Waiver of Consent

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CONSENT FORM

YOU UNDER

WAIT... I CAN'T READ THE FINE PRINT!

I TOLD YOU~ THAT'S WHY YOU NEED TO BE IN MY VISION STUDY!
Waiver of Documentation of IC
Waiver of Documentation of IC

May be granted in 2 situations for research that is not regulated by the FDA:

1. When the only record linking subjects and research is the ICD and a breach of confidentiality could cause harm to subjects
2. When research is no more than minimal risk and involves no procedures for which consent is required
Waiver of Documentation of IC

May be granted in 2 situations for research that is regulated by the FDA

1. When research is no more than minimal risk and involves no procedures for which consent is required
2. Planned emergency research
Once a Waiver of Documentation is Granted

The IRB may require the PI to provide subjects with a written statement regarding the research.

The PI must submit the verbal script to the IRB for approval.
Waiver or Alteration of Consent
Waiver of IC

For studies not regulated by the FDA, the IRB may waive or alter some elements of IC.

FDA regulations do not permit a waiver of IC, but do have certain exceptions.
Non-FDA Studies

The IRB, on its own initiative or by a request from a PI, may waive some or all elements of IC.

A waiver must be granted by the full-board majority vote.
Criteria for Waiver of IC for Non-FDA

- The study involves no more than minimal risk;
- The waiver will not adversely affect the rights and welfare of the participants;
- The research can not practically be carried out without the waiver; AND
- Whenever appropriate, the participants will be provided with the additional pertinent information after their participation in the research.
Emergency Medical Care Exception for FDA Regulated Studies

- In certain emergency care situations, IC for the use of an FDA regulated item does not need to be obtained by the PI, nor approved in advance by the Emory IRB.
Criteria for Waiver of IC in Emergency Care Situations for an FDA Item

- The subject is confronted by a life-threatening situation that requires the use of the item;
- IC cannot be obtained because of an inability to communicate with the subject;
- There is not sufficient time to obtain IC from the LAR; and
- There is no available alternative treatment
Criteria for Waiver of IC in Emergency Care Situations for an FDA Item

- The PI and a licensed physician who is not participating in the research must certify in writing that all criteria are met prior to the use of the item.

- If there is not time to obtain certification from an uninvolved physician, the PI may make his/her certification and provide it to the uninvolved physician for the completion of that physician’s certification within 5 working days after the item is used.
HHS Regulations

- HHS regs do not permit the initiation of research activities without prior IRB approval, even in emergency situations. If emergency care is initiated without IRB review, the care may not be considered research; the patient may not be considered a human subject; and no data regarding the care may be included in any report of a prospective research study.
Waiver of Consent for Planned Emergency Research (PER)
Requirements for Waiver of IC for PER

- There is concurrence of an IRB MD who is not participating in the research
- The subjects are in a life threatening situation
- Available treatments are unproven or unsatisfactory
- The collection of valid scientific evidence is necessary to determine the safety and effectiveness of the item
Requirements for Waiver of IC for PER

- The protocol sets forth IC procedures for whom it is feasible to obtain IC
- The protocol defines the potential therapeutic window, and the PI commits to attempting to obtain IC within that window
IRB Approval Criteria

- Participation in the research has the prospect of direct benefit to the subjects
- The protocol provides additional protections (IRB consultation, public disclosure to the communities involved, establishment of independent DSMB)
DHHS permits the IRB to approve a waiver of IC for PER on items that are both regulated and not regulated by the FDA.
PER, non-FDA, IRB Waiver Requirements

- Participants are in a life threatening situation
- Available treatments are unproven or unsatisfactory
- Collection of valid scientific evidence is necessary to determine the safety and effectiveness of interventions
- Obtaining IC is not feasible
PER, non-FDA, IRB Waiver Requirements

- There is no reasonable way to identify prospective individuals likely to become eligible for participation
- Participation holds out the prospect of direct benefit
- The research could not be practicably carried out without the waiver
PER, non-FDA, IRB Waiver Requirements

- The therapeutic window is defined and the PI attempts to get IC within that window.
- IC will be obtained in situations it can be.
- The protocol provides for additional protections.
IRB Responsibilities for Waiver of IC in PER

- Procedures are in place to inform, at the earliest opportunity, each participant/LAR/family member, of the details of the research.
- There is a procedure to inform the participant/LAR/family member that the subject may discontinue participation at any time without penalty or loss of benefits.
IRB Responsibilities for Waiver of IC in PER

- If the LAR/family member is told about the research and the participant’s condition improves, then the participant will be told about the research at the earliest possible time.
- If the participant is entered into the study by IC waiver and dies before the LAR/family member can be contacted, information about the research is provided to the LAR/family member.
PI Responsibilities for PER Waiver of IC

- Consult with the IRB Director or Chair before submitting the protocol
- PIs must submit the IRB materials describing their plan for community consultation and public disclosure
- PIs must submit a summary of efforts to contact LARs at CR