

DO I NEED TO SUBMIT FOR THIS?...

& OTHER FREQUENTLY ASKED
QUESTIONS

Topics

- Quality Assurance/Quality Improvement Projects
- Informed Consent- when is a waiver appropriate?
- Retrospective/Prospective Research- when can my research be exempt?
- Modifications
- Will OHR help me?
- About my PI....
- I have a grant due!!
- Other frequently asked questions and concerns



Quality Assurance / Quality Improvement

When do I need IRB review?

What is QA/QI?

- QA/QI generally refers to a range of activities conducted to assess, analyze, critique, and improve current processes of health care delivery in an institutional setting.
- QA/QI activities are often observational and unobtrusive and can involve the collection and analysis of data to which investigators have legitimate access through their institutional roles.
- These activities do not prevent or hinder the delivery of clinically indicated care to patients, nor do they impose more than minimal additional risks or burdens on patients or providers.

QA/QI Projects

- Quality assurance/quality improvement initiatives:
 - ▣ Are only intended to assess or improve internal practices, programs, or systems AND
 - ▣ Are not designed to contribute to generalizable knowledge.
- Does a quality improvement project that involves research need to be reviewed by an IRB?
 - ▣ Yes, in some cases. IRB review is needed if the project meets the definition of human subjects research.
 - ▣ If your project involves research and a QA/QI component, use the standard IRB initial application form. If you are uncertain if your project qualifies as a QA/QI project, please contact OHR.

QA/QI Checklist

CONDITIONS FOR DETERMINATION OF QA/QI STATUS	Yes	No
The primary intent of the project is not peer reviewed publication and if publication of the results was prohibited, the project would still have merit as a QA/QI effort.		
The purpose is to improve the quality of the program under investigation by assessing and encouraging standard medical care or educational goals.		
The PI has both clinical supervisory responsibility and the authority to impose a corrective plan based on the outcomes of the project.		
The project does not involve prospective assignment of patients to different procedures or therapies based on a predetermined plan such as randomization.		
The project does not involve a “control group” in whom therapeutic or study intervention is intentionally withheld to allow an assessment of its efficacy.		
The project does not involve the prospective evaluation of a drug, procedure or device that is not currently approved by the FDA for general use (including “off-label” indications).		
Participants won't be exposed to additional physical, psychological, social or economical risks or burdens (beyond patient satisfaction surveys) in order to make the results of the project generalizable.		
Adequate protections are in place to maintain confidentiality of the data to be collected and there is a plan for who can access any data containing participant identifiers.		

Informed Consent

Can I get a waiver?

What kind of waiver?

When Can I get a Waiver??

- If your minimal risk study meets the criteria for either:
 - ▣ waiver of documentation of consent (you would still obtain verbal consent)
 - ▣ waiver of consent (no consent process; typically only granted in cases where you will not have contact with participants)
- A study is not granted a waiver for convenience.
 - ▣ You must provide justification for a waiver

Waivers: Documentation and Consent

Waiver of Documentation

45 CFR 46.117.c(2)

- An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if it finds either:
 - ▣ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality;
 - ▣ The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside the research context.

Waiver of Consent

45CFR46.116(d)

- An IRB may approved the waiver of consent or altering of the elements of consent provided the IRB finds and documents all of the following:
 - ▣ The research involves no more than minimal risk;
 - ▣ The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - ▣ The research could not practically carried out without the waiver or alteration;
 - ▣ And...whenever appropriate the subjects will be provided with additional pertinent information after participation.

Waiver of Documentation Examples

- The consent form would be the only place the participant's name is linked to the study (the study is otherwise anonymous) and association with the study via a signature (or possession of consent form) poses risk. There is still an informed consent conversation, with a script.
- An minimal risk study involves a phone survey. Subjects give oral consent over the phone but are not available to sign a form. Telephone call may be followed with mailing of information.
- An expedited review internet survey that retains the identity of the respondent provides all required elements of informed consent, however documentation is waived.

Waiver of Consent Example

- Non-sensitive data will be obtained from 5,000 existing medical records. ALL data being reviewed is already in existence at time of IRB submission. Investigators need to document and maintain identifiers in order to compare medical records from different sources.
- ▣ There will be no participant contact and it is not feasible to contact all participants for consent

Retrospective vs. Prospective

What is retrospective?

When can this study be Exempt?

Why is it considered not Exempt?

Retrospective vs. Prospective

Retrospective

- Retrospective research may be reviewed as exempt or expedited.
- Generally does not obtain consent (waiver).
- May request a full or partial HIPAA waiver.
- Information is already collected (“on the shelf”) prior to study submission.

Prospective

- Prospective research may only be reviewed as expedited.
- May request consent or waiver of consent.
- May request full HIPAA authorization or waiver of HIPAA (full or partial).
- Information has not yet been documented or collected at time of study submission.

When can a Retrospective Study be Exempt?

Exempt

- Information recorded by the researcher must not identify the subject. Individually identifiable data elements may not be recorded.
- Retrospective projects will not qualify for exempt status if partial identifiers are needed or if a linking list is desired.
- This must be stated in the protocol, synopsis application, and HIPAA waiver, if applicable.
- If a project does not qualify for exempt status, then all federal research regulations will apply to the project. In that case, informed consent of the participant is the default requirement.

Expedited

Chart reviews may be reviewed under the expedited procedures if:

- Researcher will be maintaining identifiable information
- A code link is created
- Both prospective and retrospective data are accessed

When is Retrospective Research No Longer Retrospective?

- The PI wishes to include data that did not exist at the time of the initial IRB submission.
 - ▣ If the study was initially determined to be Exempt, you must submit a modification and it will be upgraded to Expedited;
 - ▣ If the study is already considered Expedited, you must submit a modification indicating you are now collecting prospective data.

Example of When Research is No Longer Retrospective

You submit an IRB application on 3/18/15 proposing to conduct a retrospective chart review. That means all data you will be accessing was collected prior to 3/18/15. At the next continuing review on 3/17/16, you decide you want to look at records that have been collected over the last year from 3/18/15 to 3/17/16. This is no longer a retrospective chart review since all the data was not in existence at the time of INITIAL IRB submission on 3/18/15. You will need to submit a modification stating you are conducting a retrospective and prospective chart review and if the study was initially reviewed as exempt, it will now need to be reviewed as expedited.

Modifications to Research

What constitutes a modification?

Modifications

Yes! Submit!!

- ❑ Adding text or images to study documents;
- ❑ Changing the study's population, recruitment methods, adding visits or instruments, or anything else that may alter the study risk;
- ❑ Anything not mentioned in the “no” category.

No Need to Submit

- ❑ Updating documents to correct typos (typos);
- ❑ Changing font, color, size of text in materials;
- ❑ Moving two IRB approved forms into one or vice versa;
- ❑ If not sure...contact us!

Help!!

OHR assistance

Form review

Pre-review process

OHR Staff Assistance

- OHR welcomes your questions.
- We are available to help you identify categories of review and let you know when to submit documents for review.
- We can help guide you through the forms by clarifying what certain sections mean or what is required for review.
- We will meet with you to discuss your study and provide clarification or recommendations prior to submission.

Review Process

- For any category of human subjects research, the following process occurs:
 - Once a study is submitted in its entirety (including all signatures, CITI, etc), it is assigned to an OHR staff member for preliminary review.
 - The staff member will contact the PI and primary contact with questions and clarifications about the study.
 - Once all preliminary review questions are resolved, the study is forwarded for formal review by full committee (for greater than minimal risk), a member of the IRB, or a designee.
 - Formal review may result in additional questions.
 - Final approval is issued.

Principal Investigators

Who can be PI?

What if my PI is out of the country?

What if my PI is on sabbatical?

Who can sign my form?

Principal Investigator

- The Principal Investigator (PI) is the individual who assumes full responsibility for a research project.
- At GW, the PI must be a full-time faculty member (with limited exceptions).
- One research team member should be designated as the “Principal Contact” for communication with the IRB.

PI Responsibilities

- ❑ Securing prior IRB review and approval for research, including any modifications to approved research
- ❑ Following institutional policies and procedures
- ❑ Ensuring informed consent is properly obtained and documented
- ❑ Ensuring that Continuing Reviews are submitted at least 30 days in advance of study expiration
- ❑ Submitting study modifications and obtaining receipt of approval before changes to research are carried out
- ❑ Ensuring prompt reporting of any unanticipated problems involving risks to subjects or others and any serious or continuing non-compliance
- ❑ Research record-keeping

Who can be PI?



- Full Professor
- Associate Professor
- Assistant Professor
- Research Professor
- Research Scientist

What if My PI is Away?

- Is your PI just gone for a week or two?
 - ▣ No need to do anything. Should something happen while the PI is away, such as an unanticipated event, contact the IRB as soon as possible to report the issue, but let us know your PI will sign off on the appropriate documents upon their return.
- Is your PI out of country for an extended period (longer than month)?
 - ▣ It is recommended to have another faculty member serve as PI in his/her absence.
- Is your PI on sabbatical?
 - ▣ A PI on sabbatical cannot provide research oversight as required by the GW IRB. Please obtain a different PI.

Who can sign a form?

- The PI's signature is required on the following forms:
 - ▣ Synopsis or Exempt Application
 - ▣ Modification
 - ▣ Renewal
 - ▣ Problem Report
 - ▣ Closure
- A designated research team member may sign informed consent documents on behalf of the PI. The team member should be appropriately trained in the consent process and able to address all subject questions or concerns. Additionally, this designation must be stated in a retrievable record, such as a Delegation of Authority log.

Grants and Other Funding Sources

When do I submit?

Can I get an IRB number?

How long will this take?

What if I don't get funded?

When should I submit my study?

National Institutes of Health (NIH)

- If you receive an impact score of 40 or under from the NIH on a pending grant, you may have what is termed a “Just in Time” or JIT grant.
- On February 10, 2014, the NIH published the following in regards to JITs:
 - IRB Approval: If the proposed project involves human subjects research, the certification date of IRB review and approval must be submitted. Pending or out-of-date approvals are not acceptable.
 - Human Subjects Education: If the proposed project involves human subjects research, certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects must be submitted.
 - We understand that obtaining IRB and/or IACUC approval may take more than two weeks. Therefore, you may submit these approvals at the earliest date they are available.

National Science Foundation (NSF)

- Per the NSF Grant Manual Policy, Section 711.3 Certification of Compliance:
 - “All projects involving human subjects must either (1) have approval from the organization's Institutional Review Board (IRB) before issuance of an NSF award or, (2) must affirm that the IRB or an appropriate knowledgeable authority previously designated by the organization (not the Principal Investigator) has declared the research exempt from IRB review, in accordance with the applicable subsection, as established in section 101(b) of the Common Rule.”
- Per the NSF Office of Budget, Finance and Award Management (BFA) regarding timing of IRB review:
 - Researchers should file their proposal with their local IRB at the same time they submit it to NSF, so that the approval procedure will not delay the award processing.

But I need IRB approval tomorrow...

- Do you need IRB Approval?
 - Many funding sources will only request IRB approval after submission of the grant application. If you require approval prior to submission, please be sure to provide the IRB with the application stating such.
- Do you need an IRB Number?
 - Submit your study in its entirety to the IRB and request your number be provided to you for application purposes. We cannot provide an IRB number without a submission.

How long will IRB approval take?

- An Exempt study may take up to 2 weeks to review, provided all documentation is submitted.
- An Expedited study may take 4 weeks to review.
- REMINDER: Your submission will not be accepted if any research team members have not completed human subjects protection training (CITI) within the previous TWO years. The PI must verify all team members are up to date BEFORE submitting to the IRB.

What if I don't get a NOGA?



- It happens...
- You may either close your study (if annual review is required), or keep it open to pursue other funding options.
- Funding is not a requirement to conduct a study or obtain IRB approval!

Be Advised...

- ❑ Sponsors are setting increasingly aggressive timelines (sometimes within a matter of days for IRB exemption or approval).
- ❑ Your project may have phases, some of which would not be considered human subjects research. Work on the non-human subjects research component, such as literature reviews, may commence without prior IRB review and approval.
- ❑ Your sponsor may still require that you obtain approval regardless of when you intend on initiating the human subjects research phase.
- ❑ Sometimes the funding source may disagree with the IRB's determination.
- ❑ The funding source can request a study undergo IRB review even if the GW IRB determined it to be not human subjects research.
- ❑ It is important to be prepared for this situation.
- ❑ Already have human subject protection training completed by all team members.
- ❑ Be prepared to submit all documents (surveys, interviews, consent documents) as applicable.
- ❑ Identify how collaborators will be involved and plans for IRB review and approval and their institution (or ability to do a reliance agreement).

Potpourri

Frequent questions and concerns that come to OHR...

Other Questions and Concerns

- I have a large subject pool and I'm concerned that I won't be able to recruit enough people if I have to get consent from all of them. Can I get approval for waiver of consent because it would be easier?
 - ▣ No. Your study must meet specific criteria to be granted a waiver of consent.

- Is “anonymous” data the same thing as “de-identified” data?
 - ▣ No. De-identified data is collected as identifiable and then scrubbed of all information that may potentially identify a subject. Anonymous data never contains any identifiers.

- I have all the IRB application forms saved on my computer/linked to my google drive – can I use those forms when submitting an application?
 - ▣ No. Our forms are continually being revised. Please always download the form you need from our website to ensure the most recent version is used.

Other Questions and Concerns

- A subject got into a car accident after leaving a study visit. What do I do?
 - ▣ If a problem arises that is related to study procedures, please report this to the IRB within 5 days. In this case, you should talk to the research subject to determine if the car accident could have been related to the research, such as if they recently took a study drug and became dizzy, causing them to crash. If so, you should report it to the IRB since it was unexpected and related, or you should report if the participant was instructed not to drive and still did. You should report events that are possibly related, unexpected, and caused harm to participants or others, or placed them at increased risk of harm. If the subject is in an observational study, you would not need to report this as it is not related.
 - ▣ Additional examples: if study documents are lost, if there is a breach in confidentiality, or if a subject faints during a research blood draw, this should be reported to the IRB.

The April IRB Forum will focus on problem reports and unanticipated events!

Questions?



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