National Institute of Mental Health

Human Subjects Research Protections Toolkit

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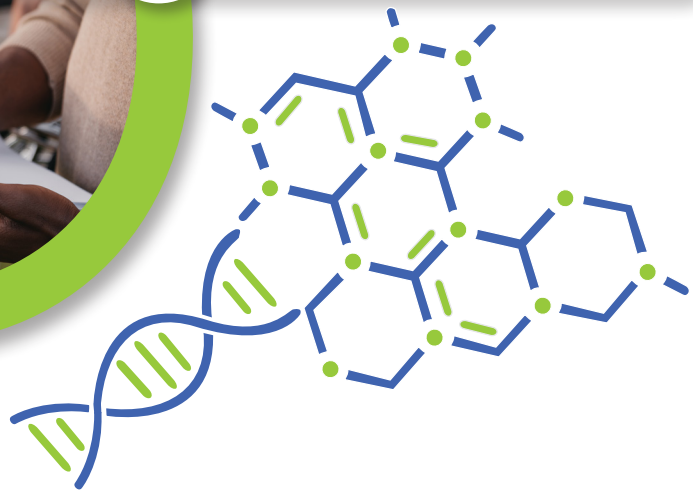

National Institute of Mental Health
Office of the Clinical Director **Human Subjects Protection Unit**
8.1.19

Introduction

A human research protection program (HRPP), in part, aims to protect human research subjects. The National Institute of Mental Health (NIMH) protects potentially vulnerable **SUBJECTS** with **ADVOCATES** who support the individual subject as well as educate and advise **RESEARCHERS**.

This NIMH Toolkit for Human Subjects Research Protections is based on the NIMH's experience conducting research with potentially vulnerable subjects. Our aim is to help research organizations assess, implement, and refine appropriate levels of human subjects protections during all phases of research (submission of the initial protocol to the Institutional Review Board [IRB] through subject transition out of the protocol). Research organizations need to tailor these practices to suit their own standards and legal and policy requirements.

SUBJECTS
ADVOCATES
RESEARCHERS

Section 4: Appendix provides a glossary, additional examples, and resources from the NIMH Human Subjects Protection Unit (HSPU).

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Disclaimer: *This NIMH Toolkit does not incorporate state or local law or organizational policies, nor does it address possible applicable federal law or speak to regulatory interpretation of 45 C.F.R. § 46. It does not address specifics for a particular type of protocol or IRB requirements. This Toolkit is the opinion of the NIMH intramural program and is subject to change.*

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NIMH Toolkit · Table of Contents

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NIMH Abbreviations and Glossary

Abbreviations

AD Advance directive
ACAT Ability to Consent Assessment Team
CC Clinical Center
CORE Centralized Office of Recruitment and Evaluation
CRA Clinical Research Advocate
DPA Durable power of attorney
HRPP Human research protection program
HSPU Human Subjects Protection Unit
IRB Institutional Review Board
LAR Legally authorized representative
NBAC National Bioethics Advisory Commission
NIH National Institutes of Health
NIMH National Institute of Mental Health
NOK Next-of-kin
OSCE *Objective Structured Clinical Examination*

Glossary

Ability to Assign a Surrogate Decision-Maker Assessment: Tool used to determine whether a potential subject has the ability to choose another person to make decisions during research participation.

advance directive: Written instruction, such as a living will or durable power of attorney for health care, recognized under state law (whether statutory or as recognized by the courts of the state), relating to the provision of health care when the individual is incapacitated.

advocate: Primary component of a human subjects protection program. Trained clinician responsible for assessing, developing, and implementing safeguards for potentially vulnerable subjects enrolling in research.

assent: Agreement to participate in a protocol by an adult without decision-making capacity or by a minor. Failure to dissent does not establish assent.

assent monitoring: Process to assure the quality of the assent discussion for adults without decision-making capacity and minors by verifying the agreement of the potential subject to participate in a protocol.

capacity: An adult potential subject's ability to provide informed consent for participation in a specific protocol. Contrast **competency.**

capacity assessment: Assessment of an adult potential subject's ability to provide informed consent for a specific protocol at a specific time.

Capacity Assessment: Generic: Basic assessment format for assessing a potential subject's ability to provide informed consent. Must be adapted when an unanticipated need for an assessment arises.

Capacity Assessment: Protocol-Specific: Tool customized to assess a potential subject's ability to provide informed consent for a specific protocol. Used for protocols requiring some or all potential subjects to be assessed.

NIMH Abbreviations and Glossary

Code of Federal Regulations: United States administrative law published by the executive departments and agencies of the federal government. Title 45 Public Welfare, Part 46 Protection of Human Subjects is the Health and Human Services federal policy for the protection of human subjects. Subpart A is also referred to as the Common Rule.

competency: A person's ability to understand legal rights and responsibilities and the authority to exercise them. Often determined by a court of law. Contrast **capacity**.

consent: Agreement to participate in research given by an adult or a surrogate decision-maker for a minor or an adult without consent capacity.

consent monitoring: Process by which an advocate assures the elements of consent are discussed by a researcher and a potential subject and/or a surrogate decision-maker.

dissent: Refusal to participate in research given verbally or behaviorally by a potential subject or a subject.

durable power of attorney: Legal document designating a person to make decisions on another's behalf if the person becomes incapacitated.

legal guardian: Person who has the legal authority and responsibility to care for another individual who is considered incapable, generally as determined by a state court.

legally authorized representative: Person who is authorized to be a surrogate decision-maker for another individual.

living will: Legal document that allows a person to state in advance the kinds of care the person would or would not want should the person become unable to make decisions.

next-of-kin: Person who serves as a surrogate decision-maker for an individual based on relationship (e.g., spouse, parent, or adult child).

short form: Consent document stating the required elements of informed consent have been presented orally to a potential subject or a potential subject's legally authorized representative.

subject: Person enrolled in a research protocol.

subject monitoring: Periodic visits by an advocate to assess a subject's current wishes, understanding, and concerns regarding continued participation in research.

surrogate decision-maker: Person assigned to act on behalf of another individual.

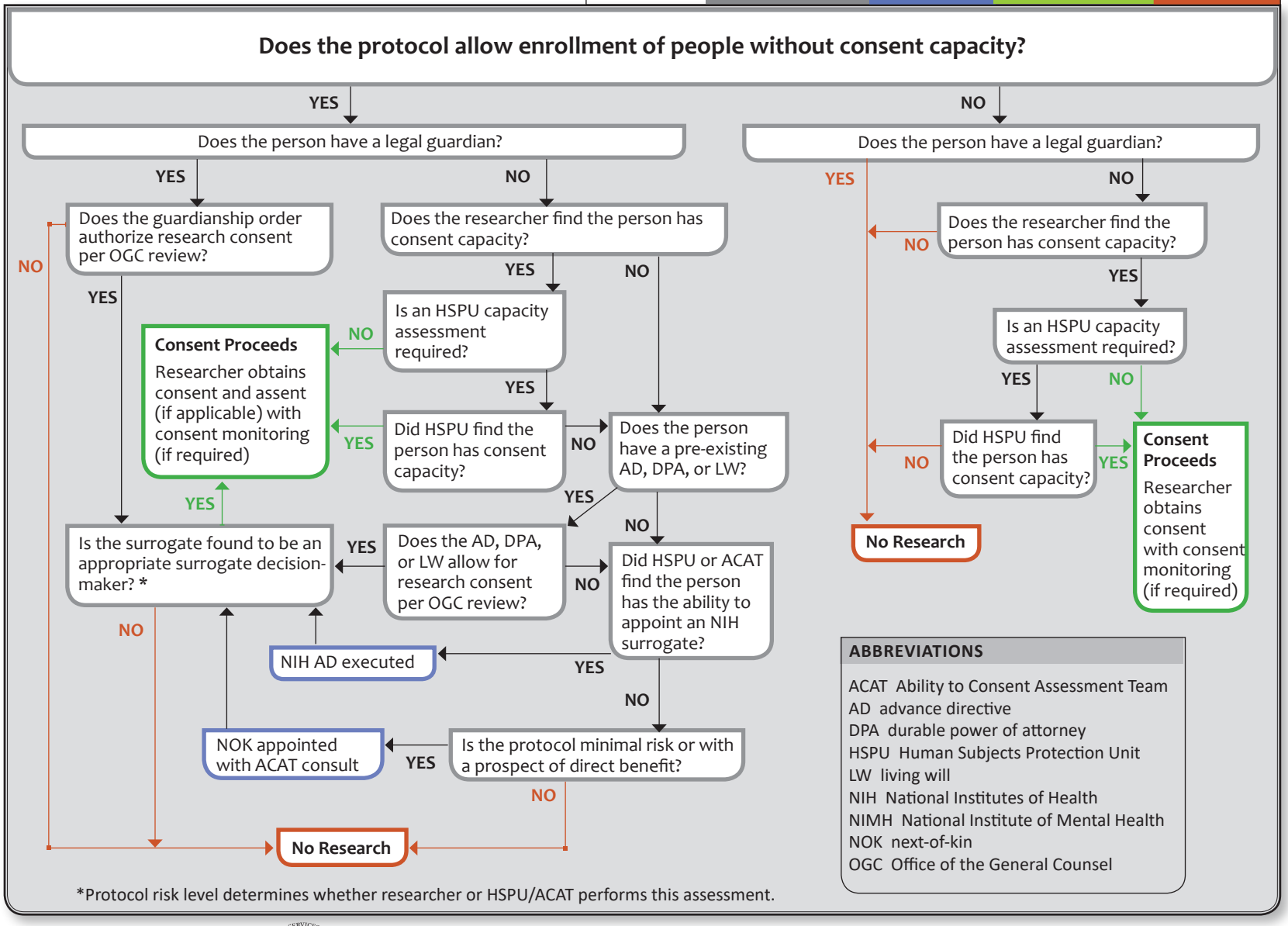
Surrogate Decision-Maker Assessment: Tool used to evaluate a potential surrogate decision-maker's ability to represent a subject's wishes regarding research participation.

therapeutic misconception: Failure of a research subject to appreciate the distinction between the imperatives of clinical research and of ordinary treatment, and therefore inaccurately attributes beneficial intent to research procedures.

vulnerable populations: Individuals who may require additional safeguards (e.g., capacity assessment, subject monitoring) to protect them from coercion or undue influence to participate in research.

NIMH Consent Process Flowchart

COLOR KEY | Researcher Decision | Action Item | Consent Proceeds | No Research



*Protocol risk level determines whether researcher or HSPU/ACAT performs this assessment.

The Clinical Research **Advocates** monitor, assess, and support **Participants** throughout research, and advise **Researchers** on human subject protections.

Participants
Advocates
Researchers

National Institute of Mental Health
Office of the Clinical Director
Human Subjects Protection Unit

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Clinical Research Advocates

National Institute of Mental Health

Office of the Clinical Director, **Human Subjects Protection Unit**

Clinical Research Advocates (CRAs)

are experienced clinicians with the Human Subjects Protection Unit (HSPU) which is part of the Office of the Clinical Director of the National Institute of Mental Health (NIMH). CRAs report directly to the NIMH Clinical Director and have no direct connection to any research programs or researchers.

CRAs provide safeguards to you throughout your study participation. Their independence is important to assure that CRAs are neutral when monitoring, assessing, and providing support.

Your CRA provides the following:

Capacity Assessment
Some studies require that you be assessed by a CRA to determine if you have sufficient understanding to proceed with consenting to the research.

Ability to Assign a Surrogate Decision-Maker Assessment
Should you be unable to make or communicate your own decisions about participating in a study, you may be able to assign someone to help you. A CRA can discuss this process with you.

Surrogate Decision-Maker Assessment
If you have chosen someone to help you with research decisions, your CRA may meet with that individual to discuss their understanding of the study and your participation.

Consent Monitoring
A CRA may be present for the discussion between you and the researcher to assure you understand what you will be asked to do and the risks associated with the study. Your CRA can help address any questions or concerns raised during this conversation.

Assent Monitoring
Assent is the affirmative agreement given by a child or an adult who is unable to give consent. Monitoring an assent discussion and your agreement to participate in research is one role a CRA provides.

Subject Monitoring
Your CRA will visit you regularly to discuss your inpatient research experience and will advocate for you as needed.

Your Clinical Research Advocate is:

Insert business card

Sample Electronic Medical Record

Capacity Assessment

The subject's ability to give informed consent was assessed using a modified MacArthur Competence Assessment Tool for Clinical Research.

The subject is being considered for inclusion in protocol number

The raters administering the tool were

At this time the subject

- ❍ is able to give informed consent
- ❍ has questionable ability to give informed consent
- ❍ is unable to give informed consent

The plan is

- ❍ research consent may proceed
- ❍ further education recommended
- ❍ research consent may not proceed

The following staff were notified of the outcome

Sample Electronic Medical Record

Consent Monitoring

Protocol number

Conducted by

Attended by

Clinical Research Advocate contact information provided	❍Yes	❍No	
Consent elements discussed			
Voluntary nature of research	❍Yes	❍No	
Purpose of research	❍Yes	❍No	
Expected duration	❍Yes	❍No	
Experimental procedures	❍Yes	❍No	
Protocol procedures	❍Yes	❍No	
Risks and discomforts	❍Yes	❍No	
Benefits	❍Yes	❍No	
Alternatives to research	❍Yes	❍No	
Confidentiality	❍Yes	❍No	
Research related injury	❍Yes	❍No	
Compensation	❍Yes	❍No	
Researcher contact information	❍Yes	❍No	
A statement on the collection of identifiable private information or identifiable biospecimens	❍Yes	❍No	
Assent	❍Yes	❍No	❍Not applicable

Additional comments

Sample Protocol Language

This language is a protocol-specific sample for a minimal risk protocol which includes adults without consent capacity. There is no prospect of direct benefit. This language will need modifications in order to apply to your protocol. Some states do not allow for legally authorized representatives to provide consent for non-beneficial research. Consequently, it is important to consult organizational representatives (e.g., legal counsel) and policies.

Sample advocate language for a protocol

Capacity to give informed consent will be assessed by an advocate. If the subject is determined to have capacity, the researcher may obtain consent with consent monitoring by the advocate. A subject may lack capacity to give informed consent, but may retain the ability to understand an advance directive (AD) and identify a substitute decision-maker. In all cases, subject dissent will be respected.

If the subject has a legal guardian, a capacity assessment is not administered. The advocate will meet with the guardian to discuss the role of the guardian and the guardian's understanding of the subject's wishes. The researcher may then obtain consent from the guardian and assent from the subject with consent and assent monitoring by the advocate.

If the subject does not have a legal guardian, lacks capacity to provide informed consent, and does not have a pre-existing AD that allows for research participation, the advocate assesses the subject's ability to assign a surrogate decision-maker. If it is determined the subject has the ability to assign a surrogate decision-maker, an AD form (e.g., durable power of attorney for health care) for research is completed. The researcher follows the AD and obtains consent from the surrogate decision-maker and assent from the subject with consent monitoring by the advocate.

If the subject does not have a legal guardian or pre-existing AD, lacks capacity to provide informed consent, and is unable to assign a surrogate decision-maker, the subject will not participate in the research.

If the subject does not have a legal guardian, does not have capacity to provide informed consent, and has a pre-existing AD that allows for research participation, the advocate will assess the appropriateness of the surrogate decision-maker. The researcher may invoke the AD, seek consent from the surrogate decision-maker and assent from the subject with consent and assent monitoring by the advocate.

Sample Consent Language

This language is a protocol-specific sample for a more than minimal risk inpatient protocol with a prospect of direct benefit for a potentially vulnerable population and will need modifications for your protocol.

Consent monitoring
An advocate, who is not part of the research team, will be assigned to you and will be present during the informed consent process. Informed consent is the discussion held between you and a member of the research team about this study. The advocate will assure that you have received the information you need to make an informed decision about participating in this study.

Capacity assessment
If the researcher has concerns about your ability to give informed consent, you may have a brief interview with your advocate. This interview, called a capacity assessment, will help determine your understanding of what is involved in the study and whether you need to have someone else, whom you have selected, give consent for you to participate.

Subject monitoring
If you are admitted to the hospital for this study, the advocate will visit you on the unit over the course of your stay to discuss your wishes regarding continued research participation.

Advance directive*
An advance directive (AD), allows you to name someone to make medical research and health care decisions for you should you become unable to make decisions yourself. An AD is a document you can use to state your health care choices, record your wishes about research participation, and identify someone to make decisions for you. If you lose your ability to make decisions, your doctor will use your AD and discussions with your identified decision-maker(s) to make medical research decisions on your behalf based on your preferences. The best substitute decision-maker is someone you discuss your medical wishes with and who knows you well. The person you name as your substitute decision-maker must be eighteen years old and cannot be your physician.

*It is important to know your state regulations regarding research participation and legally authorized representatives. Please seek guidance from your organization's policies and legal counsel.

Sources for More Information

Belmont Report
https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects
Pre-2018 Requirements
https://www.ecfr.gov/cgi-bin/text-idx?m=12&d=19&y=2018&cd=20190715&submit=GO&SID=f7fd0e619099f6996b9f3807b2a1c753&node=pt45.1.46&pd=20181219
2018 Requirements
https://www.ecfr.gov/cgi-bin/text-idx?m=07&d=19&y=2018&cd=20181203&submit=GO&SID=b4acc9904d76b17e36a45eaa93e1 57f1&node=pt45.1.46&pd=20180718

The Ethical and Regulatory Aspects of Clinical Research Online Training
https://www.bioethics.nih.gov/courses/ethical-regulatory-aspects.shtml

Human Subjects Protection Unit (HSPU) National Institute of Mental Health (NIMH) Office of the Clinical Director
https://www.nimh.nih.gov/ocd-hspu
Contact: nimhhspu@mail.nih.gov

Informed Consent Checklist
https://www.hhs.gov/ohrp/policy/consentckls.html

MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR)
Appelbaum, Paul S., and Thomas Grisso. Sarasota, FL: Professional Resource Press, 2001.

NIH Clinical Center (CC) Bioethics Department
https://www.bioethics.nih.gov

NIH Clinical Trials
https://www.clinicaltrials.gov/

Office for Human Research Protections
https://www.hhs.gov/ohrp/

Research Involving Human Subjects
https://humansubjects.nih.gov/

Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity National Bioethics Advisory Commission
https://bioethicsarchive.georgetown.edu/nbac/capacity/TOC.htm