Ethics in Research
&
Navigating the IRB Process

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for
Faculty Development
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THE UNIVERSITY of TENNESSEE
GRADUATE SCHOOL OF MEDICINE

Navigating the IRB & Ethics in Research - Introduction

The IRB has an "open door" policy, (currently a remote door) signifying our willingness to assist & answer questions. We will set up a Zoom/Teams session to walk you through a submission or discuss projects at any point.

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Navigating the IRB & Ethics in Research - Introduction

Learning Objectives

- Give examples of unethical historical research which led to IRB oversight for clinical research
- Determine the category of IRB review based on risk to subjects
- Know how to complete an IRB application in iMedRIS
- Avoid common pitfalls that may delay IRB approval
- Know who to call when you have questions or need assistance

Ethics in Research – Historical Perspective

1900 WALTER REED YELLOW FEVER STUDY – [SUBJECTS DELIBERATELY INFECTED - 3 DIED]

1932—1973 TUSKEGEE STUDY - [NONE OFFERED PENICILLIN DEEMED EFFECTIVE IN 1943 - STUDY CONTIUED TO 1973]

1939 STUTTERING STUDY [ORPHAN CHILDREN WERE SUBJECTED TO HARRASSMENT IN AN ATTEMPT TO GET THEM TO STUTTER]

1946 NAZI DOCTORS' TRIAL [CRIMINAL PROCEEDINGS OF DOCTORS PARTICIPATING IN INHUMANE EXPERIMENTS ON WW2 PRISONERS]

1946 — 1953 RADIOACTIVE CEREAL EXPERIMENTS AT FERNALD [MENTALLY DISABLED CHILDREN FED RADIOACTIVE CEREAL]

1956 — 1972 WILLOWBROOK EXPERIMENT [MENTALLY DISABLED CHILDREN DELIBERATELY INFECTED WITH HEPATITIS]

1956 — 1962 THALIDOMIDE EFFECTS [MANUFACTURERS REQUIRED TO ESTABLISH DRUG'S EFFECTIVENESS PRIOR TO MARKETING]

1961 — 1962 MILGRAM STUDY [SOCIAL SCIENCE STUDY TO UNDERSTAND ROLE OF OBEDIENCE TO AUTHORITY]

1963 JEWISH CHRONIC DISEASE HOSPITAL [INJECTION OF LIVE CANCER CELLS INTO INDIGENT, CHRONICALLY ILL ELDERLY PATIENTS]

1971 STANFORD PRISON EXPERIMENT [PSYCHOLOGY OF IMPRISONMENT – MOCK PRISON WITH VOLUNTEER COLLEGE STUDENTS]

1995 US RADIATION EXPERIMENTS DISCLOSED [RADIATION EXPERIMENTS ON THOUSAND'S OF US CITIZENS DURING WW2]

1998 JESSE GELSINGER [18 YEAR OLD DIED FROM GENE TRANSER EXPERIMENT EVEN THOUGH DISEASE WAS NOT SEVERE]

2001 ELLEN ROCHE [HEALTHY VOLUNTEER GIVEN DRUG TO INDUCE A MILD ASTHMA ATTACK]

2003 SUPPORT [COMPARATIVE EFFECTIVENESS RESEARCH ON PREMATURE INFANTS - INAPPROPRIATE RANDOMIZATION?]

2005 — 2009 HAVASUPAI SETTLEMENT [BLOOD COLLECTED IN 1990'S TO STUDY DIABETES WAS USED FOR UNRELATED STUDIES]

2010 GUATEMALA SYPHILIS STUDY EXPOSED [IN 1940'S GUATEMALANS DELIBERATELY INFECTED WITH STD ORGANISMS]

2010 THE IMMORTAL LIFE OF HENRIETTA LACKS [CANCER CELLS FROM HENRIETTA LACKS ORIGINATORS OF THE HELA CELL LINE]

2014 — 2016 EBOLA OUTBREAK [RAPID APPROVAL OF CLINICAL TRIALS IN AFFECTED AREAS RESULTING IN UNPROVEN THERAPIES]

2014 FACEBOOK EMOTIONAL CONTAGION STUDY [NEWS FEEDS OF OVER 600,000 FACEBOOK USERS MANIPULATED]

2018 CRISPR EXPERIMENT [EMBRYONIC GENOME EDITING]

2019 SARS-COV-2 PANDEMIC [EMERGENCY USE OF NEW DRUGS &THERAPIES]

PRIM&R Research Ethics Timeline

Ethics in Research – Historical Perspective

Tuskegee Study, 1932-1973, PHS natural progression study of untreated syphilis in African American men. The men were not told of their diagnosis or possible treatments, spinal taps to assess for neurosyphilis were described as "special free treatment" and penicillin became the drug of choice for syphilis in 1947, but researchers did not offer treatment to the research subjects even though the study didn't end until 1972.

Stuttering Study, 1939, This social science experiment set out to prove that stuttering is a learned behavior that can be induced through psychological pressure. This theory was tested on 22 children at Iowa's Soldiers' Orphans' Home. The children were subjected to steady harassment and badgering in an attempt to get them to stutter.

Willowbrook Hepatitis Study, **1950s,** Cognitively impaired children (5-10 yrs old) were intentionally given hepatitis in order to track the development of the viral infection. The study began in 1956 and lasted for 14 years.

(The results eventually contributed to the development of a successful vaccine.)

These examples demonstrate inadequate or non-existent informed consent and unjust distribution of risk to vulnerable populations.

Ethics in Research – Historical Perspective

Jesse Gelsinger – 1999, Gene therapy

Teenager died 4 days after receiving gene therapy. The researchers had earlier told the FDA they would tighten up the trial's eligibility criteria, but they never followed through. When two patients suffered serious side effects, the scientists did not put the study on hold as required. It turned out Jesse's pretrial test results showed he had poor liver function, indicating he shouldn't have received the gene injection.

- **Audit findings cited an inadequate informed-consent process. Researchers hadn't told Jesse about the earlier patients' side effects. Study investigator was accused of a conflict of interest: he had a stake in the company that owned the gene-transfer technology and stood to benefit if the trial succeeded.**
- **Gene therapy research in the U.S. was drastically affected and delayed by this one event**

Ethics in Research – Historical Perspective

CRISPR TECHNOLOGY - FIRST GENE-EDITED BABIES

2018

- Contrary to the scientist's claim, the aim of his experiments was not to treat any serious genetic disease. There was in fact no medical necessity of the experiment at the outset.
- Questions remain regarding the content of the informed consent process, whether there was institutional oversight, and the presence of political pressure on the scientist from the Chinese government to "be the first" to use this technology.
- Debate began related to the ethical dilemma of whether allowing parents to choose to genetically alter their future children can be ethical if they're not the one who is having their DNA changed.

This scientist's actions led to a call for a moratorium on editing human germline cells to produce genetically modified babies.

Why Human Germline Editing Might Never Be Legal in the U.S. By Jennifer M. Gumer, The Hastings Center Bioethics Forum, Published on August 9, 2019 .

Ethics in Research – Recent Perspective

SARS – COV-2 PANDEMIC

- Under tested or poorly studied treatments were publicized and politicized as proven and legitimate
- Unverified or impetuously authorized testing kits flooded the market
- EUA is not the same as FDA approved - messaging gets lost
- Retraction of several published articles due to questionable research practices
- Initial Astra-Zeneca vaccine efficacy data from the US is questioned by DSMB

THE LANCET

Retraction – Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis

This article was retracted because questions were raised related to the authenticity and reliability of the data and analyses. The company that performed the analysis refused to share the dataset and other documentation when requested by the journal. An independent and private peer review was not allowed to proceed, and the article was retracted.

Ethics in Research – Historical Perspective

Lack of Ethics in Research

Lack of Trust in Research

Fortunately, ethical standards do not remain fixed; they transform in response to evolving situations, so we continue to revise measures to improve transparency and trust with the research participants. It is important to revisit the beginning of the modern story of human subjects protection starting with the Nuremberg code of 1947.

Ethics in Research – Historical Perspective

The *Nuremberg Code* (of 1947), was developed for the Nuremberg Military Tribunal as the standard by which to judge the human experimentation conducted by the Germans. The code includes 10 provisions.

Hermann Göring
under cross-examination

The Code provides details implied by such a requirement:

- capacity to consent;
- freedom from coercion;
- and comprehension of the risks and benefits involved.

Other provisions require:

- the minimization of risk and harm;
- a favorable risk / benefit ratio;
- qualified investigators using appropriate research designs;
- and freedom for the subject to withdraw at any time.

Ethics in Research – Historical Perspective

1964

Similar recommendations were made by the World Medical Association in its Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects – first adopted in 1964.

1974

In the U.S., regulations protecting human subjects first became effective in 1974. The regulations established the IRB as one mechanism through which human subjects would be protected.

Ethics in Research – Historical Perspective

The **National Research Act**, passed in 1974, led to the issuance of **The Belmont Report** which set forth the basic ethical principles of respect for persons, beneficence, and justice.

Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. This principle underlies the need to obtain *informed consent*.

Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle underlies the need to engage in a risk / benefit analysis and to *minimize risks*.

Justice requires that the benefits and burdens of research be distributed fairly. This principle requires that subjects be *fairly selected*.

Ethics in Research – Key Element - IRB

An Institutional Review Board is a federally mandated committee that oversees research at an institution. The role of the IRB is to protect the rights and welfare of human research subjects involved in research activities

- UTGSM IRB includes 28 members: Physicians, nurses, pharmacists, scientists, non-scientists and community members.
- Office for Human Research Protections (OHRP) and the FDA oversee IRB functions at academic institutions with federal funding and will perform periodic audits. The OHRP and FDA may halt or suspend research not in compliance. Investigators and institution can be sanctioned and reputation damaged.
- Local audits performed by IRB staff – (not for-cause audits and for-cause audits) may result in recommendations for the investigator or possible suspension of research until issues are resolved.

The IRB is only <u>one</u> part of the research enterprise designated to protect human research subjects.

Ethics in Research – Key Element - Faculty

Faculty members who supervise student research also have an obligation to consider carefully whether their students or residents are adequately qualified to safeguard the rights and welfare of research participants.

Faculty should provide instruction and guidance which includes:

- **Ensuring the identified subject population is the appropriate source of data to answer the research question.**
- **Checking the planned method for data collection is valid and will yield data that answers the study question**
- **Verifying that the planned analysis of the data is appropriate and will answer the study question**
- **Monitoring the progress of the study and providing oversight in the conduct of the research**
- **Having current CITI training**

Ethics in Research – Key Element - PI

In submitting a new study/project application or revision for review and approval by the UTGSM IRB, as principal investigator you agree to assume the following responsibilities and to faithfully execute them in accord with applicable federal regulations for the protection of human subjects and UTGSM IRB policies and procedures:

1. **To conduct the research according to the IRB-approved protocol;**
2. **To obtain and document the informed consent and/or assent of subjects or subjects' legally authorized representatives, using the UTGSM IRB-approved informed consent process and documents, prior to the subjects' participation in any research procedures, unless these requirements have been altered or waived by the IRB;**
3. **To obtain prior approval from the IRB for any modifications of previously approved research, including modifications to the informed consent process and documents.**
4. **To ensure that progress reports and requests for continuing review and approval are submitted in the time frame and the manner prescribed by the IRB, but no less than once per year;**
5. **To provide the IRB with prompt reports of any unanticipated problems involving risks to subjects or others, including adverse events and protocol deviations;**
6. **To provide the IRB with prompt reports of serious or continuing noncompliance with the federal regulations for the protection of human subjects or the requirements or determinations of the IRB;**
7. **To notify the IRB regarding the completion of the study/project;**
8. **To maintain study/project records for the specific lengths of time denoted in the IRB's "Responsibilities of Investigators" policy regarding all records, consent forms, drug study records, and device study records;**
9. **To assure that all collaborating investigators and other key research personnel involved in the research study/project are fully informed regarding: (a) the study/project procedures; (b) informed consent requirements; (c) the potential adverse events associated with study/project participation and the steps necessary to minimize potential risks; (d) reporting requirements for unanticipated problems; and (e) data collection and record-keeping requirements;**
10. **To assure that all key research personnel personally complete required training regarding the protection of human subjects prior to their initiation of study/project activities;**
11. **To disclose to the IRB all conflicts of interest as defined in institutional policy that may relate to the conduct of the research; and**
12. **To permit inspection and audit of all records related to the conduct of the study/project by authorized representatives of the IRB and departments or agencies supporting or conducting the research.**

Ethics in Research – Key Element - PI

- **To conduct the research according to the IRB-approved protocol – this serves as a roadmap**
- **To maintain study records (including data collection, sharing & storage)**
- **To assure all key study personnel are fully informed of procedures**

In submitting a new study/project application or revision for review and approval by the UTGSM IRB, as principal investigator you agree to assume the following responsibilities and to faithfully execute them in accord with applicable federal regulations for the protection of human subjects and UTGSM IRB policies and procedures:

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11. To disclose to the IRB all conflicts of interest as defined in institutional policy that may relate to the conduct of the research; and
12. To permit inspection and audit of all records related to the conduct of the study/project by authorized representatives of the IRB and departments or agencies supporting or conducting the research.

Ethics in Research – Key Element - PI

Similar to Faculty responsibilities, an investigator should consider several pieces of their project that could impact the research participants.

- Co-Investigator/study personnel selection - research experience, subject specific knowledge, attention to detail, availability to dedicate time to research
- Study Design – what is appropriate? secondary or primary research, observational, experimental?
- Study Population - carefully consider inclusion/exclusion criteria, vulnerable populations, diversity – extra care & extra time involved
- Data Collection – how will you securely access, collect, share and analyze data? Excel, REDCap, UHS OneDrive, Encryption, Passwords
- Data Analysis - garbage in = garbage out. Appropriate use of statistics is a must, consider a biostatistician from the start

All of these should be carefully considered prior to IRB submission

Navigating the IRB Process – Common Delays

- Study team members do not have **current** CITI training

  https://www.citiprogram.org

  → **Group 3: Investigators and key Study Personnel**
  → **Group 4: Fellows, Residents and Students**

  → **GCP: Federally funded/Clinical Trials**

- Selecting the wrong IRB

  → **Select UT GSM/UTMC Knoxville or else we won't get it!**

- Email address not associated with you

  → **Go to profile and check email address ****@utmck.edu**

- Selecting a review type that is not applicable – these are generally based on risk level – call if unsure

  → **Exempt** → **Expedited** → **Full Board**

Navigating the IRB Process – Common Delays

- Failing to adequately explain what you intend to do
  → **read iMedRIS questions and instructions carefully**
- Forgetting to attach supporting documents
  →**surveys, consents, protocols, data collection sheets**
- Forgetting to route for signatures
  → ** (Residents: PI, Faculty Advisor & Department Chair must sign-off)**
  New in 2020 – not all study personnel are required to sign-off
- Study team does not sign-off in a timely manner
  → (**the IRB office does not receive your application until all sign-offs are completed so we probably won't know the existence of your project!)**
- Not checking the status of your project
  → **contact the IRB office to verify IRB receipt if more than a week goes by**

Navigating the IRB Process - iMedRIS

1

- To get started, click on the iMedRIS link: https://imedris.uthsc.edu
- iMedRIS can also be accessed from the IRB Website

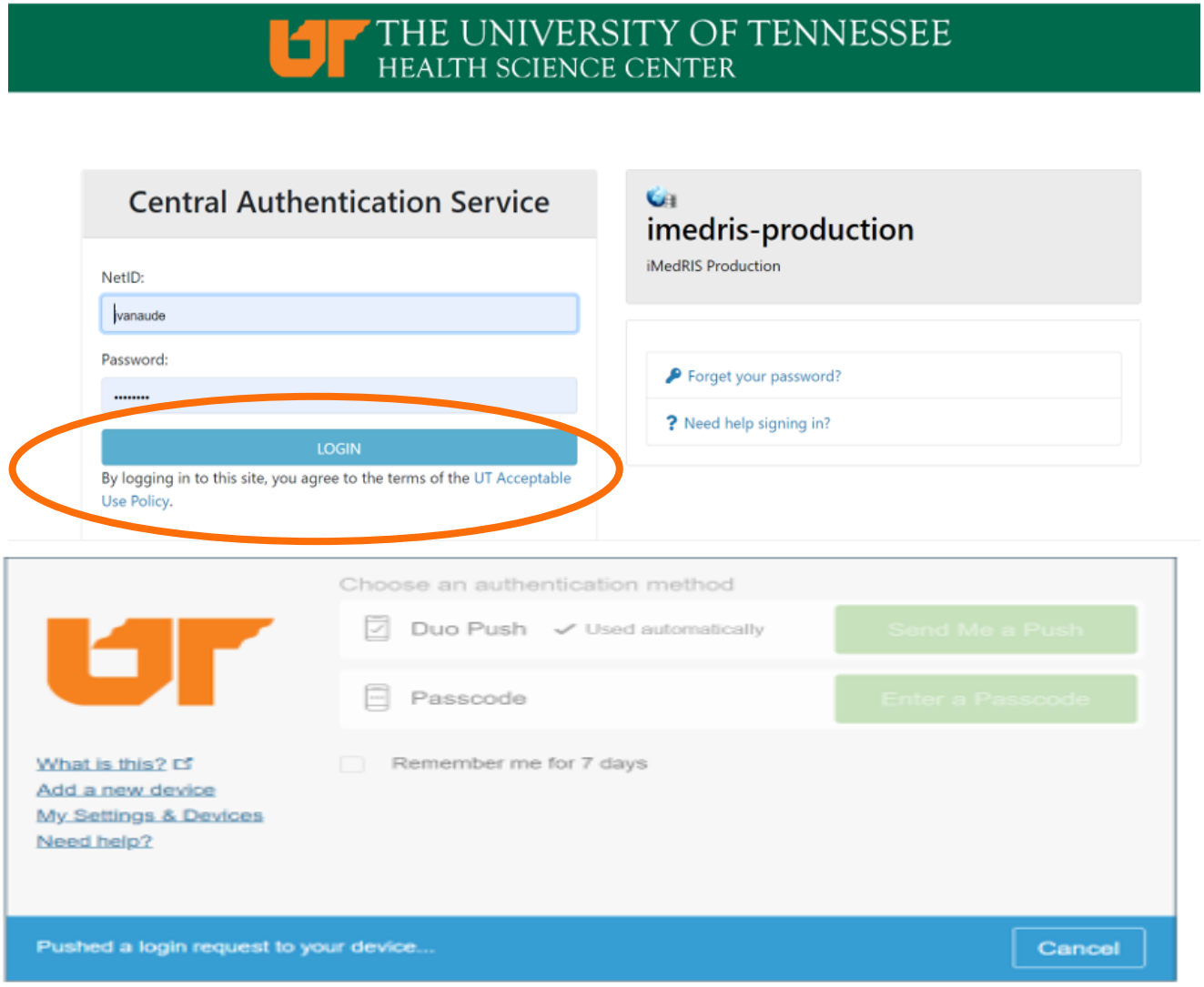
2

- Helpful hints:
- Chrome is the browser of choice
- Turn popup blockers off

3

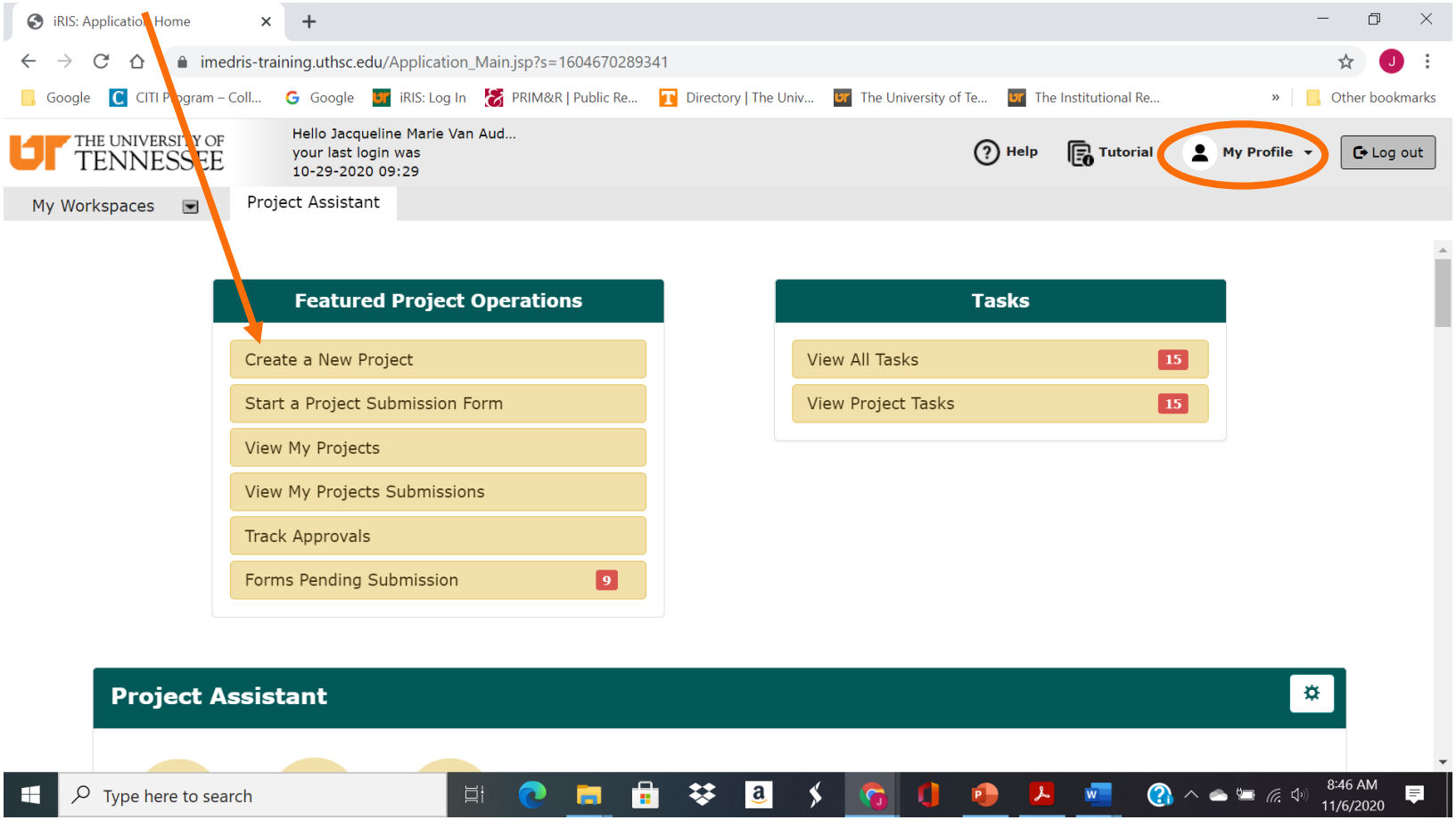
- iMedRIS uses 2-factor authentication so you must have your UT NetID and Password. If your password is not current, it must be reset
- You will either receive a DUO push or passcode

Navigating the IRB Process - iMedRIS



Navigating the IRB Process - iMedRIS

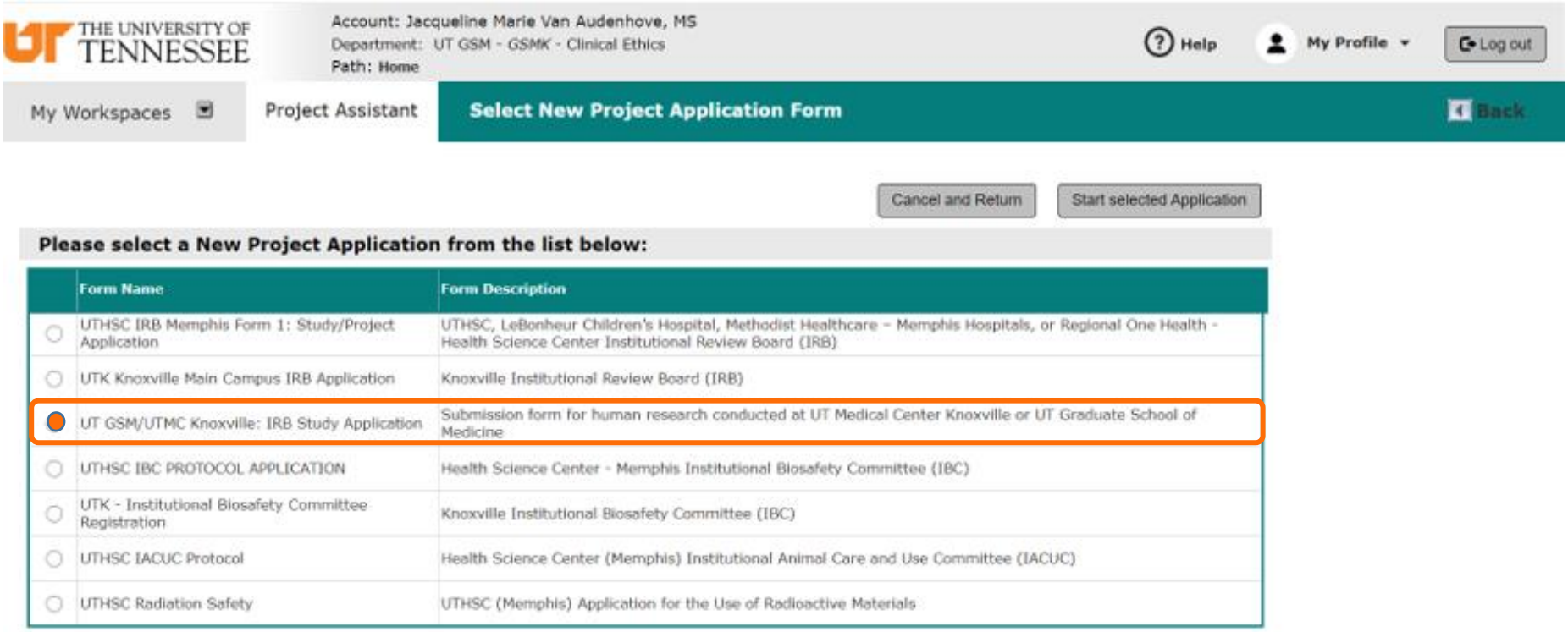
To get started, once in iMedRIS, click on the create a new project tab – (you may want to check profile to see if your information is correct)



Navigating the IRB Process - iMedRIS

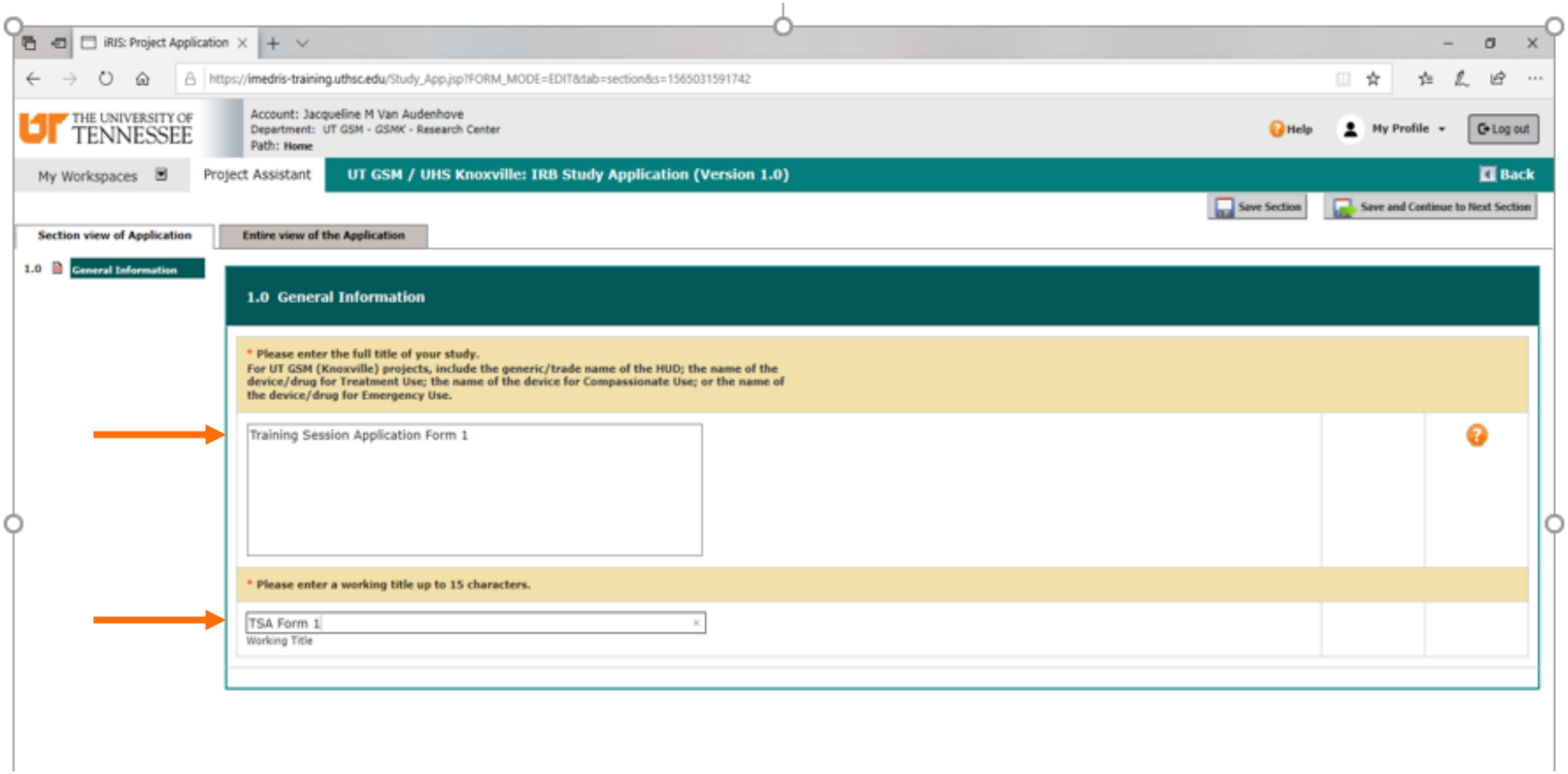
Select UT GSM/UTMCK study application for human research conducted at UT Medical Center Knoxville or UT Graduate School of Medicine

****IF YOU MAKE THE WRONG CHOICE, WE WILL NOT RECEIVE YOUR APPLICATION****



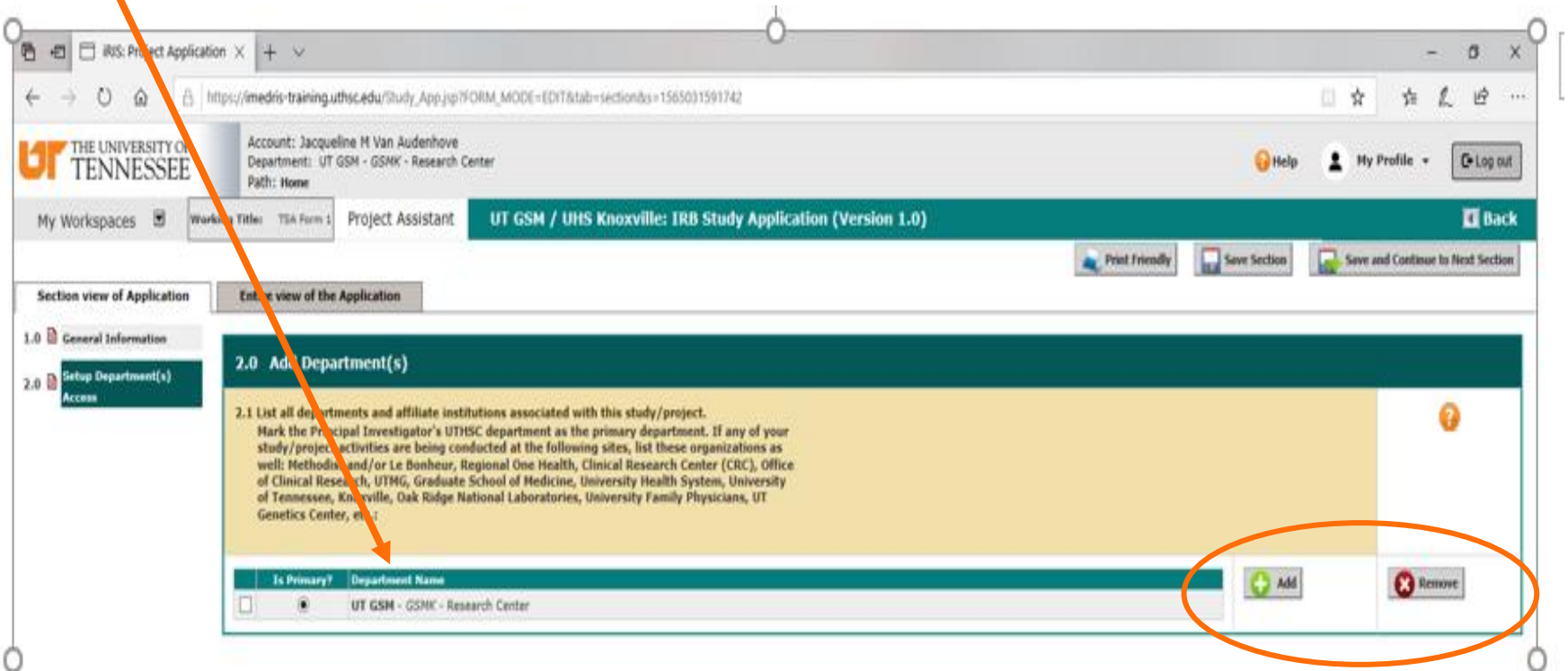
Navigating the IRB Process - iMedRIS

At section 1.0, enter full project title. Underneath, enter a short working title you may want to use with study team.



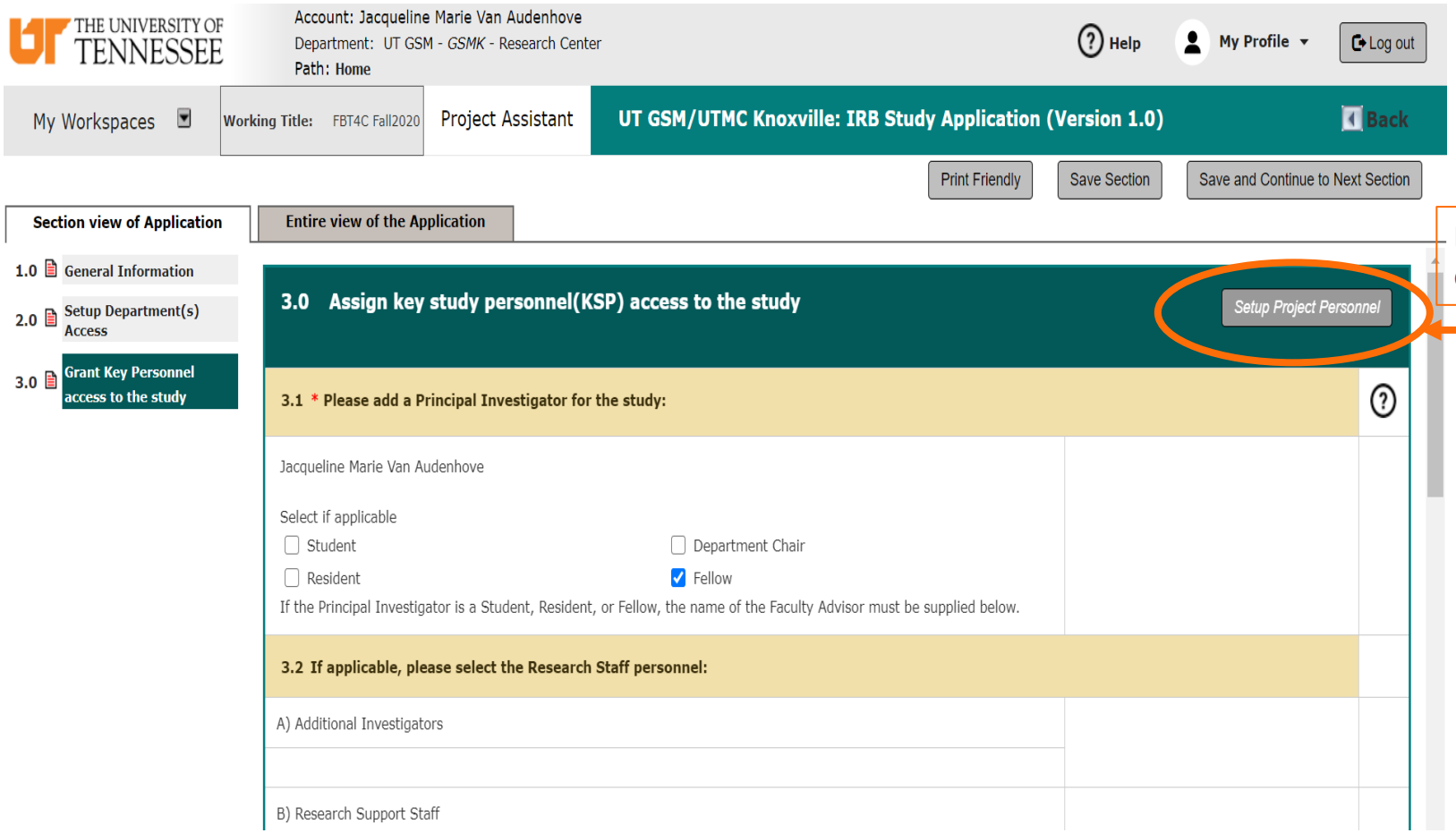
Navigating the IRB Process - iMedRIS

At section 2.0, the department will default to your department. You can also add other departments as applicable to your project



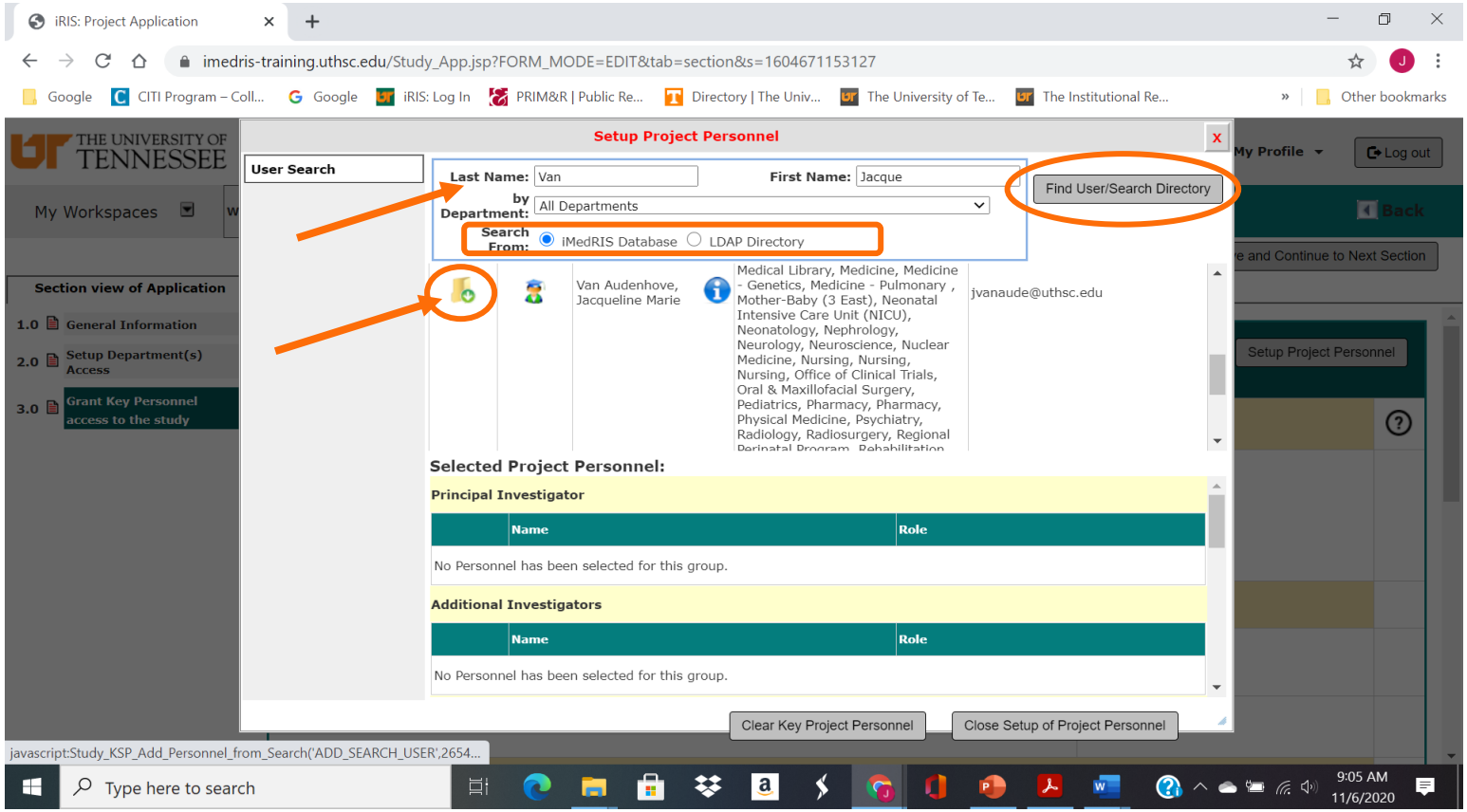
Navigating the IRB Process - iMedRIS

At section 3.0, add your project team by clicking on Setup Project Personnel



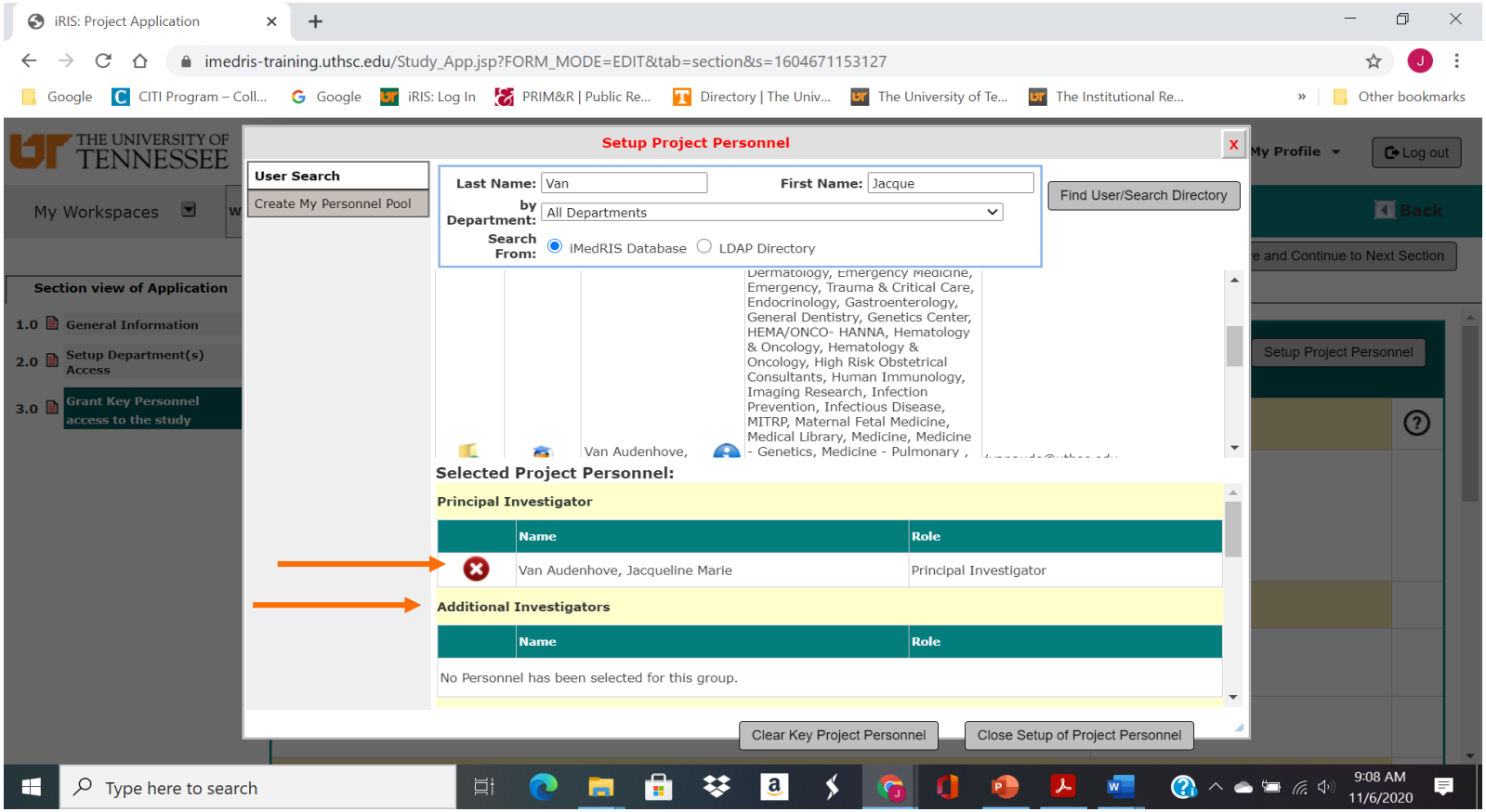
Navigating the IRB Process - iMedRIS

To add personnel, you must search in the iMedRIS or LDAP directory. After identifying who you want to add, click on the yellow folder. Repeat this for each additional person involved in the study.



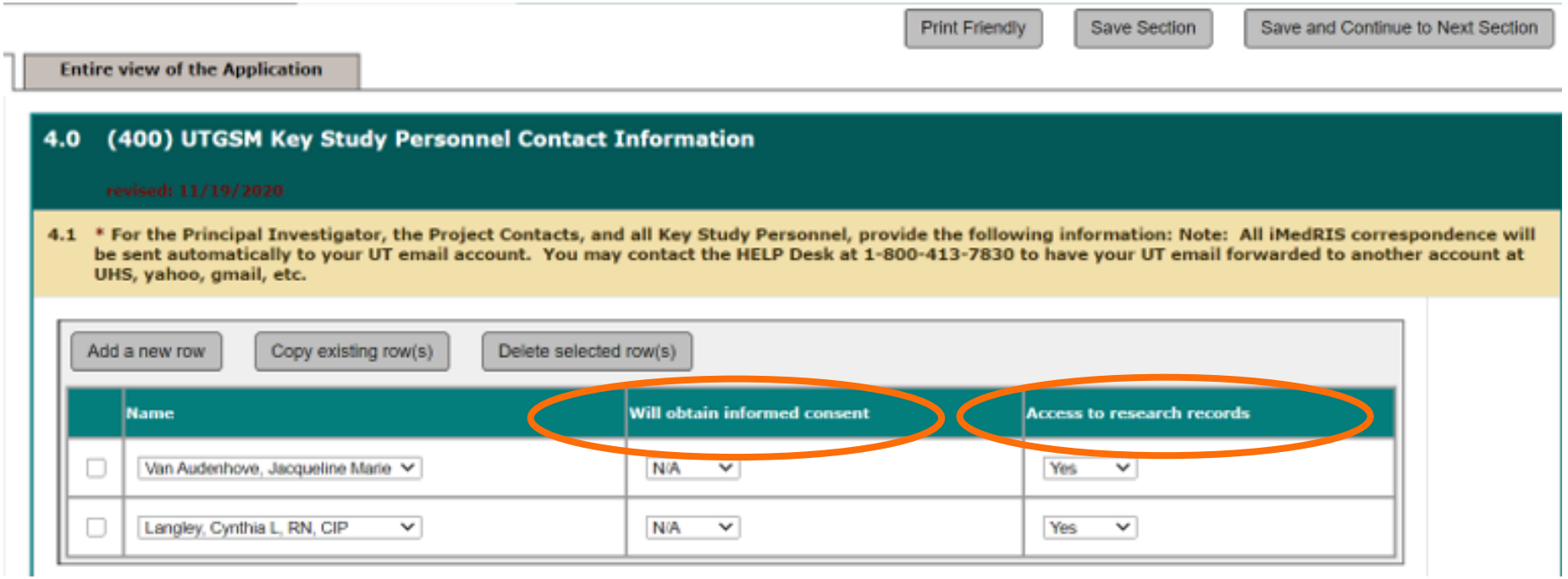
Navigating the IRB Process - iMedRIS

Jacque has been added as PI. Continue to add all study personnel and assign roles for each.



Navigating the IRB Process - iMedRIS

At section 4.1, note who will be obtaining consent and who will have access to research records. Anyone obtaining consent or viewing PHI must be included on your study application and approved by the IRB.



Navigating the IRB Process - iMedRIS

At section 5.2, indicate if you will be getting a collaboration form or department letter of support/approval. This applies when you need departmental assistance beyond standard of care.

5.0 (403) Additional UTGSM / UHS Committee or Department Approvals

5.1 GSM Requires completed, signed Collaboration forms or letters of support as indicated below. These are due at the time of IRB submission and should be attached to the Submission Routing Form at the end of the application.

Collaboration forms are available on the IRB Website at http://gsm.utmck.edu/irb/forms.
Letters of support may be letters or emails saved as a PDF.

- Infection Prevention/Control: Letter of Support, contact Mark Rasnake, MD at 305-7655 or mrasnake@utmck.edu with questions regarding support from Infection Prevention.
- Nursing (supporting other departments): Collaboration Form, if you need support/assistance from staff nurses at UTMC, submit a collaboration form signed by the Nurse Manager for the area where you need assistance AND Leslie McKeon, PhD, RN.
- Nursing (Research by Nurses): Approval letter Present your project to the Nursing Research Council (NRC) before submitting your IRB application and attach a copy of the NRC approval letter with your application. Contact Leslie McKeon at LMcKeon@utmck.edu for questions regarding the review by the Nursing Research Council.
- Pathology: Collaboration Form, contact Dr. Amila Orucevic at 305-9080 or AOrucevic@utmck.edu with questions regarding the Pathology Collaboration form.
- Pharmacy: Collaboration Form, contact Dr. Barbara Faircloth at 305-8380 or BFairclo@utmck.edu with questions regarding the Pharmacy Collaboration form.
- Radiology: Collaboration Form, contact Dustin Osborne, PhD at 305-8264 or DOsborne@utmck.edu with questions regarding the Radiation Collaboration form and review by the Radiology Research Committee.
- Radiation Safety: Approval Letter, contact Stephen Handley at 305-9664 or SHandley@utmck.edu with questions regarding review by Radiation Safety.
- Simulation Center: Collaboration Form, contact Melinda Klar at 305-4626 or at MKlar@utmck.edu with questions regarding the SIM Center form.

5.2 Collaboration forms and/or approval letters (check all that apply).

- [x] NA
- [ ] Pharmacy Review (Collaboration form)
- [ ] Pathology (Collaboration form)
- [ ] Radiology Department (Collaboration form)
- [ ] Radiation Safety Review (Approval letter)
- [ ] O.R. Committee (Device Trials) (Approval letter)
- [ ] Infection Control Committee (Approval letter)
- [ ] Nursing (Collaboration form)
- [ ] Nursing Research Council (UHS Nursing only) (Approval form)
- [ ] Advanced Medical Simulation Center

Navigating the IRB Process - iMedRIS

At section 5.3, indicate participating Centers of Excellence as it applies to your research project.

5.3 * Please select any participating Centers of Excellence below.

- [x] NA
- [ ] Brain and Spine
- [ ] Cancer
- [ ] Emergency and Trauma
- [ ] HLV
- [ ] Orthopedic
- [ ] Women and Infants

Navigating the IRB Process - iMedRIS

At section 6.1, indicate why you are filling out the application. For initial submissions, you select the first option. At section 6.2, indicate if you will be using data from another study to include in this study. If yes, explain how the previous data is related to the new data to be collected.

6.0 (418) UTGSM IRB Submission

6.1 * Please indicate the correct status of this submission: Note: If you are submitting a Form 2 for revision, DO NOT change your answer in this section.

- (●) I am requesting initial approval for research.
- ( ) I am registering a research study that will be ceded to another IRB through a Reliance Agreement
- ( ) I am requesting initial approval for the use of a Humanitarian Use Device (HUD).
- ( ) I am notifying the IRB regarding the emergency use of an investigational device.
- ( ) I am notifying the IRB regarding the emergency use of an investigational drug, or biologic.
- ( ) I am requesting approval for compassionate use of an unapproved medical device.
- ( ) I am requesting approval for the treatment use of an unapproved medical device.
- ( ) I am requesting approval for the treatment use of an unapproved drug or biologic.
- ( ) I am registering the use of an anonymized human cell line purchased or acquired from commercial vendors, IRB approved repositories or government tissue banks.

6.2 Is this proposal associated with any other IRB-approved studies?

- ( ) Yes
- (●) No

Navigating the IRB Process - iMedRIS

At section 7.0, indicate the level of review (Exempt, Expedited, or Full Board) and type of study. If you aren't sure, call the IRB office. Most chart review studies are Exempt. At section 8.0, indicate if there is a funding source. This includes a source providing drugs or a device.

7.0 (419) Level of IRB Review

7.1 * Are you requesting Full Board, Expedited or Exempt review by the IRB?

- (●) Exempt
- ( ) Expedited (Minimal Risk to Subjects)
- ( ) Full Board (Greater than Minimal Risk to Subjects)

7.2 * Please indicate the type of study:

- (●) No drug/biologic or device is being administered and evaluated as part of study procedures.
- ( ) A device is being administered and evaluated as part of the study procedures.
- ( ) A drug/biologic is being administered and evaluated as part of the study procedures.
- ( ) A drug/biologic AND a device is being administered and evaluated as part of the study procedures.

8.0 (460) Funding Source

8.1 Is there a funding source associated with the study? This includes a source that will provide study drug/biologic/device at no cost.

- ( ) Yes
- (●) No

Navigating the IRB Process – Review Levels

Exempt - Less than minimal risk to subjects

- 8 Categories **– Category 4 most often used (secondary use of data)** – may choose more than one category. Category 1: [Educational Settings - FERPA], **Category 2: [Surveys]** Category 3: [Benign Behavioral Interventions]
- Waiver of HIPAA authorization might apply (chart review studies)
- No Continuing Review but given a 3 year expiration date at that time closed or renewed
- **IRB deadlines do not apply (study does not go to convened IRB meeting)**

Expedited - Minimal risk to subjects

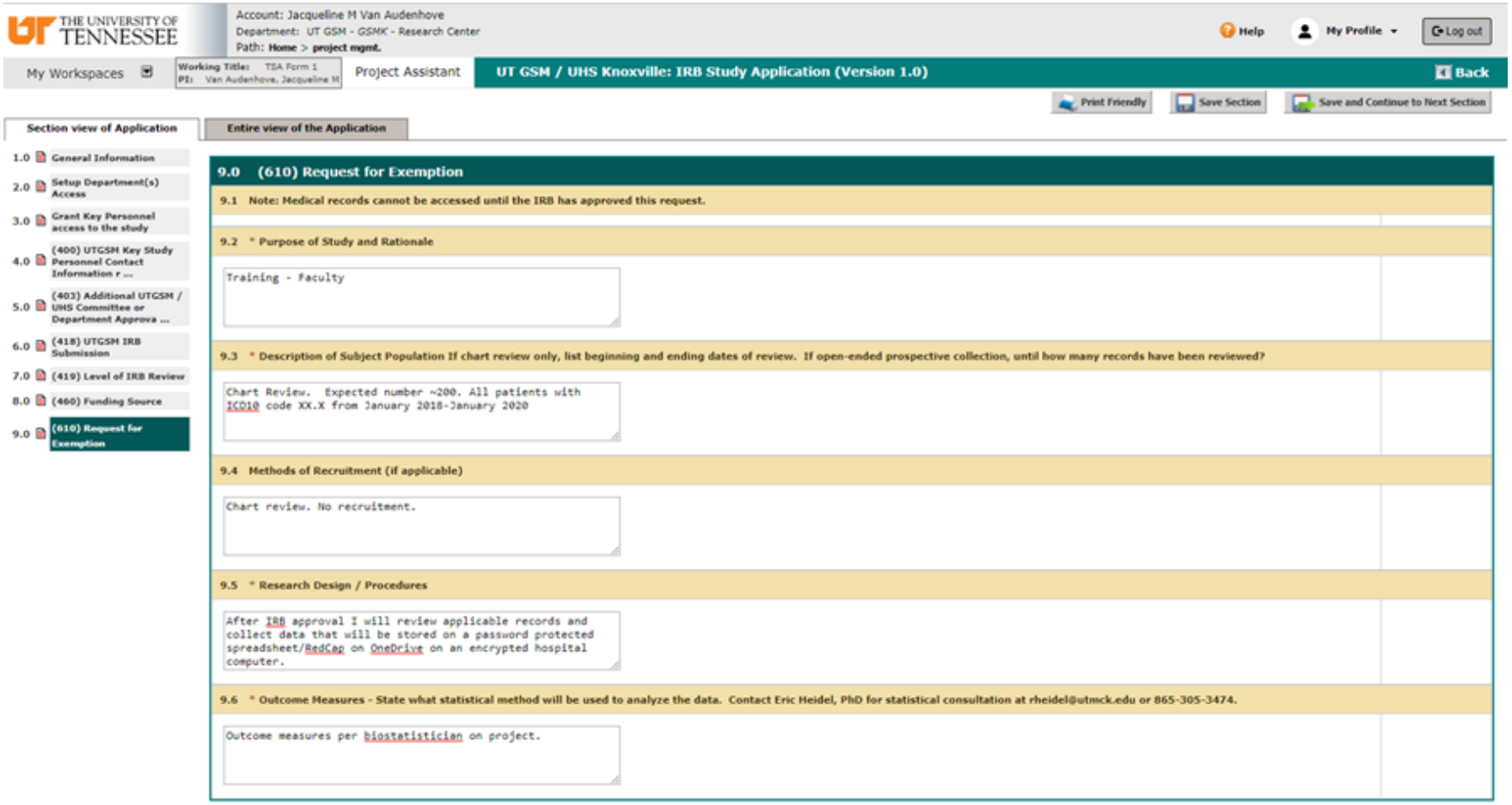
- 7 Categories – may choose more than one – minimally invasive (e.g. blood draw)
- Waiver/Alteration (verbal) of Consent & Waiver/Alteration of HIPAA Authorization may apply
- No requirement for Continuing Review every year unless specified in outcome letter
- **IRB deadlines do not apply (study does not go to convened IRB meeting)**

Full Board - Greater than minimal risk to subjects – drug / device trials

- Continuing Review every year
- **IRB deadlines do apply – will be reviewed at a convened IRB meeting**

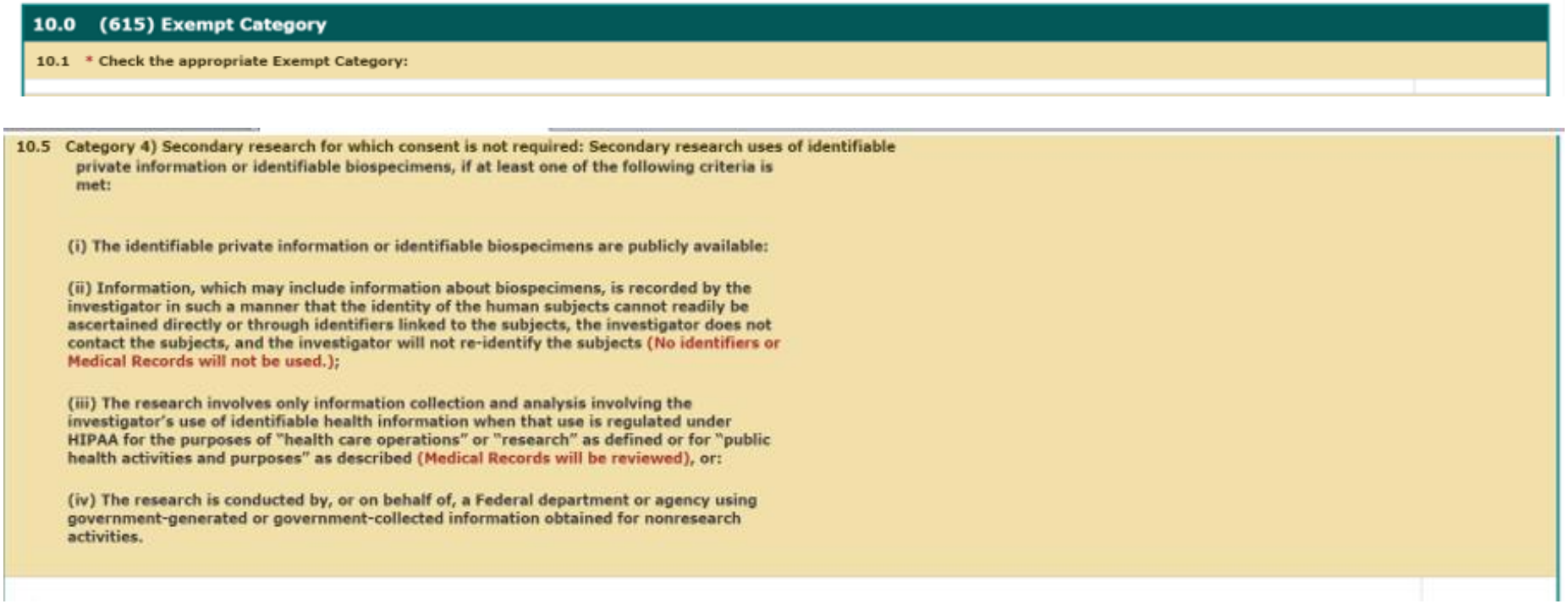
Navigating the IRB Process - iMedRIS

At section 9.0, describe purpose & rationale, study population, method of recruitment, research design & procedures, and outcome measures.



Navigating the IRB Process - iMedRIS

At section 10.0, if you chose an Exempt level of review, you must select the appropriate category. Most chart review studies are Category 4 (select section 10.5). If viewing medical records, you will need to select sub-category (iii).



10.0 (615) Exempt Category

10.1 * Check the appropriate Exempt Category:

10.5 Category 4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available:

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects (No identifiers or Medical Records will not be used.);

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA for the purposes of "health care operations" or "research" as defined or for "public health activities and purposes" as described (Medical Records will be reviewed), or:

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

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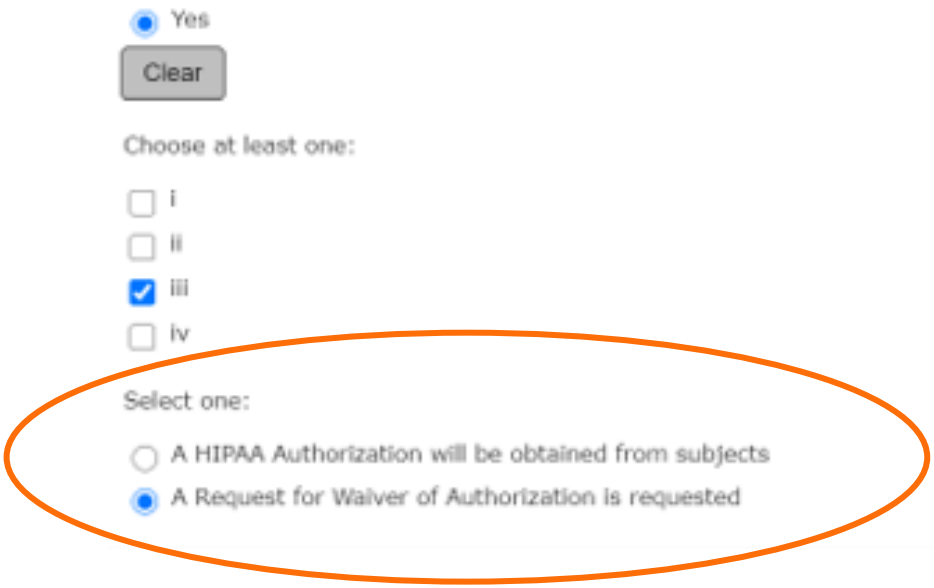
At this point, you will be prompted to select either:
A HIPAA Authorization will be obtained from subjects or
A Request for Waiver of Authorization is requested.
If selecting a Waiver of Authorization, the criteria for this waiver must be satisfied for the IRB to approve a waiver.



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The following three criteria must be satisfied for an IRB to approve a waiver of authorization under the Privacy Rule:

- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
  - ✓ an adequate plan to protect the identifiers from improper use and disclosure;
  - ✓ an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - ✓ adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted without access to and use of the protected health information.

Navigating the IRB Process - iMedRIS

At section 11.0 & 12.0, if a HIPAA waiver is requested, you will be asked to describe the justification for the waiver

11.0 (3466) HIPAA Waiver or Alteration

11.1 * Briefly describe the plan to protect the Protected Health Information (PHI) identifiers.

PHI will be stored on a password protected excel spreadsheet on an encrypted hospital computer with access only to key study personnel noted on this application.

11.2 * Briefly describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a justification for retaining the identifiers or such retention is otherwise required by law, this should be explained.

Identifiers will be destroyed at the earliest opportunity once he investigators no longer need to use it. The remaining data will be kept per regulatory and institutional policy.

11.3 * Will the Personal Health Information (PHI) be reused or disclosed to any other person or entity?

○ Yes ◉ No

11.4 * Is it true that the Personal Health Information (PHI) will not be reused or disclosed to any other person or entity EXCEPT as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI is approved by the IRB?

◉ True. PHI will not be reused or disclosed unless as excepted above.
○ Not true. PHI may be reused or disclosed as noted below.

11.5 * Briefly explain why you must have access to the PHI in order to complete your research.

This is a chart review that requires access to pertinent PHI in order to conduct the research.

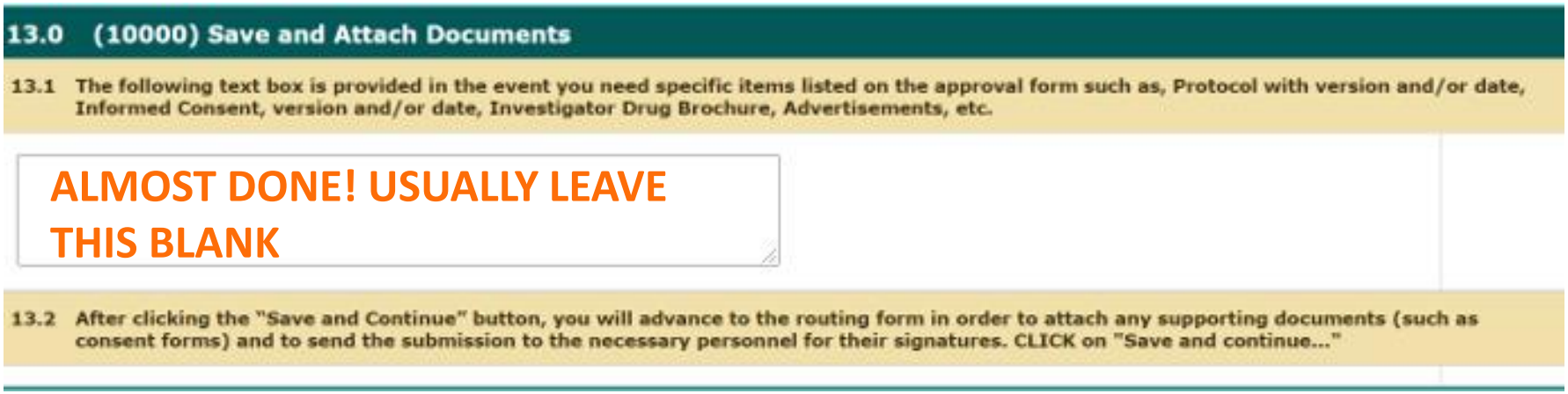
12.0 (3467) HIPAA Alteration Practicality

12.1 * Briefly explain why the research activity could not practicably be conducted without alteration of the authorization requirement.

There isn't a feasible way to contact all potential subjects (some have died, left town, contact information not current) and sufficient personnel is not available to contact all subjects. Not including all subjects may skew data.

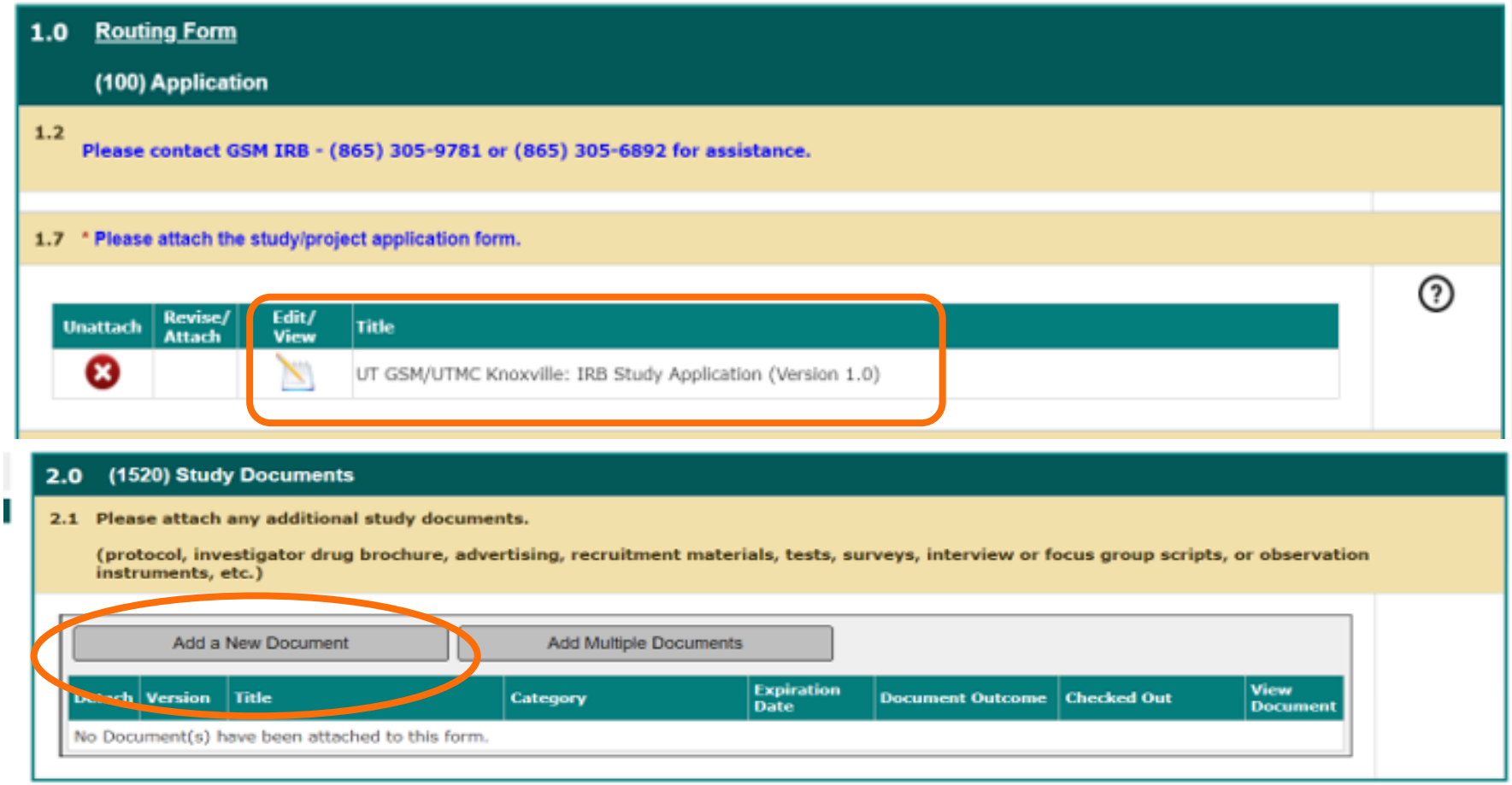
Navigating the IRB Process - iMedRIS

At section 13.1, you can leave the text box blank and select save and continue to attach documents and route for signatures.



Navigating the IRB Process - iMedRIS

Your application form is complete and attached to a routing form automatically. At section 2.0, you can attach study documents like consents, surveys, protocols, data collection form.



Navigating the IRB Process

HOW TO DE-IDENTIFY PHI?

Health information by itself **without the 18 identifiers** is not considered to be PHI. For example, a dataset of vital signs by themselves do not constitute protected health information. However, if the vital signs dataset includes medical record numbers, then the entire dataset must be protected since it contains an identifier.

SAFE HARBOR – THE REMOVAL OF SPECIFIC IDENTIFIERS

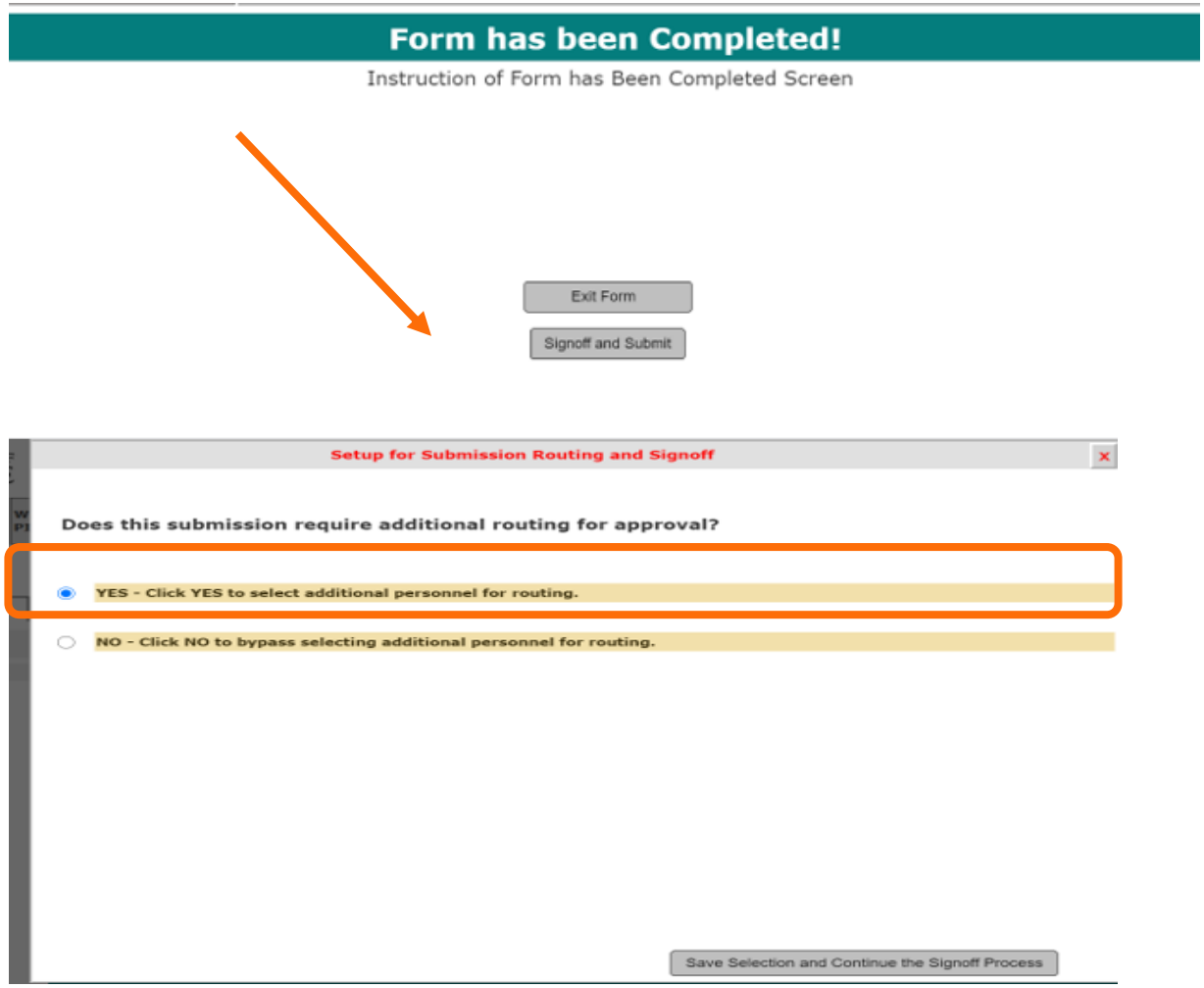
The HIPAA compliant way to de-identify protected health information is to remove specific identifiers from the data set. The identifiable data that must be removed are:

- Names
- Geographic subdivisions smaller than a state
- All elements of dates (except year) related to an individual (including admission and discharge dates, birthdate, date of death, all ages over 89 years old, and elements of dates (including year) that are indicative of age)
- Telephone, cellphone, and fax numbers
- Email addresses
- IP addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Device identifiers and serial numbers
- Certificate/license numbers
- Account numbers including FINs
- Vehicle identifiers and serial numbers including license plates
- Website URLs
- Full face photos and comparable images
- Biometric identifiers (including finger and voice prints)
- Any unique identifying numbers, characteristics or codes

In the case of zip codes, covered entities are permitted to use the first three digits provided the geographic unit formed by combining those first three digits contains more than 20,000 individuals.

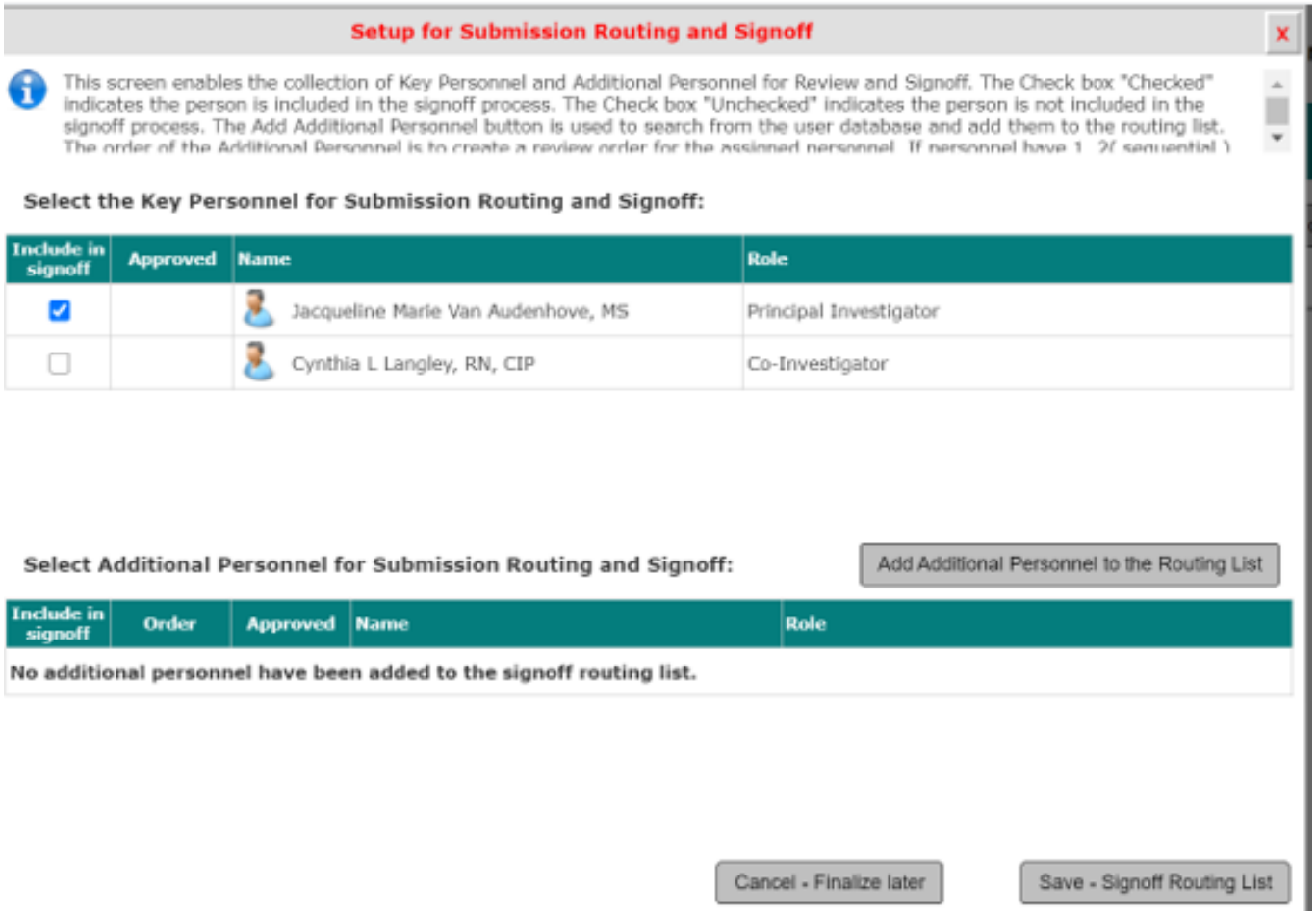
Navigating the IRB Process - iMedRIS

If you are finished, select "signoff and submit." You will then select "YES" to route for additional signoff.



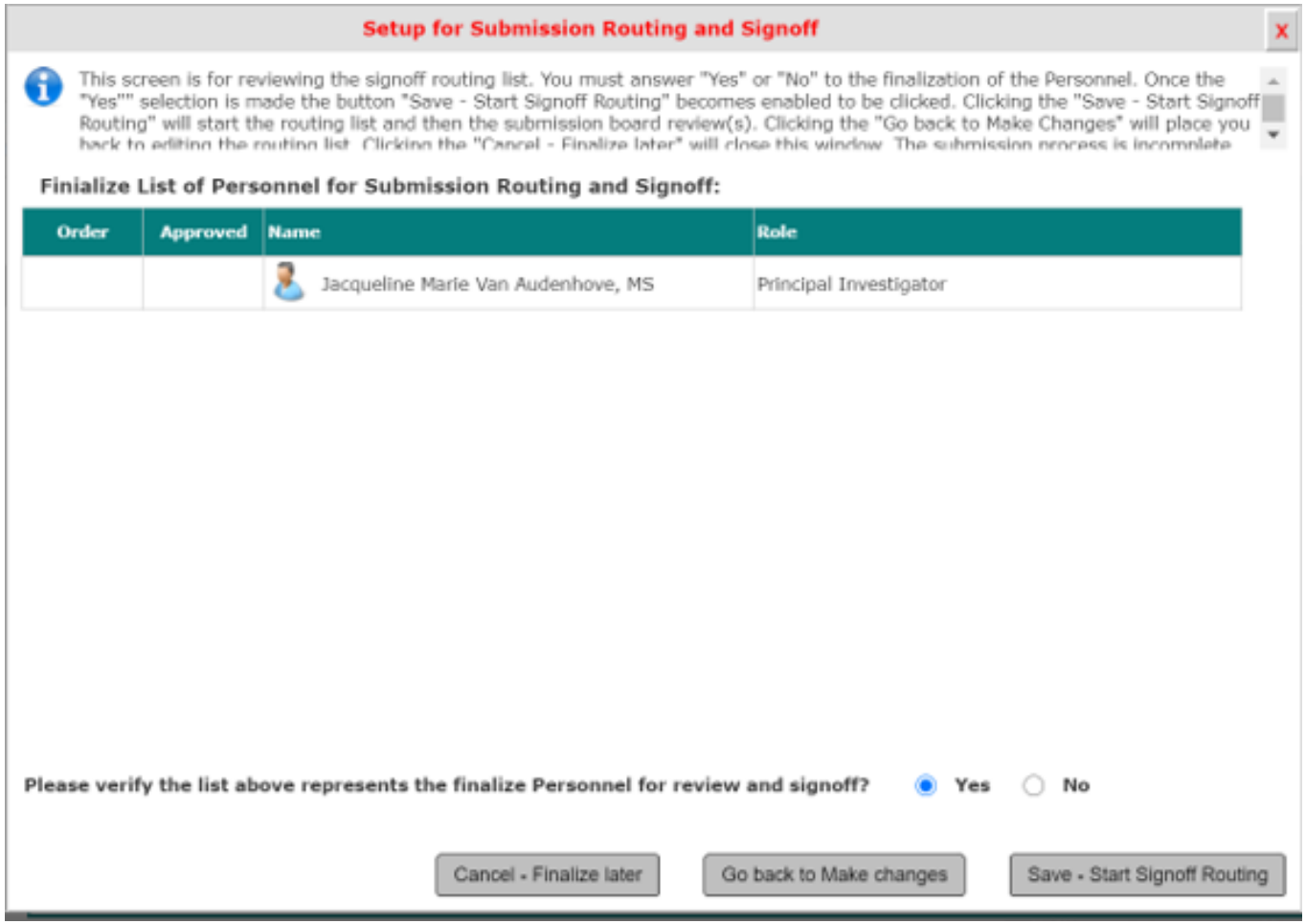
Navigating the IRB Process - iMedRIS

Principal Investigator, Faculty Advisor and Department Chair must sign-off on all resident, fellow or student initial applications. If you listed them on the project application, their name should show up on this screen or you can add them.



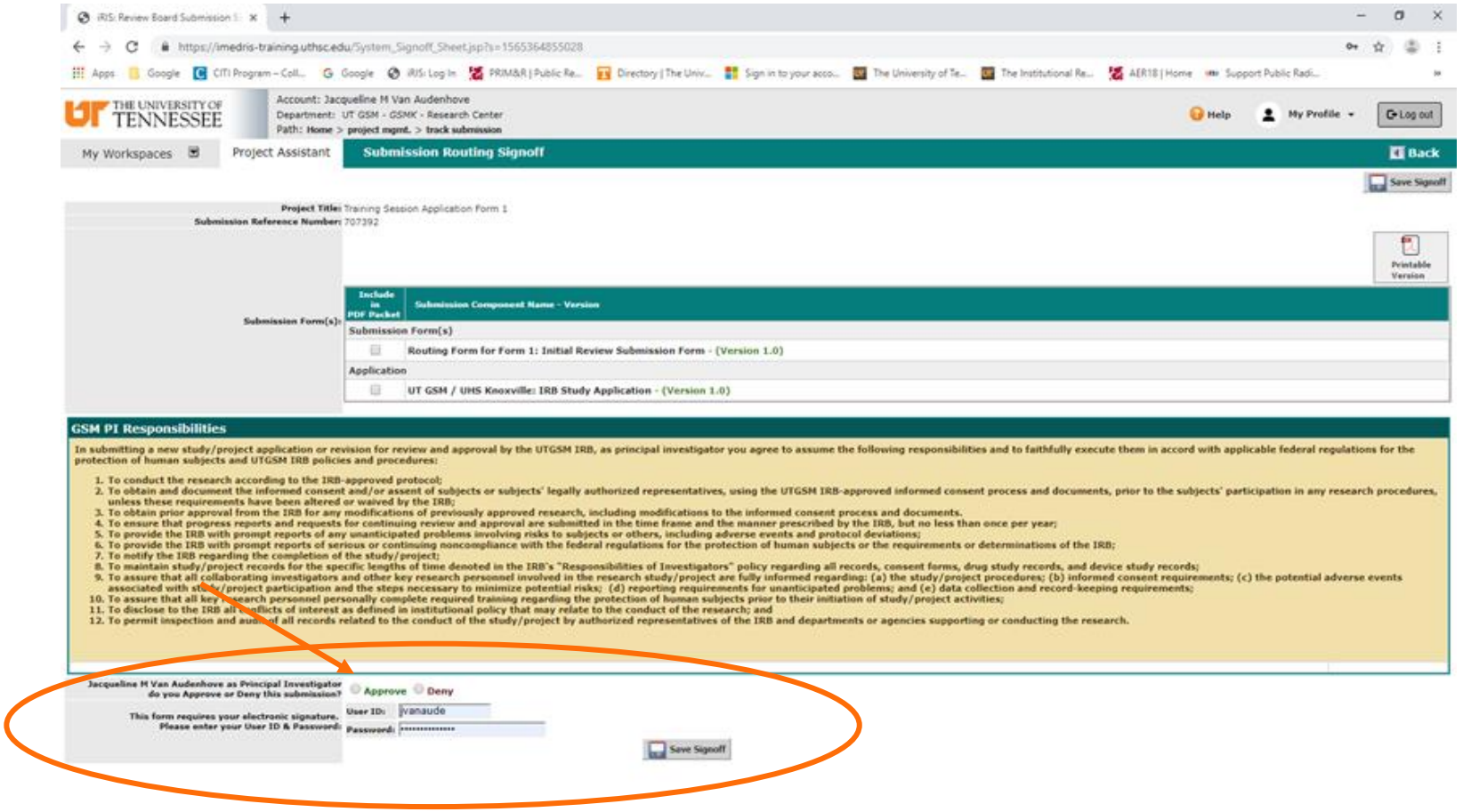
Navigating the IRB Process - iMedRIS

This is your last chance to review signoff list. If you are ready to route for signatures, select yes and click on the save-start signoff routing tab.



Navigating the IRB Process - iMedRIS

Once you approve and select "save signoff" your submission will be routed to those you designated to signoff. The IRB does not receive your submission until everyone signs off.



Navigating the IRB Process - iMedRIS

Reminders: Forms & Routing for signature

- **Form 1 – Initial Submission** – PI, Department Chair, Faculty Advisor (if applicable). No longer require routing to everyone on the study
- **From 2 – Amendment** – PI or other Investigator
- **Form 3 – Continuing Review** – PI or other investigator
- **Form 4 – Deviations/AEs/Unanticipated Problem** – PI
- **Form 5 -- Change in Personnel** - PI and personnel being added or removed

Navigating the IRB & Ethics in Research - Website

https://gsm.utmck.edu/irb/main.cfm

IRB Forms and Documents

Case Report
Not Human Subjects
Quality Improvement

Pre-Application

UHS HIPAA Data Collection Preparatory to Research Form
UTGSM HIPAA Data Collection Preparatory to Research Form

Submitting an Application to the IRB

To submit applications to the IRB, please follow the link to iMedRIS.

Please note: Completion of the CITI Basic and Refresher Course is required at the time of IRB submission.

Collaboration Forms:

- Collaboration Form - Nursing
- Collaboration Form - Pathology
- Collaboration Form - Pharmacy
- Collaboration Form - Radiology and Radiology Research Process Form
- Collaboration Form - Simulation Center

IRB Documents

Glossary of Lay Terms
Consent Form Template
Protocol Template
Notice of Research Template
Data Sharing - Data Use Agreement (De-identified)
Data Sharing - Data Use Agreement (Limited Data Set)

The Institutional Review Board

- iMedRIS
- 2021 Deadline and Meeting Dates
- Forms
- The IRB Process
- Fee Schedule
- Standard Operating Procedures (Current)
- Standard Operating Procedures (Pre-2018)
- Contact Us