WITHDRAWAL OR TERMINATION OF STUDY PARTICIPATION: HOW TO HANDLE

Emory IRB Webinars

WHAT IS COVERED

- Fielding and clarifying the request.
- Steps for withdrawal
- Documentation and notification
- Bonus topic: eIRB modernization project updates

TWO TYPES OF WITHDRAWAL

CONSENT

- Relevant for *all* human research
- If a participant no longer wishes to remain in a study, that is considered withdrawal of consent.

HIPAA AUTHORIZATION

- Relevant *only* if study falls under HIPAA
- If a participant no longer wants their prospective protected health information accessed for purposes of the study, that is considered revocation of HIPAA authorization. If a participant withdraws authorization in a study that requires the use and/or disclosure of PHI, it means that consent is also withdrawn.

FIELDING THE REQUEST

- A participant informs a member of the study team that they no longer wish to participate in a study. What should you do?
  - A participant may withdraw consent at any time in writing, verbally, or by failure to further participate.
  - The PI may also withdraw a participant if he/she believes it is in the participant's best interest, or for any reason.
  - If a participant withdraws from a study either verbally or in writing, the participant's information, including PHI, should no longer be collected.

Emory IRB P&P Chapter 75 HIPAA AND OTHER APPLICABLE PRIVACY LAWS AND POLICIES

REQUEST FOR DESTRUCTION OF SPECIMENS AND DATA

Note, in cases where specimens or data do not contain identifiers, it will not be possible to destroy or exclude from analysis.

This should be clearly outlined in the informed consent document.

TERMINATION OF PARTICIPATION BY INVESTIGATOR

Document the decision in research record.

Per HIPAA, other regulatory guidance, and Emory template consent form language, investigators can retain and analyze data that is already collected, even with identifiers.

https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/subjectwithdrawal.pdf

NOTE ABOUT SAFETY

Investigator/CRC/CRN should advise the participant if any safety procedures are recommended and determine if the participant is willing to complete those along with any other end of study activities.

PER PARTICIPANT'S REQUEST

Does the participant wish to withdraw consent, revoke authorization, or both?

If consent, are they comfortable having their *data* accessed going forward?

Determine if the subject is willing to allow access to additional PHI (e.g. to look at outcomes for long-term follow-up), or if subject wishes to revoke authorization for further collection of PHI.

WITHDRAWING CONSENT + REVOKING AUTHORIZATION

The participant wants to revoke both consent and authorization to collect any additional information:

- In this case, the participant revokes authorization to permit the researchers to collect and use any more information.
- Participants need to be informed that the researchers may need to use their information despite the revocation. For example, to maintain data integrity, inform about safety issues, or to make any required reports to governmental regulatory agencies. This is allowed under HIPAA and research regulations.

WITHDRAWING CONSENT ONLY

- The participant wishes to be withdrawn from further research procedures and interventions, but authorizes continued collection and use of information.
- The data collected should only be used as described in the consent form.

DOCUMENTING WITHDRAWAL

Document the request to revoke authorization and/or withdraw consent. Specifically, identify who received the revocation request & effective date of revocation when PHI will no longer be collected or disclosed.

Best practice is to ALWAYS obtain a written request to revoke.

Note: Any means of documentation will suffice.

DOCUMENTING WITHDRAWAL

If available, place a copy of the Revocation Form in the Research record.

A member of the study team should update the participant's research record, sponsor database, ERMS, if applicable. In most cases, the IRB should be informed at the time of renewal.

NOTE: If the withdrawal is related to an unanticipated problem involving risks to the subject, prompt reporting would be required.

NOTIFICATIONS

Who to inform, for example:

- Study team members
- Sponsors or Funders
- Regulatory Support staff
- Data entry staff

Per FDA IND regulations investigators are required "… to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation" (21 CFR 312.62(b)). The IDE regulations also require an investigator to maintain "Records of each subject's case history and exposure to the device" (21 CFR 812.140(a)(3)).

Guidance on data retention following withdrawal

FDA CONSIDERATIONS

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If a participant revokes authorization in an FDA study, the investigator may only review study data related to the subject that was collected *prior* to the subject's withdrawal.

The investigator may consult public records, such as those establishing survival status, even when a participant revokes authorization.

DATA DESTRUCTION: OHRP + FDA CONSIDERATIONS

- What is a participant requests to have their data and/or specimens destroyed or excluded from any analysis ?
  - For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, certainly can choose to honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis. Nothing in the OHRP guidance is intended to discourage such a practice. For example, an investigator studying social networks in a community may agree to omit all of the data they have collected from a subject of the study at the request of that subject.
  - If the funder is not willing to allow for destruction the consent form should clearly specify what, if any, specimens and/or data could be destroyed.

https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/subjectwithdrawal.pdf

EXTERNAL IRB?

Plan to document as directed in prior slides

Report any terminations or withdrawals per their respective policies and procedures

MOVING FORWARD

Look on the IRB website for forms and guidance to assist in capturing details specific to participant withdrawal.

For example:

Templates for documentation, both verbal and written	FAQs

EIRB UPGRADE PROJECT

DATA MIGRATION

How will we minimize the impact?

By rehearsing the data migration process. The first rehearsal will be completed at the end of July, beginning of August.

We will institute a strategic "freeze" or reduction in submissions.

Why a "freeze"?

Only fully-approved submissions can be migrated – nothing that is in the review process. The bulk of existing studies will be migrated before the new system goes live. The IRB will meanwhile work hard to approve in-process items, so they can be in the next phase of migration. Reducing new submissions during this time will maximize the amount of data that can be migrated in the first pass of data migration, and minimize further disruption

DATA MIGRATION

How long will the "freeze" last?

Not sure how long or how we will ensure that new submissions are adequately reduced

We will know more after the first migration rehearsal

We will let you know ASAP!

What about WIRB/XIRB studies?

We are working on an alternative process to use during the "freeze"

IRB COMMUNICATION PLAN

- **Webinars**: find future installments and previous recordings at http://www.irb.emory.edu/Training/webinars.html
- **Website**: dedicated page with updates at http://www.irb.emory.edu/eirb_project_huron_saas/index.html
- **Email blasts**: if not receiving these emails, contact Jessica Blackburn at jessica.blackburn@emory.edu to be added to the email group
- **In person training**: we will be in contact with University Departments to offer in person trainings. If you are interested, email Shara Karlebach at swilli7@emory.edu
- **Zoom Training**: we will offer training sessions at the end of the year when the system is ready for training and testing. We will post dates when we know more
- **Videos**: the vendor (Huron) will create training videos that will be available in our website (in process)

CAN YOU HELP WITH TESTING?

- We need all types of users to help with testing the new system
- Interested in adding your 2 cents?
  - Email Maria Davila at: maria.davila@emory.edu
- You will be contacted around October with an invitation.

WHAT IF I HAVE ADDITIONAL QUESTIONS?

If you have additional questions, contact any member of our staff leadership at http://www.irb.emory.edu/about/staff.html#tab2

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thank you
gracias
danke
謝謝
ngiyabonga
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Баярлалаа
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go raibh maith agat
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