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February 2017

February marks the beginning of our busiest time of year. The number of submissions typically increases from February to April as many researchers want to initiate and complete their studies before the end of the academic year. In this issue, the Human Research Protection Program announces the upcoming presentation, **Social Media as a Research Recruitment Tool**. We also provide tips researchers can use to help decrease IRB review time. This month's **Tip of the Month, Common Mistakes in the IRB Application**, identifies the top reasons the IRB Application Form is returned to researchers for revision during the review process.

– *HRPP Staff*

Announcements

Change to ClinicalTrials.Gov Regulations

The federal requirement to register clinical trials and to report information throughout and after the trials has been expanded to include prospective clinical studies of health outcomes, require additional information elements and *new penalties for non-compliance*. These expanded requirements are the joint results of a new NIH policy and an expanded regulation from the Food and Drug Administration (FDA). The new requirements went into effect on January 18, 2017. A [summary table](#) posted in the November 2016 issue of the New England Journal of Medicine (p. 2000) describes the changes. More information will be provided in the March issue of the HRPP Newsletter.

Newsletter Archives

View past issues of our newsletter archived on our [website](#).

Tip of the Month: Common Mistakes in the IRB Application Form

Listed below are some common errors made when completing the IRB application form. Where applicable, the IRB application section has been noted and the mistakes that either slow the IRB's review or result in returning the application back to researchers for revisions are identified to help avoid them in the future.

Lack of consistency

If the different sections of your IRB application contain inconsistencies or the information contained in the IRB application is inconsistent with that in your consent forms and other study documents, it may become difficult for the IRB to understand the research. This may

include inconsistent use of terminology, names of procedures, references to supporting documents not matching document titles, etc.

Not including faculty advisors as Study Contacts – 3.3 Study Contact

Study Contacts receive all correspondence related to the study including requests for revisions, expiration notifications, continuing review reminders, etc. It is imperative that student PIs include their faculty advisors as Study Contacts as the IRB holds the advisor responsible for the conduct of the research. As such, the faculty advisor must be included in all IRB communications related to the study.

Missing study procedures – (925) Study/Project Synopsis

The IRB must be informed of all planned study-related procedures. This includes any expectations the researcher has regarding follow-up procedures. Some commonly used procedures that are frequently not mentioned in the IRB application but are discovered later are:

- Recordings and/or the type of recordings (audio, visual, etc.) that will be conducted.
- Collecting, obtaining, or reviewing existing records or other data. When records and other existing data are used for research, the specific records to be used must be identified. These can include and datasets, course assignments, artifacts, etc. In the case of datasets, identify each data point to be obtained/reviewed/abstracted from records.
- Follow-up interviews or data collections.
- Returning transcripts to research participants to review for accuracy and feedback.
- Identification of all data collection instruments to be used including requests for demographic information.
- When conducting education research specific to a class or course, identify all information and activities to be used for the research. Distinguish between which of those activities and collected information would occur even if the research were not conducted (i.e., regular class activities) and which are occurring only because the research is being conducted.

Not identifying or describing activities of non-UT collaborators – (1200) Site Information

Researchers collaborating with individuals who are not affiliated with UT Knoxville should identify these individuals, their institutions, and their specific research activities. This also holds true for collaborators from UT Health Science Center and UT Graduate School of Medicine. Although individuals from those UT campuses can be included under application item 3.2 Research Staff, a description of their specific research activities is still required. Alternately, a description of collaborators' research activities can be included under application item 925, Study Synopsis. A copy of the IRB approval from a collaborator's institution should be submitted with the IRB application. Feel free to contact our office at 865-974-7697 or utkirb@utk.edu with any questions.

Omitting the anticipated number of individuals whose records/data are obtained or reviewed for the research – (1400) Participant Population

When a person's information is used for research, that individual is considered a research participant even if that information is not obtained directly from him/her. Therefore, the number of participants to be accrued in the research should reflect the number of individuals whom the records/datasets represent.

Not describing pre-existing relationships – (1488) Vulnerable Participants

When researchers indicate they have a pre-existing relationship with potential research participants, the IRB needs to understand the nature of the relationship(s) in order to determine what, if any, additional safeguards may be required. Unfortunately, the current version of the IRB application does not provide additional space in this section to include that information. The application will eventually be revised to correct that, but in the meantime, we recommend including that information in either application item 925, Study Synopsis under Study Population or application item 417, UTK Key Study Personnel Credentials.

Neglecting to describe the recruitment process – (1600) Participant Recruitment

Recruitment typically includes multiple stages: identification of potential participants, initial contact, and sometimes follow-up contact and screening. Obviously, not all studies include each stage and its related procedures, but all of these procedures form the foundation of the informed consent process.

- Identification procedures range from posting flyers allowing individuals to self-identify by contacting researchers, to using records, membership lists, class enrollment, etc. All procedures used to identify potential participants must be described.
 - When using records, lists, etc. to identify participants, explain how the researcher has access to that information.
 - When using “snowball sampling” with already enrolled research participants, the IRB recommends that participants be asked to forward study information to potential participants allowing them to contact the researcher directly rather than providing names and contact information of potential participants.
- Descriptions of initial contact procedures to inform participants about a research opportunity should include both how that contact will be made and by whom. Explain if an intermediary will be used, such as an instructor forwarding an email from the researcher to students informing them about the research.
- Describe any follow-up contacts that will be made including the mode of communication to be used, the frequency of the contacts and maximum number of attempts.
- Screenings often occur before informed consent is obtained in order to determine if individuals are eligible for the study. A description of these procedures should include all of the following information.
 - The specific information to be obtained (which should be limited to the information required to make an eligibility determination).
 - How that information will be obtained (phone call, email, survey, etc.).
 - Who will conduct the screening activities.
 - What will be done with the collected screening information if the individual is either found ineligible or does not enroll in the research study.

Not recognizing loss of confidentiality as a possible risk related to the research – (2000) Risks and Benefits

Loss of confidentiality is the most frequently overlooked risk related to the conduct of human subjects research. Absolute confidentiality cannot be guaranteed and researchers must inform participants of any limits to their confidentiality. Unless data or specimens are collected/received anonymously and there is no record of participants enrolling in the research (e.g., signed consent documents, signing a receipt log for compensation), then participants can typically be linked to the study if not their data/specimens. If participants are informed that their participation in the research and collected information will not be

confidential, then obviously, this risk does not apply. However, most studies collect some identifiable information and frequently promise to protect participant confidentiality.

No detail on how risks will be minimized – (2000) Risks and Benefits

This issue applies to many types of research but is particularly relevant to confidentiality safeguards. Describe the storage and how long identifiable data and research records such as consent forms will be retained. Explain if and when data will be de-identified or coded and if a code key will be retained and for how long. Also, describe any intended future uses of identifiable information (future research, teaching, etc.).

Leaving out confidentiality procedures or using inadequate safeguards – (2800) Confidentiality

Strategies to safeguard confidentiality may include any of the following procedures.

- Keep paper records in a secure location. IRB policy requires that signed consent forms will be stored **on campus** for a minimum of three years **after** the study has been completed and closed with the IRB.
- Transcribe recordings as soon as possible and explain when the recordings will be destroyed.
- Describe safeguards for storing and transferring electronic records/data. Describe access privileges.
- When storing identifiable research records/data and recordings, the IRB highly recommends using UT's services certified for the storage of personally identifiable information (e.g., GoogleDrive, OneDrive for Business).
- When transferring identifiable research records/data and recordings electronically, consider using a secure service such as UT Vault.
- Ensure only research personnel have access to research records/data.

Misuse of the terms *Anonymous*, *Confidential* and *De-Identified* – (2800) Confidentiality

This may be the most frequent mistake seen with IRB applications. Anonymous, confidential, and de-identified are not the same and cannot be used interchangeably.

Anonymous means that a participant cannot be linked to either his/her data/specimens or as having enrolled the research study by anyone, not even the researcher.

Anonymous data collection means that the participant's identity cannot be linked to the research either directly (e.g., name, email address, ID number), by coding system or by indirect identifiers. Video and voice recordings are not anonymous.

Indirect identifiers are variables, none of which link to a participant on its own, that when combined may enable a reasonably informed and determined person to deduce a participant's identity. Examples of indirect identifiers include race and ethnicity, sex, college major, geographic information such as county, employer, dates, etc.

Confidential refers to the handling of information disclosed by an individual (or specimens provided) with the expectation that it will not be divulged to others in ways inconsistent with his/her understanding of the original disclosure.

De-Identified* refers to data or specimens from which all identifiers (both direct and indirect) that would allow re-identification of participants have been *permanently* removed; and if coded,

- the code is not derived from or related to information about the participant (e.g., code made up of participant's first name and age); and

- no code key exists that could link back to the participants; or
- if a code key exists, it is held by the provider who either
 - is not a collaborator in the recipient's research;
 - is prohibited from releasing the code to the recipient; and
 - with whom coded results from the recipients' research will not be shared.

***When research involves health information that is covered by HIPAA regulations,** data or specimens have been de-identified only when either

- all **18 types of identifiers** that could identify the participant, participant's relatives, employers or household members have been removed as specified by the HIPAA Privacy Rule; or
- has been determined to be de-identified by a statistician in accordance with the standards established by the Privacy Rule (45 CFR Part 164.514).

Not fully describing gift card usage or including extra credit as compensation – (3045) Payment and (3050) Describe Payment

When offering credit for research participation,

- identify whether the credit offered is extra credit or course credit (required by the instructor in order for the student to fulfill a requirement in a course);
- disclose the amount of credit offered;
- identify the class/course providing the credit; and
- confirm that students in those courses have a non-research alternative offering the same amount of credit and is comparable in both time and effort to the research participation option.

When offering gift cards as compensation,

- identify the type of gift card (Kroger, Amazon, Visa, etc.);
- provide the amount of the gift card;
- describe when (e.g., last study visit, two weeks after completion of the last questionnaire) and how (e.g., in person, email) participants will receive the gift card; and
- describe any participant information to be shared with researcher's department/business office to facilitate payment to participants. See [UT's gift card policy](#).

No description of the consent process – (3440) Consent Process

Often, this section of the application states only that informed consent will be obtained before data are collected. The IRB needs to know if consent will be obtained in person or if sent, how and how will signed consent be returned to the researcher.

Not knowing when protected health information (PHI) is being used/accessed – (3450) Protected Health Information

When research involves health information that is covered by HIPAA regulations, researchers need to identify what PHI is being obtained/reviewed. PHI is defined as being any health information that includes any of the **18 types of identifiers** that could identify the participant, participant's relatives, employers or household members (45 CFR Part 164.514).

If the information being obtained/reviewed does not include any of the **18 types of identifiers** that could identify the participant, participant's relatives, employers or household members, then it is not protected health information and this question should be answered "no."

iMedRIS Tip: Reduce Review Times Using MS Word Documents



We highly recommend submitting these documents in MS Word format when possible. iMedRIS includes an internal document comparison tool. Both researchers and the IRB can use this tool to see what changes were made in different versions of any documents submitted MS Word format. This tool helps the IRB review revised materials more quickly. **Do not use Track Changes when revising these documents.** The comparison tool tracks any changes made.

To use this tool, open your study record in iMedRIS. Under Protocol Items, open either Informed Consent or Other Project Documents depending on which documents you want to compare, then scroll down the screen and find the documents you want to compare. To view multiple versions of a document, click on the  as shown below.

	View History	Edit/View	Title	Version	Language	UnApproved Consent
<input checked="" type="checkbox"/>			Informed Consent Form			
<input checked="" type="checkbox"/>			Main Consent Form	1.1 02/10/2017	English	
<input checked="" type="checkbox"/>			Informed Consent Form			
<input checked="" type="checkbox"/>			Main Consent Form	1.0 01/11/2017	English	

Check the box to the far left of both documents that you want to compare.

Then click  located above the selected documents.

The Differencer window appears with the top half of the window showing the old and new versions side-by-side

The bottom half displays the two versions combined; additions in green underlined text and ~~deletions in red strikethrough text~~. See screenshot below.

*This comparison tool can also be used for the IRB Application (i.e., Protocol Application).

Training and Outreach Opportunities

We are proud to offer the **Social Media as a Research Recruitment Tool** webinar to be screened in Blount Hall, Room 113 on Thursday, February 23 from 1–2:30 p.m. Presented by

Public Responsibility in Medicine and Research (PRIM&R), this webinar is designed to benefit both researchers and IRB members. [Registration](#) is required due to limited seating. See description on [ORE's Training and Workshops website](#).

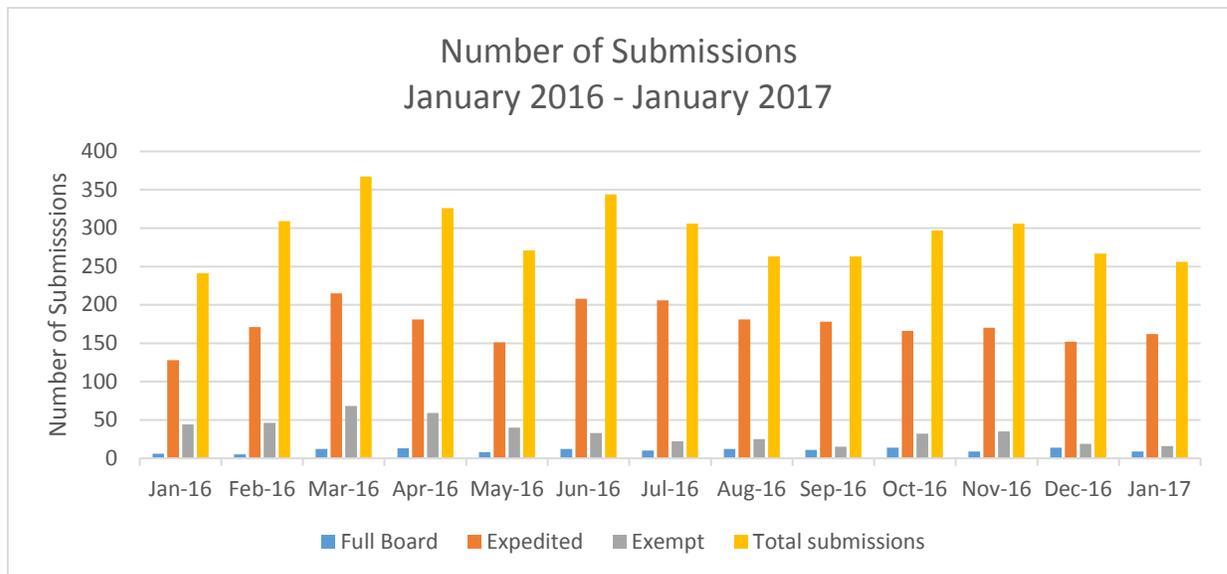
Upcoming IRB 101 training sessions have been posted in the [ORE's Training and Workshops website](#) as details become available.

Take advantage of our video, [Path to IRB Approval](#). Recorded at the Responsible Conduct of Research (RCR) Lunch Series held in January 2016. This presentation instructs you on preparing your IRB application and contains several helpful tips.

IRB Metrics Update

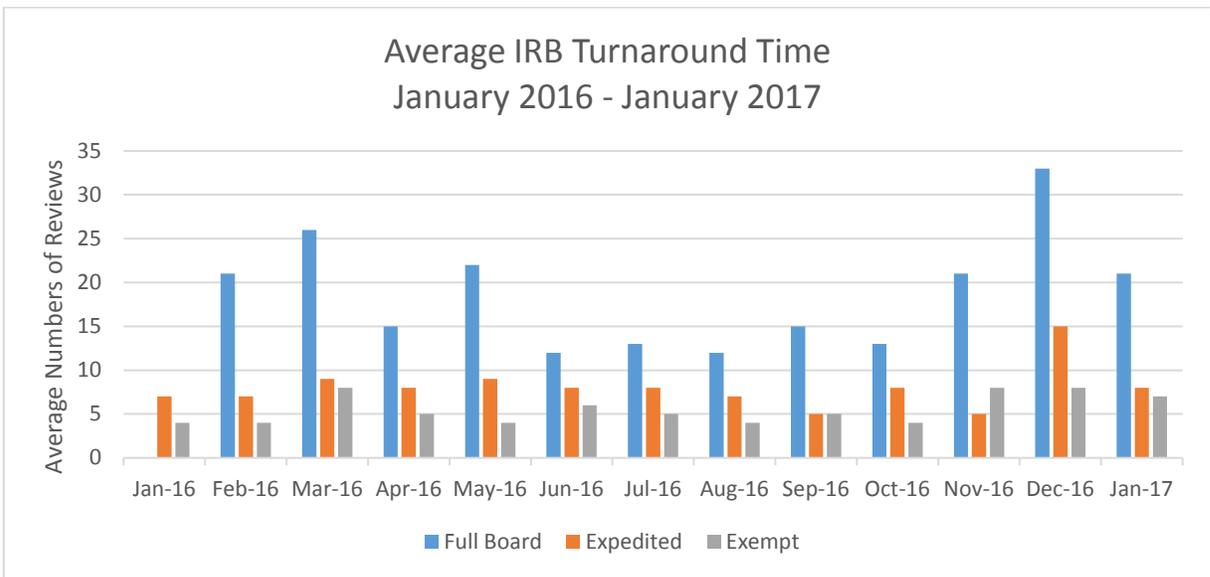
New Submissions by Review Type

The chart below shows the number of new submissions received by the IRB during January 2017 compared to those received on a monthly basis throughout 2016. The IRB received 256 submissions during January 2017. During 2016, the IRB received an average of 309 submissions per month.



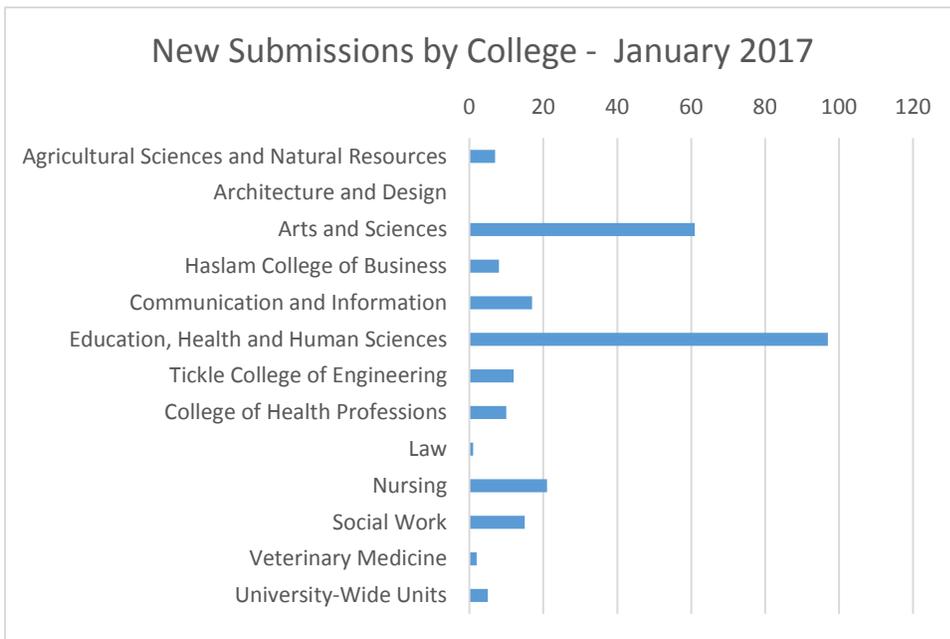
Turnaround Time Averages by Review Type

The IRB is always striving to improve our services to the UT research community. The charts below highlight how the IRB has significantly reduced its average review time across all review types. The average review time in January 2017 was **eight days for expedited review** submissions and **seven days for exemptions**. The average review time for all submissions was seven days.

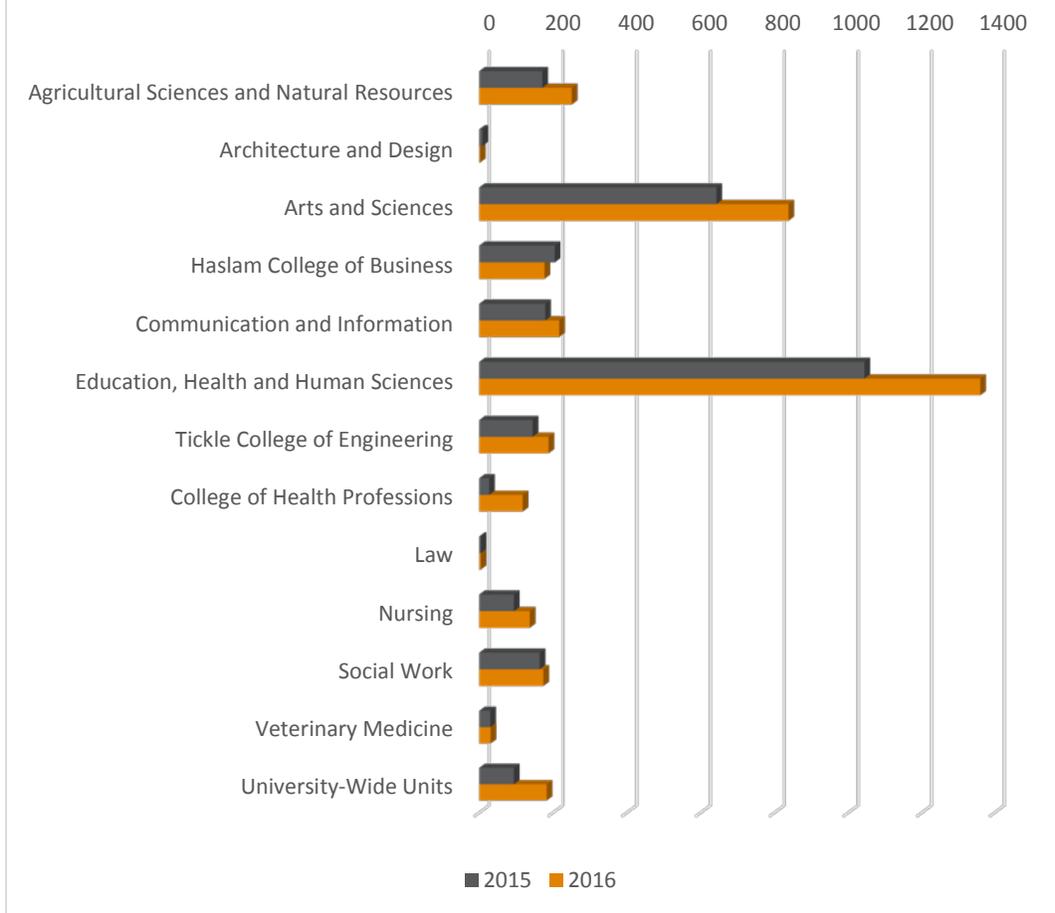


Submissions by College

The charts below show the number of submissions the IRB received from each college during January 2017 plus calendar years 2015 and 2016.



Number of Submissions by College - 2015 and 2016



Contact Information

If you have questions or concerns, please do not hesitate to contact any of [our team members](#).