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Research News

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Clinical Research Ethics Mini-Cases

Clinical research carries with it potential ethical dilemmas regarding such things as data integrity, authorship, industry involvement in research, payments to investigators, and such potentially career-ending mayhem such as plagiarism and fraud. Here are a few cases I have either seen myself or have heard discussed by colleagues, and some questions for discussion. There are not necessarily "right or wrong" answers to these questions, but I have added my thoughts, and you can come to your own conclusions.

A. INDUSTRY DOES NOT LIKE MY RESEARCH FINDINGS

Jill Smith is an assistant professor at Anystate University and is first author on a study comparing the efficacy of superstatin (a new statin drug) and other, more established statin drugs. Her study shows not only no increase in efficacy when compared to older drugs, but that this new drug may also be associated with worse outcomes.

Her department chair, Johnny Milquetoast, reads the article and concludes that Dr. Smith and her team did a good job with the study. However, he recently received a phone call from the senior vice president of Fatcat Pharmaceuticals (the sponsor of the study), and Fatcat has requested that the study not be published as it paints a poor picture of their new statin drug. Of note, Fatcat sponsors many of the department's clinical trials through grant funding.

1. What do you think of industry wanting not to publish negative findings about a drug?
2. What should Dr. Smith do?
3. What recourse does she have if her boss (the department chair) keeps insisting on not publishing the data?

Thoughts:

1. It is not uncommon for industry to desire negative findings about their drug be squelched. They have spent much in research/development and obviously want the drug to go to market in order to make a profit; this article will not help that initiative. This can lead to something called "publication bias," which occurs when the outcome of an experiment or research study influences the decision whether to publish or otherwise distribute it; publishing only "positive" studies is not in the best interest of science and can influence the balance of findings. One tool for detecting publication bias is the funnel plot, which is used as a visual aid for detecting bias or systematic heterogeneity. A symmetric inverted funnel shape arises from a proper data set, in which publication bias is unlikely. An asymmetric funnel indicates a relationship between treatment effect estimate and study precision and possible publication bias.

2. There is no right answer, but Dr. Smith does not work for Fatcat Pharmaceuticals, and likely her primary interest is one of scientific discovery and proper data reporting. Most would feel that she should publish in the interest of scientific integrity.

3. The intervention of her department chair seems unethical, and may be driven by financial concerns (e.g., lack of departmental or even personal financial support by Fatcat). A university should have a research integrity office she can discuss this with, although she may be reluctant to do so given she is not a tenured professor yet.

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B. ERRORS IN MY DATA: "I KNOW NOTHING, I SEE NOTHING"

Dr. Joe Detail has been working on a project and often has graduate assistants help him with data, usually for six month periods. He recently submitted a manuscript for publication, and his last graduate assistant, Ben Careless, helped organize and analyze the data. Fortuitously, the manuscript was accepted and is scheduled for publication in three months by a respected peer-reviewed journal.

His new graduate assistant, Carrie Full, was reviewing Ben's work to learn more about Dr. Detail's research, and she found several errors. Most of these consisted of either duplicate or transposed data, and likely were the result of unintentional errors rather than intentional fabrication or alteration of data on Ben's part. However, it is her determination that those errors likely affected the outcome of the study and hence influenced the decision of the journal to accept for publication.

1. Given the new information, what should Dr. Detail do? He is up for promotion to full professor and the publication of this new manuscript could really help his cause.
2. What are the consequences of inaction on Dr. Detail's part?
3. What are the options for Ms. Full if her concerns are not heard?

Thoughts:

1. He should review Ms. Full's findings himself to verify her concerns before doing anything else. Assuming she is correct, the only ethical course of action is to contact the journal and retract the paper due to the new discovery of erroneous data.
2. While this publication may accelerate Dr. Detail's promotion, the consequences of not reporting a known instance of erroneous data could severely derail his career, if it is discovered. While the data errors are likely unintentional, he is ultimately responsible for his workgroup's product, and inaction carries with it severe ethical consequences. His own ethics and sense of professional pride should compel him to do the right thing. It's better for his promotion to be delayed than to be fired and not promoted at all.
3. Ms. Full can go to a department chair or research integrity office if she feels strongly enough about her findings, although ultimately Dr. Detail bears responsibility for this.

C. I'VE SEEN THIS MATERIAL SOMEWHERE BEFORE

Dr. Ron Writer is a local medical school instructor who has written a book of case studies for internal medicine residents. He frequently has residents, medical students, and nurse practitioner students rotating with him, and he gives his learners a copy of his book.

One month he had a medical student who shared with him some of the materials she had obtained from Dr. Jenny Docter, a former student of his who is now an instructor at the main medical school campus. He looked through the materials and found they had an uncanny resemblance to his case studies book. However, the clinical vignettes were not simple copies from Dr. Writer's book, but clearly had been re-formatted and labeled with Dr. Docter as the author.

1. What ethical breach, if any, has occurred here?
2. What would have been a permissible way for Dr. Docter to use Dr. Writer's materials?
3. What are some actions Dr. Writer might take?

Thoughts:

1. Taking someone's work and attempting to pass it off as her own is a clear case of plagiarism. If she had simply copied a few of the vignettes and handed them to students, it might still be a violation of copyright (but might well fall under the "fair use" exception for educational purposes); here, there is no intent to deceive the recipients about who the author is. But once she reformatted the documents and tried to pass herself off as author, this crosses the boundaries of ethical academic standards.
2. She should have contacted Dr. Writer and received his permission. If the copyright is retained by the publisher, then the publisher would need to get permission. Perhaps copies of the book could be obtained at an educational discount.
3. He should contact Dr. Docter immediately and demand she immediately remove all plagiarized materials from her course; if a publisher is involved, it might be prudent to notify them so they can respond to the incident as well. If the problem persists, there may be no choice other than to pursue legal action and speak to the department chair.

Hopefully these three brief cases have helped you think a little bit about how ethical problems can weave their way into academics and research. As always, when confronted with ethical dilemmas, it is best to turn to your institutional official, IRB administrator, and/or research integrity office for guidance. Many issues are due to simple ignorance of regulations or errors in data reporting, but others such as data fabrication and fraud can lead to severe professional consequences.

How Oncology Patients Become Clinical Trial Participants

The Cancer Center at IU Health Ball Memorial Hospital has been participating in oncology clinical trials since the early 1980's. Oncology research at IU Health Ball Memorial hospital exists because of the efforts of Dr. William Fisher. In 1985, Dr. Fisher and a small group of community medical oncologists collaborated with faculty at Indiana University Cancer Center and founded the Hoosier Oncology Group, now known as the Hoosier Cancer Research Network (HCRN). The group's vision was to bring academic and community physicians together to develop cancer clinical trials in the community setting. Our medical oncologists at IU Health Ball Memorial Hospital Cancer Center continue this work of bringing cancer patients access to cutting edge clinical trials close to home.

The oncology research team currently consist of William Fisher, MD, Joseph Spahr, MD, Michael Williamson, DO, Mark Pajeau, MD, Stacey Cadogan, NP, Abby Koons, NP, Cathleen Carlos, RN, MSN/Ed., CCRP and Angie Patterson, RN, CCRP. The team is looking forward to welcoming Dr. Maitri Kalra and Dr. Mohammed Salhab who will be joining the oncology research team later this summer following the completion of their oncology fellowships.

You might wonder how a patient seen in the Cancer Center might come to be involved in an oncology clinical trial. The process starts with the referral from a patient's physician requesting a medical/hematology consultation. Once all the needed records are obtained, they are reviewed and an initial assessment is made as to the availability of a clinical trial, to offer to the patient. If a potential clinical trial is available the research coordinator will discuss the potential trial with the physician, communicating that the patient initially looks like a good candidate. The current IRB (Institutional Review Board) approved Informed Consent document and any other pertinent study information is provided to the physician for the consultation appointment.

During the consultation visit the physician will discuss the clinical trial with the patient. They review all the therapy involved in the study, discussing the known side effects and the purpose of the study. Often, Cathleen and Angie are given the opportunity to meet the patient the day of their consultation visit. The patient is scheduled for a return clinic visit in 2 -3 days to further discuss the clinical trial, to assess their interest in participating and if the patient is interested the informed consent document is signed which allows study required screening assessments to begin.

Once all study required screening assessments are complete a full determination of patient eligibility is made and if the patient meets all study eligibility criteria the study treatment delivery begins. The study protocol dictates how long the study therapy will be given, the length of follow-up that will occur and when the study will end.

The goal of the oncology research team is to offer participation on a clinical trial to every patient receiving treatment in the center, this includes newly diagnosed patients and patients needing second-line, third-line and beyond treatment. On occasion a patient will come to the center seeking out a clinical trial they have discovered as well.

Angie Patterson, RN, CCRP
Oncology Clinical Research Coordinator

Our team accesses clinical trials through a variety of avenues such as, ECOG-ACRIN (Eastern Cooperative Group & American College of Radiology Imaging Network), HCRN (Hoosier Cancer Research Network), CTSU (Clinical Trial Support Unit), NRG (formerly, NSABP, RTOG and GOG) and pharmaceutical company sponsored clinical trials. As a team we comply with all regulatory agency requirements and follow ICH GCP guidelines in the conduct of clinical research.

Thinking and Living with Cancer

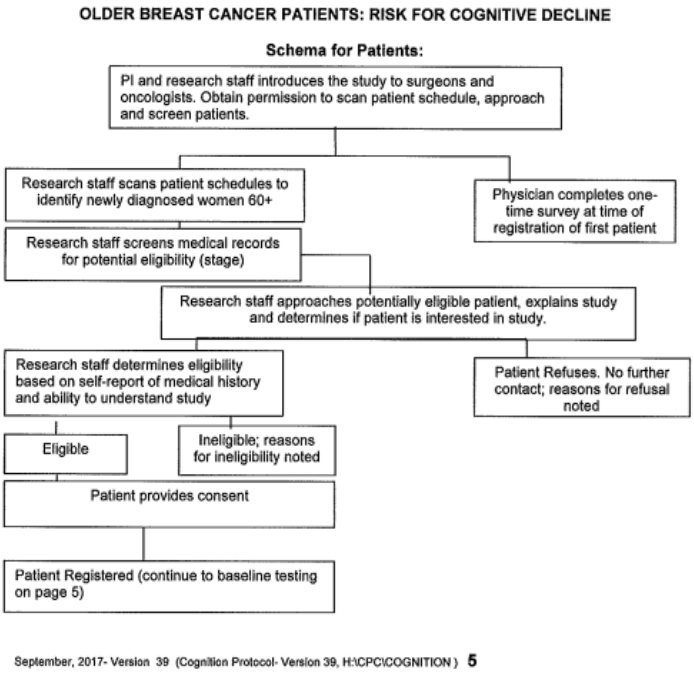
Cathleen Carlos,
RN, MSN/Ed., CCRP
Oncology Research
Coordinator

Chemotherapy and hormonal regimens has been the mainstay in breast cancer treatment over the years. Unfortunately, this has not been without its challenges. We often hear patients complain of what they refer to as "chemobrain." This may involve difficulty with memory, trouble concentrating and multitasking, as well as performing other cognitive tasks. Unfortunately, very little research has been devoted to cognitive changes in breast cancer patients, let alone, those patients over the age of 60 that are already battling the challenges of natural cognitive decline. Fortunately, IU Health Ball Memorial Hospital has been given the opportunity to assist IU Neuroscience in offering the Thinking and Living with Cancer Study (TLC Study) to our local clients.

Sponsored by the National Cancer Institute and led by Georgetown University, the TLC Study's main objective is to evaluate the cognitive changes of systemic chemotherapy and hormonal treatment in older breast cancer patients. The study sponsor plans to enroll a total of 850 subjects with IU enrolling 150 of those subjects. The following eligibility criteria are required to participate in the trial: 60 years of age or older; breast cancer stage 0-3 but not bilateral; no formal diagnosis for neurodegenerative disorders; and no history of chemotherapy/hormonal therapy to treat former cancers. A key point to this study, the baseline visit occurs before any systemic cancer treatment is administered to the patient. The remaining visits occur yearly for a total of 5 years. Each visit involves questionnaires, basic medical information, and neuropsychological testing. Optional testing within this study comprises of neuroimaging via head MRI; blood and/or saliva for genetic testing and biobanking; and participation in the use of a physical activity monitor.

The primary outcome for the study consists of a change in cognition from baseline compared to each timepoint as measured through the Executive, Functioning, Working Memory, and Psychomotor Speed Test (EWP). Other domains such as language, attention, visuospatial, and learning/memory are used to analyze additional outcomes. A change in cognition within the domain will dictate which domains are more sensitive to systemic therapy.

With the projected growth of our elderly population in the upcoming years, the outcome of the TLC Study may have a significant impact on how we treat our older breast cancer patients. Standard of care treatment and preventative care may need to be adjusted to accommodate a new elderly population that can tolerate aggressive treatment modalities. Additionally, this population may desire to pursue treatment that corresponds with their extended life expectancy.



OLDER BREAST CANCER PATIENTS: RISK FOR COGNITIVE DECLINE

Schema for Patients:

PI and research staff introduces the study to surgeons and oncologists. Obtain permission to scan patient schedule, approach and screen patients.

Research staff scans patient schedules to identify newly diagnosed women 60+

Physician completes one-time survey at time of registration of first patient

Research staff screens medical records for potential eligibility (stage)

Research staff approaches potentially eligible patient, explains study and determines if patient is interested in study.

Research staff determines eligibility based on self-report of medical history and ability to understand study

Patient Refuses. No further contact; reasons for refusal noted

Eligible

Ineligible; reasons for ineligibility noted

Patient provides consent

Patient Registered (continue to baseline testing on page 5)

Indiana Biobank-Why Participate?

Mona Geinosky, MSN, RN, CCRP
Manager - Research

The Indiana Biobank is recruiting participants across the system, including Indiana University Health Ball Memorial Hospital! If you are interested in participating, you will need to meet with one of the Department of Research staff members. They will offer a consent that explains the Indiana Biobank donation process, and explain all of the details to you.

Your donation is strictly voluntary, you do not have to participate if you choose not to do so. However, if you agree to participation, the staff member will draw a tube of blood from you. Researchers are using the samples in trying to find new and innovative ways of treating or possibly curing diseases. For the donated biological samples to be the most useful, the sample will be linked to your medical record. This will greatly increase the usefulness of your sample for research purposes. Your sample will be given a unique study number and your personal information will not be attached. Researchers using your sample will not know who you are nor will anyone else, except the authorized Indiana Biobank staff and they will keep this information strictly confidential. De-identified samples and medical information will only be released to Indiana Biobank approved researchers.

If you would like help the Department of Research meet their Indiana Biobank enrollment goals by donating, or if you have a question about doing so, please contact Mona Geinosky at 765.747.8457.

Approved Research Projects

From January 1, 2018 through April 30, 2018, the following research projects and their principal investigators (PI) have been approved:

Risk of developing acute kidney injury in hospitalized patients treated with the combination of vancomycin plus piperacillin-tazobactam versus piperacillin-tazobactam alone
PI: Chidiebere Eze, PharmD

A Humanitarian Device Exemption Treatment Protocol of Enterra II Gastric Electrical Stimulator
PI: Michael Thorpe, MD

Themis D513BC00001: A Multinational, Randomised, Double-Blind, Placebo-Controlled Trial to Evaluate the Effect of Ticagrelor 90 mg twice daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Stroke in Patients with Type 2 Diabetes Mellitus
PI: Bruce Graham, MD

AWARE: CNT0148ART4011 Janssen: Comparative and Pragmatic Study of Simponi Aria versus Remicade in Rheumatoid Arthritis
PI: Gordon Hughes, MD

Akebia: Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Maintenance Treatment of Anemia is Subjects with Non-Dialysis-Dependent Chronic Kidney Disease (NDD-CKD) (PRO2TECT-CONVERSION) AKB-6548-CI-0015
PI: Unnikrishnan Pillai, MD

Meet the Research Department!

The Department of Research works with virtually every department in the hospital and has actually doubled in size over the past year and a half. You may be surprised at the amount of staff that it takes to run such a successful research department, so we wanted to take some time to introduce all of our team members and tell you a little bit about each one of us.

SHERRY ADAIR, RN, BS, RESEARCH COORDINATOR

- Research experience – 11 years
- What she likes most about research – "It is so beneficial to patients in our community. They have access to cutting edge treatments. We have seen multiple drugs and devices for diseases of the heart, lungs, kidneys, and autoimmune system come to market and improve the quality of life of patients with chronic illnesses."
- Fun fact – She is a certified Master Gardner but has killed every plant she has ever tried to care for.

ARLINE APPLEGATE, ADMINISTRATIVE ASSISTANT

- Research experience – 1 year
- What she likes most about research – "I like being a part of something that is ultimately working on better outcomes for our patients."
- Fun fact – She likes going on morning walks and listening to the birds sing before anyone else is up.

ALI BELANGEE, RN, BSN, RESEARCH COORDINATOR

- Research experience – 6 years
- What she likes most about research – "I enjoy the interactions and relationships that we build with our research patients over the course of the study and being able to advocate/assist them with their overall health and well-being."
- Fun fact – She was named after the actress, Ali MacGraw, from the movie Love Story but has yet to actually see the movie.

CAMIE CARPENTER, RN, RESEARCH COORDINATOR

- Research experience – 4 months
- What she likes most about research – "Right now, being new, it's like a big puzzle that I am trying to piece together. It has been fun and interesting!"
- Fun fact – At home, she is called the fun police (someone has to be the parent!).

CATHLEEN CARLOS, RN, MSN/ED, CCRP, ONCOLOGY RESEARCH COORDINATOR

- Research experience – 4 years
- What she likes most about research – "Research aligns with my continual desire to learn and grow within the nursing profession."
- Fun fact – She loves to travel in order to explore each country's culture, especially the food! She is a huge foodie! She has been to 7 European countries – as far away as Peru, South America and the Philippines.

HALEY EDWARDS, RESEARCH ASSISTANT

- Research experience – 8 years
- What she likes most about research – "I like having a small role in the advances of modern medicine, especially when we are participating in a study with a breakthrough drug."
- Fun fact – She is completely in love with the show, Stranger Things. She is also utterly obsessed with all things related to the book series, Harry Potter, by J.K. Rowling.

Meet the Research Department!

TERRY GARLAND, CLINICAL TRIAL BILLING SPECIALIST

- Research experience – 1 year
- What she likes most about research – "I like being able to help the patients and our department with the financial aspects of research."
- Fun fact – She enjoys teaching her granddaughter all of the cool things she knows.

ERIN LOOMIS, RN, BSN, RESEARCH COORDINATOR

- Research experience – 3 years
- What she likes most about research – "It has been very interesting being part of the behind the scenes work that goes into the approval of a new medication, device, and/or therapy. Those new treatments, in turn, can benefit the patients in our community and give them access to the latest and greatest options in medicine today."
- Fun fact – Her family loves to play board games. She owns over 100 different games and is running out of room to store all of them in her house!

MONA GEINOSKY, RN, MSN, CCRP, MANAGER

- Research experience – 10 years
- What she likes most about research – "The best thing about clinical research is feeling we are doing our part in bringing new medical interventions to our patients. Our work is something that is important to other human beings, and that makes the journey worth the effort."
- Fun fact – She played on the pro tennis circuit in Florida.

RACHAEL MADDOX, MS, IHCM, RESEARCH ASSISTANT

- Research experience – 2.5 years
- What she likes most about research – "I like being part of a department that offers treatment alternatives to patients that may not have otherwise been able to receive it."
- Fun fact – She grew up on an apple orchard.

ANGIE PATTERSON, RN, CCRP, ONCOLOGY RESEARCH COORDINATOR

- Research experience – 18 years
- What she likes most about research – "I like working with our Cancer Center patients and their families, as well as the Cancer Center team at IU Health Ball Memorial."
- Fun fact – She is a huge country music fan and will be seeing 40+ country music artists over the summer.

CHRISTINA YENCER, CRT, RESEARCH COORDINATOR

- Research experience – 3 years
- What she likes most about research – "I have really enjoyed learning more about Cardiology and other diseases besides those related to Pulmonology."
- Fun fact – She enjoys hiking trails (esp. getting off the trails to climb), spelunking, and going to haunted houses to get scared.

Changes to Review of Human Subjects Research

The Office of Protection of Human Research Subjects (IRB Office) is happy to announce several changes to IRB policies and procedures effective July 19, 2018.

Why the Change

These changes were prompted by new requirements outlined in the revised Common Rule and have the goal of reducing the administrative burden of conducting research and better protection of research subjects. At this time, implementation of the revised Common Rule for **federally funded research and FDA regulated research** has been delayed until July 19, 2018. Federal departments and agencies are considering further delaying implementation until January 21, 2019 to allow institutions additional time to comply.

To ensure that IU Health Ball Memorial Hospital's IRB Office and its research community positions itself to be compliant with the new regulations when finalized, and to be consistent with how research is overseen throughout IU Health, effective July 19, 2018 IUH Ball Memorial Hospital will implement these changes for any research that is **NOT** federally funded and **NOT** subject to FDA regulation. (Once the final date for implementation of the revised Common is determined, the new regulations will also apply to research that is federally funded and FDA regulated.)

What Are the Changes

- Changes to exempt & expedited research categories
- Elimination of annual review for expedited research and full board research which is in long-term follow-up or data analysis only
- New informed consent requirements
- Elimination of annual adverse event reporting
- Waiver requirements and more
- Revisions to applicable IRB forms, templates and policies and procedures.

Here's what you need to know.

Changes to Exempt Research

Three additional exempt categories are now available to investigators for research that is not federally funded and not subject to FDA regulation. The three categories, known as "flex" categories to represent the additional flexibility, expand the types of research which are eligible for exempt review. All current exempt categories continue to be available as well.

What to Expect:

New research - The IRB forms and templates will be updated on July 19, 2018 to reflect the revised exempt categories. Many studies which are currently expedited may be eligible for exempt review under the flex categories, so please review the information about the flex categories and their impact below.

Ongoing research - Previously-approved exempt research will not be affected and will continue to be conducted under the category applied at initial approval.

Category 2 Flex

Category 2 Flex is based on an existing exempt category which allows conduct of research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior when subjects cannot be identified via research data and/or disclosure of research responses would not place subjects at any additional risk. Additional risks include risk of criminal or civil liability or potential damage to the subjects' financial standing, employability, educational advancement, or reputation.

Category 2 Flex expands the current category to allow exemption even when subjects can be identified and disclosure of responses may place subjects at additional risk, as long as an IRB member determines adequate protections are in place.

Category 3 Flex

Category 3 Flex is a completely new category which allows exempt review of research involving benign behavioral interventions with information collection from adult subjects, if the subjects prospectively agree to the intervention and information collection. A large majority of research which is currently approvable under expedited category 7 will now be eligible for exemption under this category.

Benign behavioral interventions are considered to be brief in duration, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subjects. In addition, the investigator must have no reason to think that subjects would find the interventions offensive or embarrassing. If the research involves deceiving subjects regarding the nature or the purpose of the research, subjects must prospectively agree to participate in the research knowing about the deception.

Information should be recorded so that subjects cannot be identified; or the investigator should assure that any disclosure of the subjects' responses would not place the subjects at additional risk. If the information is recorded so that subjects can be identified, and disclosure of the subjects' responses could pose additional risk, the study may still be exempt but an IRB member must determine adequate protections are in place.

Category 4 Flex

Category 4 Flex is a supplement to the existing exempt Category 4 which allows for research use of existing data if the data is recorded in a de-identified manner. The flex category is much expanded, allowing for exempt review of all chart reviews, many of which were previously approved under expedited category 5, regardless of identifiability of the data or when the data was created.

For more detailed information, see the IRB Policy on Exempt Research.
Removal of Annual Review (Renewal) Requirements Renewal is no longer required for the following research (unless the IRB specifically deems it necessary for additional protection of human subjects):

- Expedited research that is not federally funded and not subject to FDA regulation
- Full Board research that is not federally funded and not subject to FDA regulation AND for which research procedures are limited to clinical follow-up (i.e. accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care) or data analysis only

What to Expect:

All study teams must submit the next scheduled renewal regardless of funding or applicable regulations. Research which is federally funded and subject to FDA regulation will continue to receive annual renewal based on the current expiration date.

For research that is not federally funded and not subject to FDA regulation:

- New Expedited Research will no longer be assigned an expiration date in IRBNet and renewals will not be required (unless requested by the IRB).
- Previously-Approved Expedited Research will be reviewed at the time of the next scheduled renewal. Upon approval, no expiration date will be assigned and no additional renewals will be required (unless requested by the IRB).
- Full Board Research in Clinical Follow-up/Data Analysis Only will be reviewed at the time of the next scheduled renewal. Upon approval, no expiration date will be assigned and no additional renewals will be required (unless requested by the IRB).

Additional Important Changes

Waivers of consent for FDA-regulated research
Historically, FDA regulations did not allow the IRB to waive informed consent for minimal risk research. In an attempt to harmonize with the Common Rule, the FDA has released notification that it will allow IRBs to grant waivers of informed consent for FDA-regulated research if the criteria defined by the Common Rule are met. The IRB forms and templates have been updated to allow investigators to request waivers of informed consent for FDA-regulated research.

Use of information and/or biospecimens for recruitment and screening
The revised Common Rule eliminates the requirement for an IRB to grant screening or recruitment waivers. Investigators are allowed to access medical records or stored biospecimens, or collect data directly from subjects and to record this identifiable private information for the purpose of screening, recruiting, and determining eligibility for a research study. Consent is still required for subject participation in the study itself.

Reporting adverse events (AEs) at time of renewal
Reporting of AEs that are serious, unexpected, and unrelated to the research at the time of renewal is no longer required. These events were reported on the SAE Summary Log annually. Investigators are responsible for assessing the ongoing safety and risk of research and should continue to log and track AEs; however, IRB review of these logs is not required. For a comprehensive list of events that require reporting to the IRB including SAEs that require prompt reporting, please see the Reportable Events Guide.

Additional informed consent requirements & new templates
Consent forms are now required to be clearer and more focused. If your consent is more than a few pages, the document must begin with a concise presentation of key information most likely to assist a prospective subject in understanding why they may or may not want to participate. Clearly and concisely convey the following information: 1) Statement that the project is research and that participation is voluntary, 2) Purpose, duration, procedures, 3) Risks, discomforts, 4) Benefits, 5) Appropriate alternatives, 6) Costs, 7) Payment.

Consent templates, guidelines and instructions have been updated. Additionally, consent templates have been designed to address specific types of research: social, behavioral, educational (SBE) research; research that only involves the collection of information and the only risk is possible loss of confidentiality; research that involves the future use of information and/or biospecimens; and biomedical research. Please use these templates for new projects unless one has been provided by a sponsor or funding agency.

Additional elements must now be included in the consent when applicable. Statements that address the collection of identifiable private information or identifiable biospecimens, commercial profit, the return of clinically relevant research results, whole genome sequencing and other mandatory language have been added to the new templates.

If you have questions about any of these changes, please feel free to contact me at abright@iuhealth.org or phone 765.747.8458.

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IRB Administrator

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