How to Write IRB Submissions to Reduce Review Time: The How To's and Other Helpful Hints




Speakers:

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THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Knowledge that will change your world

HUMAN SUBJECTS PROTOCOL

Problem Areas

- Item 3.a: PERSONNEL
- Item 13: HIPAA
- Item 14: PURPOSE
- Item 15: BACKGROUND
- Item 16.h& i: RECRUITMENT & SCREENING
- Item 17.a: PROCEDURES
- Item 19&20: RISKS

GENERAL NOTES

HSP: GENERAL

- Don’t cut/paste
- Read the question…every time
- Use lay language, 8th grade level
- Avoid jargon and acronyms – even UAB buildings and departments
- Careful with recycling old versions
- “Make a movie”

PERSONNEL

PERSONNEL

Large number of issues/information in Item 3.a

Are all the roles described in the HSP accounted for here?

Do we know who's doing what?

a. UAB Personnel (includes UAB affiliates and Children's of Alabama personnel)

Name, Degree, and Dept.	Blazer ID	Role	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
1 Name: Cari Oliver Degree: MPA Department: CIRTL	[redacted]	Principal Investigator	☒ No ☐ Yes	PI
2 Name: Michael Hill Degree: MPA Department: Office of the Institutional Review Board	mhpole	☒ Sub-Investigator ☐ Other	☒ No ☐ Yes	Responsible for all protocol procedures, including recruitment, consent, data collection and data analysis. 20 years experience in study coordination and implementation
Name: [redacted] Degree: [redacted] Department: [redacted]	[redacted]	☐ Sub-Investigator ☐ Other	☐ No ☐ Yes	[redacted]

3 b. Non-UAB Personnel Relying on UAB IRB -- If you are requesting that the UAB IRB serve as the IRB of record for anyone not affiliated with UAB, list these individuals below.

Name and Degree	From Institution with or without own IRB?	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
Name: [redacted] Degree: [redacted] Institution: [redacted] Email: [redacted]	☐ Has own IRB but requests that UAB IRB serve as IRB of record? *OR* ☐ Does not have own IRB and needs to rely on UAB IRB.	☐ No ☐ Yes	[redacted]

*Financial Interest — for each individual listed above, answer Yes or No as to whether the individual or an immediate family member has any of

1: My name is Carolyn.

OIRB may not know what CIRTL is

Blazer ID not complete

No information in last column

2: Thorough and accurate

3: only for NON-UAB people only

Probably should call OIRB before you submit to see how to handle

HIPAA

HIPAA

- Do you know what a covered entity is?
- Do you know the identifiers?
- Are you clear on what this question is about?

18 HIPAA IDENTIFIERS

- Obvious: Name, address, phone number, email, MRN, SSN (that's 6/18!)
- Dates related to an individual (DOB but also any date of service, graduation, surgery, hire, etc.) (7/18)
- THE NUMBERS!: Fax #, Health Plan #, Account #, License/Certificate #, VIN (car), Device # (13/18)
- Full-face (or otherwise identifiable – think tattoo) photographs (14/18)
- URLs or IP addresses (16/18)
- Biometrics (fingerprints, etc) – (17/18)

18 HIPAA IDENTIFIERS

- So What's Left?
- Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

Anonymous Data

Data that was ***collected*** without identifiers and that were never linked to an individual. Coded data are not anonymous.

Coded Data

Direct identifers have been removed and replaced with a code (not derived from or related to personal information such as initials). Original identifiers are retained with a key or link

De-identified Data

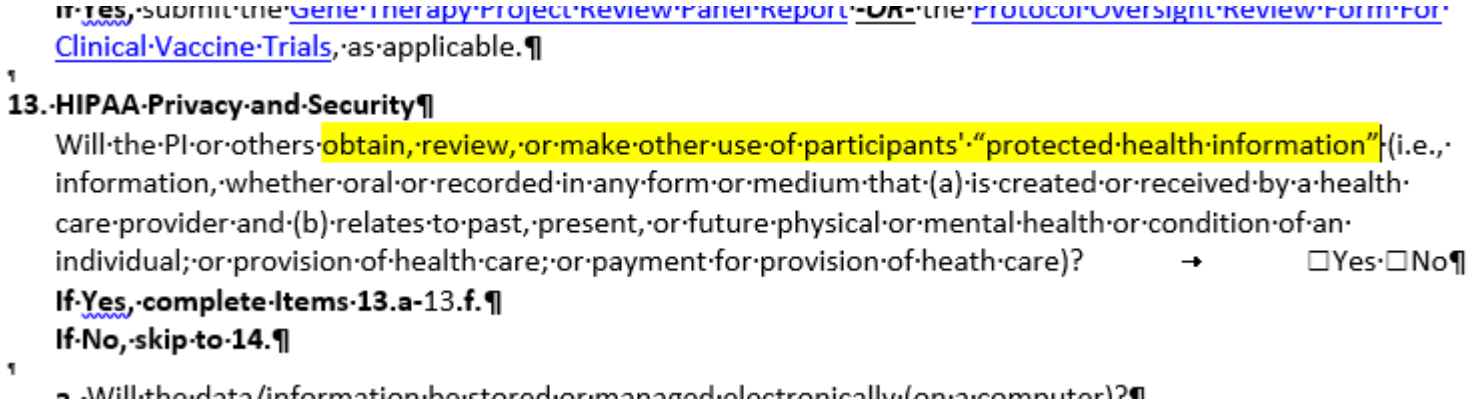
A record in which identifying information is ***removed***. No code exists.

Under HIPAA, data are de-identified if either:

- an ***experienced expert*** determines that the risk that certain information could be used to identify an individual is "very small" and ***documents and justifies*** the determination, or
- the data do not include ***any*** of the 18 HIPAA identifiers, which could be used alone or in combination with other information to identify the subject.

Limited Data Set (LDS)

A set of data in which all of the HIPAA identifiers have been removed except dates related to an individual and addresses larger than a street address (i.e., zip code, city, state).



If·Yes,·submit·the·Gene·Therapy·Project·Review·Panel·Report·-OR-·the·Protocol·Oversight·Review·Form·For·Clinical·Vaccine·Trials,·as·applicable.¶

¶

13.·HIPAA·Privacy·and·Security¶

Will·the·PI·or·others·obtain,·review,·or·make·other·use·of·participants'·"protected·health·information"·(i.e.,·information,·whether·oral·or·recorded·in·any·form·or·medium·that·(a)·is·created·or·received·by·a·health·care·provider·and·(b)·relates·to·past,·present,·or·future·physical·or·mental·health·or·condition·of·an·individual;·or·provision·of·health·care;·or·payment·for·provision·of·heath·care)? → ☐Yes·☐No¶

If·Yes,·complete·Items·13.a-13.**f.¶**

If·No,·skip·to·14.¶

¶

a.·Will·the·data/information·be·stored·or·managed·electronically·(on·a·computer)?¶

PI viewpoint centers mostly on end use – we mean at any point during the conduct of the study

PURPOSE

- The purpose of this project is to collect biospecimens from participants with pressure uclers. (not a purpose – just a description of action)

- The purpose of this project is to reduce the number of pressure ulcers in the UAB palliative care unit. (QI)

- The purpose of this study is to determine if a multi-approach, novel bed-turning protocol can reduce pressure ulcer rates in a palliative care population. (good)

PURPOSE

- Probably the most often overlooked
- Not thought through
- Too technical
- Doesn’t match consent
- Doesn’t actually state a purpose
- Sometimes contradicts the definition of research
- Literally, start with “The purpose of this project is to….”

BACKGROUND

Background

Points to Consider

- ***Summary*** of research that led to the design of the project
- Significant findings
- Justification of dosages, if needed
- Justification of population, if needed
- Current FDA status of drug/device – what's experimental about it?
- Current UAB standard of care

Background

- Lay language (this is very hard because temptation to cut/paste)
- Brief (only significant information)

RECRUITMENT AND SCREENING

Recruitment and Screening

Recruitment

All activities up to and including asking them to participate

Almost all recruitment starts one (or both) of two ways:

- Review of medical records for inclusion/exclusion criteria – you contact them
- Flyer/Website/Social Media - Self selected – they see criteria and contact you

Recruitment and Screening

Review of Medical Records…

Then what will you do? Call them? Mail Them? See them at their next appointment?

Who will do that?

What will you say?

Most of the time you can't email them

Recruitment and Screening

Self Select…

They will likely contact you.

How?

What will you say?

- Partial HIPAA Waiver may be needed if you are recruiting participants that are not your own patients or patients within research team
- Requires concurrence with the treating physician
- Recruitment materials may need to be sent jointly

Recruitment and Screening

Screening

All activities after they've been asked to participate to further determine eligibility before enrollment

- Sometimes done ***prior to consent*** – generally via questionnaire regarding criteria not in medical record
- Sometimes done ***after consent*** – generally requiring official testing of some kind

- If no proactive recruitment, no screening done at all

Recruitment and Screening

Prior to consent

Provide the script/questionnaire you will use

Partial HIPAA Waiver required

After consent

Fully describe and clarify all screening procedures and include:

- Timing of when they will learn decision and how they will learn it
- If compensation, will screen-outs get paid?

Recruitment and Screening

Sometimes there are multiple recruitment and screening procedures. Break each down and fully describe.

Lots of HIPAA issues in play here

METHODS AND PROCEDURES

Methods and Procedures

- TELL US EVERYTHING
- Present this chronologically
- Use Bullets/indentations/headers/tables just not huge blocks
- Does the protocol say it better? Probably, AND more clearly, but often not thorough enough
  - Blood draws should include mLs/Tbs, method, frequency
  - Procedures must be defined

Methods and Procedures

Often overlooked (and not in the methods sections of Sponsor protocols):

- Description of randomization
- Description of drug delivery and dosages
- Description of medical data collection from EMR
- Alternatives/contingency issues

RISKS

Risks

- Use bulleted lists
- Make sure it matches other documents
- Quantify frequency (percentages) and severity
- Make sure the risk of randomization is included and fully addressed (not just cookie cutter)

MOST OVERLOOKED SUBMISSION ITEMS

- Data collection forms/CRF
- Each survey
- Handouts
- Cards
- Emails/Letters/Reminders
- Advertisements (all)
- Intervention materials
- Drug information
- Phone Scripts
- Thank you cards
- Pre-visit communications
- Approval for Use memos
- Site approvals (CC, Lead sites, subawards)

CONSENT PITFALLS

Explanation of Procedures:

- Lay language
- Research activities vs. clinical care
- **Chronological order by visit or activity**
- Use tables, bullets, indentation, bolding/underlining to clarify

You will be in the study 3 weeks, which will involve 5 study visits. You will have 6 blood draws, 2 MRIs, and 5 urine collections, and we will conduct neurological testing twice as well as perform 3 MRIs

Vs.

You will be in the study 3 weeks, which will involve 5 study visits

Baseline Visit:

- Blood draw:……
- MRI:……..
- Neuro Testing:…..

Visit 1 (3 days after baseline visit):

Which one would you want to get and read?

CONSENT FORM

Title of Research: Bonorum Voluptua Eum Induo Alii Tincidunt

UAB IRB Protocol #: IRB-300000xx

Principal Investigator: Case Corpora M.D., Ph.D.

Sponsor: National Institute on Aging

Purpose of the Research

Lorem ipsum dolor sit amet, ad nulla facilis antiopam sed. Dicant graece ne sit, detracto recusabo vituperatoribus mel ne, omnes scripta referrentur cum an. Stet veritus lobortis cum in, ius alia saperet ut. Ad eum purto oratio adipisci, duo denique pericula ex.

Explanation of Procedures

BASELINE VISIT:

If you decide to be in the study, we would be following you for up to 24 months. While you ar in the hospital, we would

- Ea vis putant bonorum percipitur, ne mutat maiorum has.
  - Quod elitr eirmod at ius
  - Pro ut graeco insolens sadipscing, pri ea delicata assueverit,
- impedit deterruissetEa vis putant bonorum percipitur, ne mutat maiorum has.
- Stet veritus lobortis cum in, ius alia saperet ut.
- Soluta assentior te nec, ex vim nibh appetere accommodareAfter you leave the hospital, w would

VISIT 2 (Lamenti visit):

Ad mel antiopam partiendo voluptatibus, quo clita essent accommodare no. Sale dicta ad vis, no usu veri deleniti legendos, qui ea amet munere conclusionemque.

- An graeco eripuit explicari eam, vel autem reprehendunt etGive you some tests that measure attention and memory. This will take about 30 minutes.
- Give you some tests that measure how well you do on everyday activities.
- An graeco vel autem eripuit explicari eam, vel autem reprehendunt et impedit accusamus forensibus

Ad mel antiopam partiendo voluptatibus, quo clita essent accommodare no. Sale dicta ad vis, no usu veri deleniti legendos, qui ea amet munere conclusionemque. Ex per falli dicant detraxi

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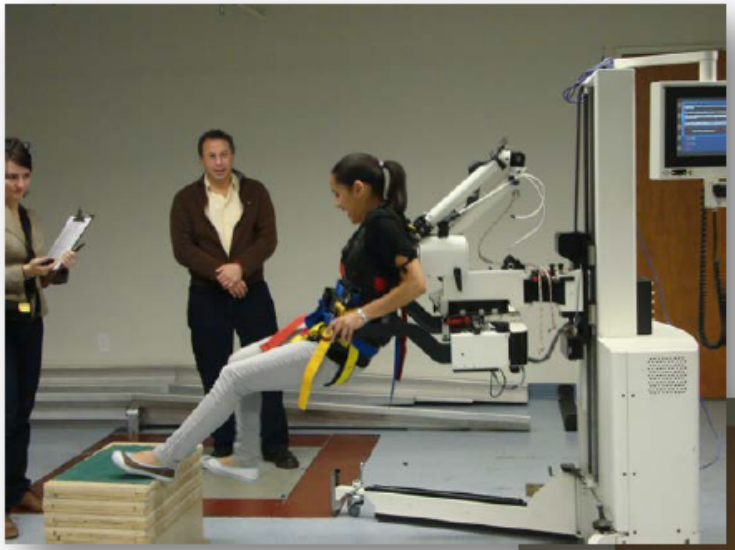
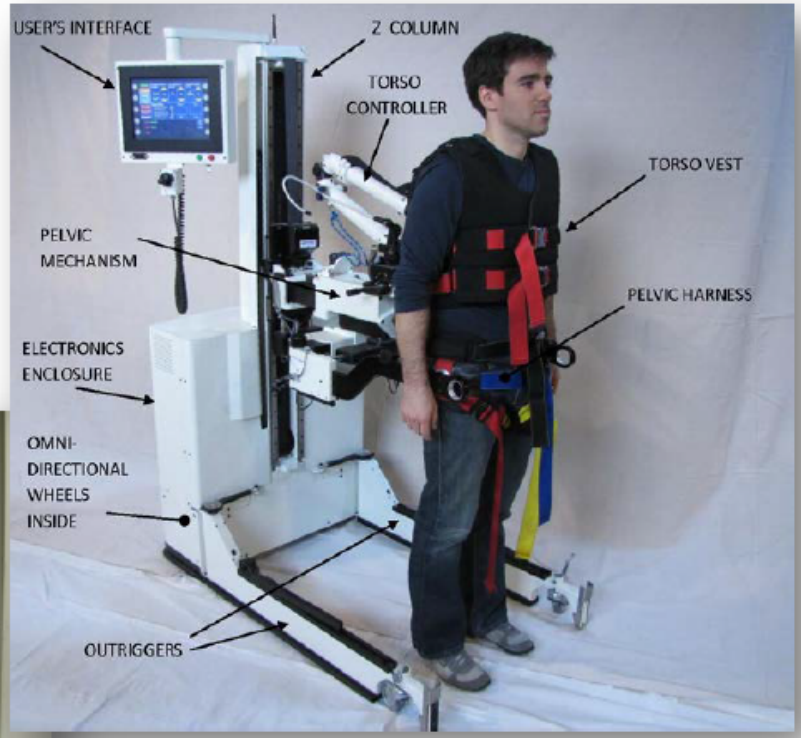
- **Risks and Discomforts**¶

If you decide to be in the study, we would be following you for up to 24 months. While you are in the hospital, we would Ea vis putant bonorum percipitur, ne mutat maiorum has. Quod elitr eirmod at ius Pro ut graeco insolens sadipscing, pri ea delicata assueverit, impedit deterruissetEa vis putant bonorum percipitur, ne mutat maiorum has. Stet veritus lobortis cum in, ius alia saperet ut. Soluta assentior te nec, ex vim nibh appetere accommodareAfter you leave the hospital, we would. And on Visit 2 mel antiopam partiendo voluptatibus, quo clita essent accommodare no. Sale dicta ad vis, no usu veri deleniti legendos, qui ea amet munere conclusionemque. An graeco eripuit explicari eam, vel autem reprehendunt etGive you some tests that measure attention and memory. This will take about 30 minutes. Give you some tests that measure how well you do on everyday activities. An graeco vel autem eripuit explicari eam, vel autem reprehendunt et impedit accusamus forensibus Ad mel antiopam partiendo

A Picture is Worth a 1000 Words

"Both forms of training will make use of body weight support provided by the KineAssist® device. The KineAssist is a robotic device that allows full freedom of motion for the body and pelvis during walking and balance tasks, and also helps to control your posture to enhance your balance and stability. The KineAssist also offers you safety while training and will catch you if you lose your balance. This assistance is available while you are strapped into the device with a harness and the device allows you to walk over the treadmill with minimal things affecting your walking."





Courtesy of David A. Brown, PT, PhD

Organization of the Consent: Required Elements

Risks and Discomforts:

- Do not include risks of standard of care
- If randomized or multiple arms, present the risks of each arm (not just the risks of the activities in each arm)
- Don’t understate or overstate
- Remember discomforts, not just risks
- Use Investigator Brochures/Package Inserts
- Whenever possible, provide percentages and severities

Organization of the Consent: Required Elements

Benefits:

- Don’t oversell the benefit of the study to humanity
- If none, so state

Organization of the Consent: Overall

- 11 pt font or higher
- 1” margins
- Use of white space
- Avoid repetition/redundancy
- Read aloud – see how it sounds
- Organize chronologically

Barriers to Approval – Common Oversights

- Used another study as template but not everything replaced
- Discrepancies compared to Protocol, Grant, HSP
- Standard of Care throughout and can't figure out what the research is
- Way too technical
- Too repetitive

Barriers to Approval – But You Approved It Last Time!!

- Obsolete template language
- Copy/paste from other studies
- Consent forms passed down for generations
- New Board Members/Staff
- New guidance from regulatory agencies/trends in oversight

Be Flexible – Things Change or Can Be Improved

The Goal is to Provide the Best Consent Form