submit a report.**

   To enter adverse event reports into iRIS, log in and open your study. The screen should open up with the tab for "Submissions" activated. The second column, "Submission Types" includes a link for "Adverse Events." By selecting that link, individual adverse events may then be entered for that study by clicking on the button: 

   Once created, adverse event reports may then be electronically signed by the PI and submitted to the IRB.

2. **Continuing Reviews (also called Periodic Progress Reviews)**

   The PI will be required to submit a continuing review. Put simply, this is just an update to the IRB of research activity since the last review and a request for authorization to continue conducting the project.
   - PIs must be careful to **submit information that corresponds to previous IRB submissions** (i.e. if the first year's continuing review report indicated that 25 subjects had been enrolled since the start of the study, the second year's report cannot list only 20 subjects; a study that is granted IRB approval for a total of 100 subjects cannot enroll 150 without prior IRB approval).
   - PIs often make the mistake of submitting a continuing review when a **final closure** would be more appropriate *(please see the section below on **After the Study Has Concluded**)*. If the study is being closed, only the study closure needs

to be submitted to the IRB. Even if the IRB has requested a periodic progress review, the study closure alone is adequate.

- Because the IRB will not necessarily be again reviewing ALL study documentation when considering a continuing review, PIs need to **provide complete, descriptive information** – so that even individuals without any knowledge of the study can understand what is being reported.
- If still enrolling subjects, **the consent form should be double-checked**. The IRB will need to use the unapproved consent version (stored in iRIS) to re-date and re-stamp the consent for future use, so this unapproved version should represent the intended/current consent form. If the PI is using a non-Tech consent, this consent file must be attached in iRIS as a file with an ".rtf" extension in "Study Documents" – only Tech consents are attached in the consent form area of iRIS.
- **NOTE: When reporting to the IRB, do not include any PHI or identifiable data pertaining to specific subjects. This information should be protected in the PI's files in a confidential manner and cannot be published or disseminated in any way.**

For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS Submissions*** *at:*
http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf.

3. **Amendments**

<u>If anything changes in the study after the initial review is approved by the IRB, the changes must be submitted to the IRB for approval, prior to implementing these changes in your project.</u>

Examples of study changes: Research personnel changes, study location changes, procedural/protocol changes (such as expanding the months requested/number of records evaluated in retrospective chart reviews, adding or changing data elements to be recorded/evaluated, dosage alterations, adjusting the number of subjects enrolled, or changing the inclusion/exclusion criteria used when enrolling, etc.).

Investigators often make the mistake of failing to clearly outline to the IRB proposed changes. Because the IRB reviewers may not review all previously-submitted study materials completely and/or may not be able to easily compare different versions of the documents, please make it as clear as possible *exactly* what you would like to change.

NOTE: **If changes affect the submitted study protocol**, **it will need to be updated and submitted with the amendment. Changes will need to be highlighted/marked in some way.** (Federal regulations require IRBs to maintain the most recent protocols on file.) Other study documents that do *not* change (such as the application, etc.) do not need to be re-submitted – they will still be accessible in the study.

For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS***

Submissions *at:*
http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf.

4. **IND Safety Reports**

If/when IND safety reports arrive from sponsors, scan them in to your computer. Log in to iRIS and open your study. The screen should open up with the tab for "Submissions" activated. The second column, "Submission Types" includes a link for "IND safety reports." By selecting that link, individual reports may then be entered for that study by clicking on the button: 

Once created, from the study management screen and under the "Outstanding Submissions" column, the reports will be listed next to the "send submission" button. After clicking on send, you will be taken to the sign-off page. Any study member may sign off on IND submissions – the PI is not required to sign off on these reports. After a study member electronically signs, it is submitted to the IRB.

After the Study has Concluded

This list is not exhaustive but will hopefully provide a starting point and will address commonly-overlooked aspects of closing human studies. Please see the IRB's website for additional, more specific information: http://www.ttuhsc.edu/research/hrpo/irb

NOTE: All IRB submissions are on the online iRIS system. The Study Closure report described below is submitted through iRIS. (For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS Submissions*** *at: http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf)*

1. **Study Closure**
   - If research personnel will NOT be returning to the gathered **subject data** for further analysis, the study can be closed.
   - Investigators can close a study and continue to evaluate their data *only if* the subject information they will be reviewing is **completely de-identified** (they would not be able to track the information back to the individual subjects – even coded numbers have been removed or the key destroyed).
   - Because the IRB will not necessarily be again reviewing ALL study documentation when evaluating a final closure report, PIs need to **provide complete, descriptive information** – so that even individuals without any knowledge of the study can understand what is being reported.
   - **NOTE: When reporting to the IRB, do not include any PHI or identifiable data pertaining to specific subjects. This information should be protected in the PI's files in a confidential manner and cannot be published or disseminated in any way.**
   - **Special note to RESIDENTS: Before leaving TTUHSC, residents *must* close their studies with the IRB.**

     For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS Submissions*** *at: http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf.*

2. **In a confidential manner, PIs need to maintain study records for 5 years.**

   Principal investigators are required to keep study documents/records for a minimum of five (5) years after completion of the study for audit by the IRB or authorized officials from the granting agency, FDA, DHHS, etc. **All such study-related documents are considered institutional/departmental records and should not be transferred to another institution with a principal investigator leaving TTUHSC.**

Protocol Template

The information below may be used as a template/guide when creating a new protocol. This is by no means exhaustive or without flexibility, but the template has been reviewed and judged to be an appropriate starting point by IRB staff. For additional information about what should be included in a protocol submitted to the IRB, please contact your local IRB office at: http://www.ttuhsc.edu/research/hrpo/irb

1. **Include a cover sheet**

   Please see page 22 of this document for a sample cover sheet.

   NOTE: Only enter pertinent information (i.e. if there is no coordinator, none need be listed).

   The **sponsor ID and protocol number** are primarily used in industry-sponsored studies; however, PIs may choose to list the TTUHSC department supporting the study, and if the PI assigns a number or brief descriptive phrase to help identify the study, that can be listed here. NOTE: The iRIS system *requires* that a sponsor and protocol number be entered in the application.

2. **Follow the outline starting on page 23 of this document to create a new protocol.**

3. After completing the protocol, it must be attached as a **"Study Document" in iRIS.** All IRB submissions are required to be submitted electronically via iRIS. When completing the **IRB Application on iRIS**, the best response to the question asking how the protocol will be submitted is **"Electronically via iRIS."** The IRB does prefer that the protocol is submitted in this way; however, if the protocol comes directly from the study sponsor in hard-copy, is not available in electronic format, and is over 100 pages, the IRB will accept a paper copy (they will need 2 complete copies). If the hard-copy protocol is under 100 pages, please scan it into the computer to attach in iRIS.

   *For additional iRIS guidance, please consult the **Investigator's Guide to iRIS Submissions** at: http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf.*

Sample Protocol Cover Sheet

FULL STUDY TITLE
SPONSOR ID / PROTOCOL #
Version Date of Protocol

PRINCIPAL INVESTIGATOR
DEPARTMENT
INSTITUTION
STREET ADDRESS
CITY, STATE ZIP
PHONE #
E-MAIL ADDRESS

CO-INVESTIGATOR
DEPARTMENT
INSTITUTION
STREET ADDRESS
CITY, STATE ZIP
PHONE #
E-MAIL ADDRESS

CO-INVESTIGATOR
DEPARTMENT
INSTITUTION
STREET ADDRESS
CITY, STATE ZIP
PHONE #
E-MAIL ADDRESS

STUDY COORDINATOR
DEPARTMENT
INSTITUTION
STREET ADDRESS
CITY, STATE ZIP
PHONE #
E-MAIL ADDRESS

Table of Contents for Protocol Template

Protocol Outline

I. OBJECTIVES
   a. What special information will this activity provide, and what is the significance of that information?
   b. How will the current study augment the existing knowledge base?
   c. State objectives clearly in measurable terms, as specified in the statistical considerations section (VI) below.

II. BACKGROUND
   a. Include pertinent literature review information, previous studies or work done by the investigator(s).
   b. This background documentation should help support the rationale behind the stated objectives.

III. ELIGIBILITY CRITERIA
   a. Inclusion
      i. List all essential requirements a potential subject must meet in order to be included as a study participant. Consider age (adult vs. <18 years of age) gender, ethnic groups, and protected populations, *as listed in the TTUHSC IRB Policy & Procedures Manual, section 9:* http://www.ttuhsc.edu/research/hrpo/files/IRB_P&P.pdf
      ii. NOTE: In the iRIS application, the inclusion criteria must be listed individually, one criterion at a time, so having these criteria clearly (and separately) delineated in the protocol is helpful. *(For additional iRIS guidance, please consult the **Investigator's Guide to iRIS Submissions** at: http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf)*
      iii. It is perfectly acceptable to conduct studies focusing on a single gender or specific ethnic group(s); however, justification of why this is necessary and what precautions will be taken to protect special populations should be provided to the IRB (in iRIS, this may be clarified in the application by using the text editor).
      iv. All subjects must be informed of the investigational nature of this study and must sign and give written informed consent, in accordance with institutional and federal guidelines.
   b. Exclusion
      i. List all essential requirements that would exclude subjects from study participation.
      ii. NOTE: In the iRIS application, the exclusion criteria must be listed individually, one criterion at a time, so having these criteria clearly (and separately) delineated in the protocol is helpful. *(For additional iRIS guidance, please consult the **Investigator's Guide to iRIS Submissions** at:*

http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf).

IV. METHODOLOGY

a. Setting
   i. Where does the research take place (examples: TTUHSC clinic, VAMC, NWTHS, BSA, Harris Methodist, etc.)?
   ii. Consider not only where the subjects will be but also where the study data will be examined, subject samples collected/stored, etc.

b. Recruitment
   i. How will subjects be identified/recruited?
   NOTE: While a retrospective chart review does not require recruiting in a technical sense, subjects *are* identified and selected based on certain criteria.
   ii. Where/how are informed consent and eligibility information obtained?
   iii. If applicable, who is authorized to obtain the informed consent?
   iv. State the type and amount of incentive or compensation to be offered to the study subjects, if any. If money is to be used as an incentive, please state the amount to be received by each subject, and explain how payments will be prorated if subjects withdraw before completion. [Any credit for payment should accrue as the study progresses and should not be contingent upon completing the entire study.]
   NOTE: Any changes in compensation must be approved by the IRB prior to implementing such change.

c. Intervention(s)
   i. List exactly what is to be done to each subject and/or what the subject is expected to do.
   ii. Indicate all procedures to be done solely for the purpose of this study that would not normally be done for or to the subject.
   iii. Identify volume of blood, tissue, or other materials to be extracted, (in lay terms such as "one teaspoonful of blood") and include methods and time intervals of extraction. Will any of these tissues/fluids be handled by personnel other than clinical laboratory technologists or a commercial laboratory?
   iv. Describe experimental intervention(s) such as genetic research, gene therapy, interviews or research questionnaires.
   v. If study drugs/devices are to be administered/used, list the drugs, injections, etc., to be administered. Indicate dosages, means and intervals of administration, and present a description of the indications and expected side effects. Indicate if drugs/devices are to be used in an unapproved manner – list IND or IDE number, if required.
   vi. If radioactive substances are to be used for research purposes only, list quantity of radiation to be received, (excluding routine

diagnostic tests such as x-rays, bone scans, etc.).
NOTE: Describe and submit the protocol to the Radiation Safety Committee for review and approval *prior to IRB submission*.

vii. If recombinant DNA (rDNA) is to be used for research purposes, explain the procedures and exactly what will be evaluated.
NOTE: Submit the protocol to the Institutional Biosafety Committee for review and approval *prior to IRB submission*.

viii. Will research data from any educational test (cognitive, diagnostic, aptitude, achievement) or data collected from already-existing information (documents, records, pathological specimens, diagnostic specimens) allow you to identify subjects directly or through codes – at *any* time?

ix. Carefully consider the dates of the study (information that must also be provided on the IRB application on iRIS). If conducting a retrospective chart review for a set span of months, no dates in the future should be listed, unless there is also a prospective element to the study. Typically, studies are either retrospective OR prospective, but not usually both.

d. Risks

i. Does the research involve more frequent or greater risks to the subject than the risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests? If so, list them. If not, state this.

ii. Potential risks include: physical, psychological, social, economic, legal, and others which result from or are an increase from ordinary risks of daily life, including recognized risks inherent to a chosen occupation or field of service.

iii. Estimate their frequency, severity and reversibility, and the steps you haven taken to minimize each.

iv. List any risks that could affect a specific subject population (e.g. can the procedure or agent of this study have any effect on the development of an exposed fetus?)

v. With any research study (even retrospective chart reviews that do not require any interaction with subjects), there is at least a minimal risk. At a minimum, subjects risk the loss of their confidentiality, if nothing else. Truly putting some thought into answering the question regarding the risk to subjects (on the iRIS application and in the protocol) and clearly outlining what will be done to alleviate the risks helps the IRB make a more informed decision and increases the likelihood that their concerns regarding protection of confidentiality (and any other potential risks) will be adequately addressed. With regard to protecting confidentiality, providing information such as who will have access to patient information and PHI, where the data collection forms will be stored and how they will be stored, and who will have access to the

data itself (not only during the study but also after completion) should be included.

vi. NOTE: Regardless of how you determine the risk, the IRB may assign a different risk.

e. Data Management

i. Will the research require access to subjects' medical records? If so, list the individuals who will have access and why this access is required. All of these research personnel must have completed their CITI training requirements *(please see number 4 under the section above on **Initial Concerns**).*

ii. Assurance that confidentiality of research data will be protected AT LEAST in accordance with the prevailing standards that apply to all clinical data is required. If the research is in any way sensitive, the data must be stored strictly under code numbers, without identifiers. The master list and consent forms for sensitive data should be stored separately under lock and key – state this location and who will have access to the secured data.

iii. No personal subject identifiers are to be used in any presentation or publication. In addition, the IRB does not need or want such PHI reported to them.

iv. Specify how confidentiality will be maintained: Who will have access to subject identifiable data? Where/how will data be stored and protected even after study completion?

v. How long will it take to complete the study (consider accrual, data collection, follow-up visits, completion of *all* study data collection and analysis)?

vi. NOTE: Data analysis can continue after the closure/completion of a study provided that no data can be tracked back to individual subjects (de-identified data only: any keys that were developed have been destroyed, etc.).

V. PROCEDURES

a. List all study interventions (examples: blood drawing, study assessments, questionnaires, etc.)

b. Clearly explain what each individual member of the research team will be doing throughout the study.

VI. STATISTICAL CONSIDERATIONS

a. This information justifies the number of study participants and controls (or records) and provides a reference for the IRB to evaluate potential benefit (benefits:risks analysis). Performing a power analysis is particularly important if the subject population is small. Justifying to the IRB that the study is viable and worth doing is important. If an appropriate number of subjects cannot practically be recruited, explain why they cannot be enrolled and why you would still like to conduct the study. Why would

the data still be valuable? If applicable, argue that this would be a valuable pilot study to guide future research.

b. If applicable, identify method of randomization, blinding, etc.
c. Explain what statistical measures/techniques will be utilized to interpret/evaluate study results.

VII. ETHICAL AND REGULATORY CONSIDERATIONS

a. The following must be observed to comply with Food and Drug Administration regulations for conducting and monitoring clinical investigations; they also represent sound research practice:
   i. Informed Consent – The principles of informed consent are defined by federal regulatory guidelines (Federal Register Volume 46, no. 17, Jan 27, 1981, part 50) and the Office for Protection from Research Risks Reports: Protection of Human Subjects (Code of Federal Regulations 45 CFR 46: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) NOTE: When creating the informed consent document, please remember that it should be no higher than a 7th-grade reading level.
   ii. Use of Specimens for Research – The subject is free at any time in the future to decide not to provide specimens or to withdraw his/her specimens from further scientific research. Such a decision will have *no* impact on his/her treatment or other aspects of participation in the study.
   iii. Institutional Review – The study must be approved by all relevant TTUHSC committees [peer review committees, Institutional Biohazards Committee (IBC), Radiation Safety Committee (RSC), Recombinant DNA Biosafety Committee (RDBC), Conflict of Interest Committee] *and* the Research Administrator (SOP, Amarillo) *and* the Department Chair or designated departmental representative *prior to* the TTUHSC IRB submission. IRB review and approval is defined by Federal Regulatory Guidelines (Ref. Federal Register Vol. 46, No. 17, January 27, 1981, part 56) and the Office for Protection from Research Risks Reports: Protection of Human Subjects (Code of Federal Regulations 45 CFR 46).

VIII. BIBLIOGRAPHY

IX. DATA COLLECTION FORMS

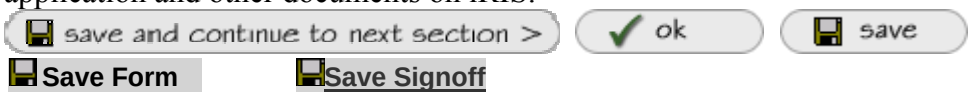
a. Forms on which the data will be recorded.
b. When considering what elements to record, please respect patient confidentiality (i.e., if you do not *need* information, do not record it!)
c. In addition, consider your own time. Recording numerous data elements from medical charts can be time-consuming, particularly in those institutions in which charts are not computerized.
d. Upload forms as *separate* documents into the "Study Documents" link in iRIS (do not incorporate them into the protocol).

X. APPENDICES
   a. Questionnaires
   b. Posters, patient recruitment notices
   c. Brochures
   d. Letters of support from outside institutions
   e. Information that the subject will see or be given
   f. Scripts or other information that will be used by study personnel when interacting with subjects
   g. Instruments/documents used to evaluate data

Additional iRIS Notes/Tips/Suggestions

- In iRIS, always ***save*** to preserve any changes and to proceed to the next section. If in doubt, SAVE.

  All of the following icons are crucial during the process of entering the application and other documents on iRIS:

- **Excel documents** do not work in the iRIS environment. If Excel documents are necessary, convert them to PDF documents before attaching them as "Study Documents" in iRIS.

- **Be careful** when using the button: 

  It will not take you back to the previous section of your Study Application but will back out of the application entirely – it doesn't always take you back just one step. Using the browser's back button will take you back to the previous page when the iRIS back button does not.

- Documents may be uploaded and stored in iRIS even before submission to the IRB. The application and other **documents may be worked on while in draft form** until the PI is ready to submit.

  NOTE: After a submission has been electronically signed by the PI and sent to other signatory authorities for approval, materials for that study may no longer be changed without withdrawing the study submission in iRIS (only the PI can withdraw the study). Changes can be made, and the study can be resubmitted, but then all signatory authorities will be required to sign off on the study again.

  After the IRB has placed a study on the agenda, no changes can be made by any member of the study team without assistance from the IRB office. After voting on a study, the IRB will notify the PI of specific changes that are necessary, but if the PI has not has not yet been informed of the IRB decision but still needs to make changes, please contact the appropriate (depending on location) TTUHSC IRB office for assistance: *http://www.ttuhsc.edu/research/hrpo/irb*. After the IRB notifies the PI of their decision, everything submitted for that study is preserved as it was originally submitted (for record-keeping purposes). Any necessary changes to that study must then be submitted as an amendment.

It is important to remember that the IRB will not evaluate any component of a study until that study is submitted. And *all* documents must be appropriately attached on the "Initial Review" form in iRIS in order for IRB reviewers to see/evaluate them.

For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS Submissions*** *at:* *http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf*.

- On the "Initial Review" form, the **"Comments" field can serve in lieu of a cover letter**. In this section, investigators may include brief notes, explanations, and clarifications to the IRB – anything you'd like for the IRB to know can be entered here, or elements from your study that you want emphasized can be reiterated in this space.

- After completing the "Initial Review" form – and attaching all appropriate documents in the correct places on that form – the PI will click on Sign and Submit. Or, the person completing the submission on behalf of the PI will click on Notify Principal Investigator. The PI will be prompted to sign off on the application/initial review submission. Your electronic signature is your iRIS password. PI's should remember to scroll down to the bottom of the sign-off page and check the box under:

I certify that I, or any others involved in the design, conduct or reporting of the research project, do not have an aggregrate financial interest in excess of $10,000 fair market value or 5% ownership interest in a single entity or hold intellectual property rights that involve products or services that are in any way related to this proposal.		
☐ Yes ☐ No		

- Another frequently-forgotten step in iRIS happens when the PI selects reviewers. The SOP Research Administrator and Department Chair (or designated signatory authority) are required to electronically sign/approve all IRB projects. After choosing desired reviewers (more than the two required individuals can be selected at the PI's discretion) and the order of their reviews (the Administrator should be listed before the Departmental signatory authority), don't forget to check yes:

Have you completed your selection of required signatures?

◉ **Yes**

○ **No**

before selecting Save Submission Reviewer(s)

- Sending **emails from within iRIS** is recommended for the sake of record-keeping. *ALL* emails sent via iRIS are archived and retained *permanently* (they cannot be deleted) in the system.

  For additional iRIS guidance, please consult the ***Investigator's Guide to iRIS Submissions*** *at:* *http://www.ttuhsc.edu/research/iRIS/files/Investigators%20Submissions%20Manual_09_14_2005.pdf*.

- **Attachments cannot be sent through the iRIS email system**. Documents can always be attached to studies in iRIS (as "Study Documents"), and references can be made to those documents in iRIS emails; but, again, attachments cannot be made directly to the emails sent through iRIS.

Document created by Melissa Lockman, SOP Office of Research, with assistance from Kathy Thomas, TTUHSC Amarillo IRB.