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|  | **SUNY Downstate Medical Center**  **University Hospital of Brooklyn**  **College of Medicine**  **College of Health Related Professions**  **College of Nursing**  **School of Graduate Studies**  **Graduate Program in Public Health** | **IRB Approval Requirements** |
| For more information please refer to IRB-01 Policy, IRB Guidance, or contact the IRB at 718-613-8480 or [IRB@downstate.edu](mailto:IRB@downstate.edu) | | |

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# Introduction

This guidance may be used by IRB Members to serve as a checklist or reminder of required IRB approval requirements for initial or continuing review.

This guidance may also be used by investigators to ensure their application materials are complete.

# Submission Materials

Items with “\*” are generally not required for “Exempt” submissions.

## New Submissions:

* Registration Form
* Application for New Study
* Scientific Review Worksheet
* Complete Protocol

## Federally Funded/Supported Studies

* Grant Application or Grant Cover sheet: *NIH application section “Key Personnel” and “Human Subjects section and Research Methodology.”*

## Informed Consent/Information Sheets (As Applicable)

* \*Consent Form(s)/Parental Permission Form(s), including Authorization to access, use, or disclose Identifiable Health Information (IIHI) or Protected Health Information (PHI). *In general, children ages 13-17 may sign the consent form when obtaining assent.*
* \*Assent Form (s). *Generally required if you are planning to enroll participants age 7-12.*
* \*Information Sheet (if applicable). *Required when requesting a waiver of documentation of informed consent, when IIHI or PHI is NOT involved.*
* Information Sheet, including authorization to access, use, or disclose IIHI or PHI (if applicable). *Required when requesting a waiver of documentation of informed consent, when IIHI or PHI is involved.*
* Short Form. *May be used for certain studies when enrolling non-English speaking participants or those with Limited English Proficiency (LEP).*

## Waivers (If Applicable)

* HIPAA Waiver(s)
* \*Waiver of Informed Consent. *Required when waiving entire consent process (e.g., for retrospective data reviews.*
* Waiver of Documentation of Informed Consent. *Required when waiving documentation (e.g., signature) of informed consent. NOTE: If PHI is involved, the IRB may accept the HIPAA waiver form to document a request to waive informed consent.*

## Documents Required, When Applicable

* HIPAA Preparatory to Research Certification Form
* Recruitment Materials (including, but not limited to flyers, brochures, ads, e-mails, telephone script, etc).
* Subject Recruitment Authorization Form (Signed by patient).
* Physician’s Documentation of Patient’s Verbal Authorization.
* Questionnaires/Surveys.
* Data Collection Tools (or list of data to be collected).
* Investigator Brochure for study involving an IND for an investigational drug or biological agent.
* \*FDA Form 1572 for study involving an IND for an investigational drug or biological agent.
* \*IND letter for study involving an IND for an investigational drug or biological agent.
* \*Device Package Insert for IDE study.
* CV or Biosketch of PI (optional). *This is generally not needed unless the PI is new; however, the IRB may request this to evaluate the PI’s qualifications, as required by the FDA and OHRP regulations.*
* Credentials of PI or other study staff (optional).
* Sponsor contract (optional). *Generally not needed, unless the IRB needs to review language in the informed consent regarding injuries or additional costs.*
* Letter of support from the external site (except KCHC) when not covered by an IRB Reliance Agreement or External IRB approval.

# Ethical Principles

* Research must be guided by the ethical principles set forth in the [Belmont Report](http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/):
* **Respect for persons:** Recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.
* **Beneficence:** Obligation to do no harm and to protect persons from harm by maximizing the anticipated benefits and minimizing possible risks.
* **Justice:** Benefits and burdens of research should be distributed fairly.
* When applicable, the principles of the [Nuremburg Code](https://history.nih.gov/research/downloads/nuremberg.pdf) and the [Declaration of Helsinki](http://www.wma.net/en/30publications/10policies/b3/) may also apply to the research; particularly for transnational research.
* All DMC staff must follow the DMC [Code of Ethics](http://www.downstate.edu/compliance/cp_ethics.html).
* In addition, research professionals are expected to following the ethical principles of their scientific and professional disciplines.

# Scientific Review

Check Scientific Review Committee (SRC) worksheet.

# COI Disclosures and Training Requirements

The IRB Office checks to ensure all COI disclosures and training requirements are met. For more information, see

# Investigator Qualifications

* Review CV if not familiar with the investigator
* Check when applicable or concerned:
  + [Lists posted on FDA’s website](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ComplianceEnforcement/default.htm)
  + [Clinical Investigator Status (Biologics)](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm165743.htm)
  + [Inspection Classification Database Search](http://www.accessdata.fda.gov/scripts/inspsearch/)
  + [Clinical Investigators - Disqualification Proceedings](http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true)
  + [Inspections, Compliance, Enforcement, and Criminal Investigations](http://www.fda.gov/ICECI/default.htm)

# PI Status

The PI must be a seasoned investigator with an advanced terminal degree (i.e., MD, PhD, etc.) who is a Faculty Member at DMC or who otherwise meets at least one of the following eligibility criteria:

* Have clinical privileges at KCHC
* Qualify to be a PI at an external site (other than KCHC), which includes an activity which makes DMC engaged in human research (see [OHRP guidance: Engagement of Institutions in Human Subjects Research (2008)](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)), including when the research includes one of the following co-investigators or key personnel:
  + Employee of SUNY DMC or the SUNY Research Foundation
  + Resident or Fellow trained under a GME program affiliated with DMC
  + Student in a DMC Academic Program
* Federal funding or support is provided to DMC
* Be a faculty member under recruitment to DMC with written approval by a Dean
* Be approved to be a PI by written memo or e-mail from the DMC Institutional Official

Multiple-PIs are permitted. See IRB-01 Policy for more information.

# Adequacy of Research Site

* Evaluate the adequacy of the facility’s staff and medical equipment
* Evaluate the adequacy of emergency or specialized care, if the need arises
* May require a statement from the research site indicating the site is adequate or require a description from the PI that includes a description of the facility where the research will take place, including staffing and resources relevant to the research under review.

# General Criteria For IRB Approval of Non-Exempt Human Research/Clinical Investigations

* Risks to research participants are minimized:
  + by using procedures which are consistent with sound research design and which do not unnecessarily expose research participants to risk, and
  + whenever appropriate, by using procedures already being performed for diagnostic or treatment purposes.
* Risks to research participants are reasonable in relation to anticipated benefits, if any, to research participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies research participants would receive even if not participating in the research). The IRB does not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
* Selection of research participants is equitable. In making this assessment the IRB takes into account the purposes of the research, the adequacy of inclusion and exclusion criteria, and the setting in which the research will be conducted. The IRB is particularly cognizant of the special problems of research involving interactions or interventions with vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
* Informed consent and HIPAA research authorization will be sought from each prospective research participants or their LAR, in accordance with, and to the extent required by the federal regulations and will be appropriately documented, unless waived.
  + The IRB members review the informed consent document to ensure all required elements and appropriate additional elements are provided to the research participant at the time of initial review.
  + At the time of continuing review, the IRB must also review the informed consent document to determine if any additional changes are required.
* When appropriate, the research plan must make adequate provision for monitoring the data collected to ensure the safety of research participants.
* When appropriate, there are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of data.
* When some or all of the research participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the IRB must evaluate whether additional safeguards have been included in the study to protect the rights and welfare of these research participants based on the IRB application materials. The IRB may require additional safeguards, if needed.
* In order to approve research involving some or all research participants that include vulnerable populations, the IRB must also ensure the research is in compliance with regulations to the extent required by 45 CFR 46, subpart B, C, and D and 21 CFR 50, subpart D and DMC Policies. See next sections for more details.
* FDA requires the sponsor or the sponsor-investigator to determine whether an IND or IDE is required for a particular study. The IRB may request the basis for the determination or request supporting documentation from the FDA. If the IRB is unable to resolve the issue, it will be considered a controverted issue and cannot approve the study until the matter is resolved.
* For investigational device studies, the IRB’s determination that a device study is significant risk (SR) or non-significant risk (NSR) can be made at a convened meeting. A SR device study must have an IDE from the FDA before the IRB can approve the investigation.

# Research Involving Vulnerable Populations

## Children

Determine category of permissible research for Children and requirements of such:

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| **Category** | **Evaluation** | **Requirements** |
| **Category 404**  (45 CFR 46.404 and 21 CFR 50.51) | * No greater than minimal risk | * Permission of one parent/guardian * Assent |
| **Category 405**  (45 CFR 46.405 and 21 CFR 50.52) | * Greater than minimal risk * Presents prospect of direct benefit to the individual research participants * The risk is justified by the anticipated benefit to the participants; and * The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches. | * Same as 404 |
| **Category 406**  (45 CFR 46.406 and 21 CFR 50.53) | * greater than minimal risk * Minor increase over minimal risk * No prospect of direct benefit to the individual research participants * Likely to yield generalizable knowledge about the research participants’ disorder or condition * Intervention/procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations | * Permission must be obtained by **both parents (or guardians)**, unless one is deceased, unknown, incompetent or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child * Assent * If children are wards of the state or any other agency, institution, or entity are included, additional requirements of 45 CFR 46.409 must also be met. |
| **Category 407**  (45 CFR 46.406 and 21 CFR 50.54) | * Research is not otherwise in category 404, 405, or 406, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. | * Includes 406 requirements * OHRP (or by the FDA, if FDA regulated) must also approve the research |

### Children Who are Wards

Additional applicable protections for research involving a child who is a ward (i.e. in custody or oversight by any state or city agency) are described in 45 CFR 46.409 and 21 CFR 50.56.

## Pregnant Women, Fetuses, Neonates, In-vitro Fertilization

#### Pregnant women or fetuses

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

* + - Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
    - The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
    - Any risk is the least possible for achieving the objectives of the research;
    - If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions;
    - If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
    - Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
    - For children who are pregnant, assent and parental/legal guardian permission are obtained in accord with the provisions of the IRB;
    - No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
    - Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
    - Individuals engaged in the research will have no part in determining the viability of a neonate.

## Neonates of Uncertain Viability and Nonviable Neonates

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

* Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
* Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
* Individuals engaged in the research will have no part in determining the viability of a neonate.

## Neonates of Uncertain Viability.

Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

* The IRB determines that:
  + The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
  + The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
* The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with regulatory requirements, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

## Nonviable Neonates

After delivery, a nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

* + Vital functions of the neonate will not be artificially maintained;
  + The research will not terminate the heartbeat or respiration of the neonate;
  + There will be no added risk to the neonate resulting from the research;
  + The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
  + The legally effective informed consent of both parents of the neonate is obtained. Waivers and alteration provisions do not apply; however, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

## Viable Neonates

A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements for Children.

## Research Involving Placenta, Dead Fetus, or Fetal Material

If information associated with material described in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and all IRB requirements applicable.

## Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Pregnant Women, Fetuses, or Neonates.

DMC may conduct research that the IRB does not believe meets the requirements for pregnant women, fetuses, or neonates, only if:

The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

OHRP, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:

* + That the research in fact satisfies the conditions for research with pregnant women or fetuses, as applicable; or
  + The following:

The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

The research will be conducted in accordance with sound ethical principles; and

Informed consent will be obtained in accordance with the informed consent provisions

## Prisoners

When reviewing research involving prisoners the IRB must ensure it satisfies all of the conditions covered by [Subpart C - Additional Protections Pertaining to Biomedical and Behavioral research Involving Prisoners as Subjects](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartc).

The IRB Member who is the prisoner representative must review the research. **If the study is federally funded or supported, the OHRP must also approve the research.** Prisoner research may not be reviewed under exempt review procedures. In order to approve research involving prisoners, the IRB must find that the proposed research falls into one of the permissible categories of research, and make the following seven findings:

1. The research under review represents one of the permissible categories of research:

* **Category #1:** Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the research participants;
* **Category #2:** Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the research participants;
* **Category #3:** Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his/her intent to approve such research; or
* **Category #4:** research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the research participants. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

1. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of receiving such advantages in the limited-choice prison environment is impaired;
2. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
3. Procedures for the selection of research participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI provides the IRB with written justification for following some other procedures, control research participants must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal;
4. The information is presented in language that is understandable to the subject population;
5. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
6. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

In order to make these findings, the IRB must be familiar with the specific conditions in the local prison(s) or jail site(s) that are pertinent to protections, before approving the proposal for the local site.

### EpidemiologIC research involving Prisoners

Health and Human Services has waived the applicability of 45 CFR 46.305(a)(l) and 46.306(a)(2) for certain research conducted or supported by HHS that involves epidemiological studies that meet the following criteria:

1. In which the sole purposes are:
   1. To describe the prevalence or incidence of a disease by identifying all cases, or
   2. To study potential risk factor associations for a disease, and
2. Where the IRB has approved the research and has fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that the following conditions are met:
   1. The research presents no more than minimal risk and no more than inconvenience to the research participants, and
   2. Prisoners are not a particular focus of the research.
3. The specific type of epidemiological research subject to the waiver involves no more than minimal risk and no more than inconvenience to the research participants. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a)(2).
4. The range of studies to which the waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the research participants.
5. In order for a study to be approved under this waiver, the IRB would need to ensure that, among other things, there are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of the data.

# Newborn Screening Spots

All HHS funded research using newborn dried blood spots must be considered human research regardless of whether the specimens are identifiable. The IRB may NOT waive informed consent under for research involving newborn dried blood spots for HHS funded research. For more information, please see [The Newborn Screening Saves Lives Reauthorization Act of 2014](http://www.hhs.gov/ohrp/news/announcements-and-news-releases/2015/the-newborn-screening-saves-lives-reauthorization-act-of-2014/).

# Planned Emergency Human Research or Clinical Trials

The specific conditions under which prospective consent of the participant may be waived for planned emergency research are provided by 21 CFR 50.24 and OHRP guidance.

The IRB must document the required findings:

* The research participants are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
* Obtaining informed consent is not feasible because:
  + The research participants will not be able to give their informed consent as a result of their medical condition;
  + The intervention under investigation must be administered before consent from the research participants’ legally authorized representatives is feasible; and
  + There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
* Participation in the research holds out the prospect of direct benefit to the research participants because:
  + Research participants are facing a life-threatening situation that necessitates intervention;
  + Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual research participants; and
  + Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of research participants, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
* The clinical investigation could not practicably be carried out without the waiver.
* The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each research participant within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.
* The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with the requirements for informed consent. These procedures and the informed consent document are to be used with research participants or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a research participant’s participation in the clinical investigation.
* Additional protections of the rights and welfare of the research participants will be provided, including, at least:
  + Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the research participants will be drawn;
  + Public disclosure to the communities in which the clinical investigation will be conducted and from which the research participants will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;
  + Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;
  + Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and
  + If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed to, if feasible, attempting to contact within the therapeutic window the research participant’s family member who is not a legally authorized representative, and asking whether he or she objects to the research participant’s participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each research participant, or if the research participant remains incapacitated, a legally authorized representative of the research participant, or if such a representative is not reasonably available, a family member, of the research participant 's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the research participant, or if the research participant remains incapacitated, a legally authorized representative of the research participant, or if such a representative is not reasonably available, a family member, that he or she may discontinue the research participant’s participation at any time without penalty or loss of benefits to which the research participant is otherwise entitled. If a legally authorized representative or family member is told about the clinical investigation and the research participant’s condition improves, the research participant is also to be informed as soon as feasible. If a research participant is entered into a clinical investigation with waived consent and the research participant dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the research participant’s legally authorized representative or family member, if feasible.

Protocols involving an exception to the informed consent requirement under this section must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies such protocols as protocols that may include research participants who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists.

If an IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception provided above or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator and to the sponsor of the clinical investigation. The sponsor of the clinical investigation must promptly disclose this information to FDA and to the sponsor's clinical investigators who are participating or are asked to participate in this or a substantially equivalent clinical investigation of the sponsor, and to other IRB's that have been, or are, asked to review this or a substantially equivalent investigation by that sponsor.

For additional guidance, see:

* [FDA 21 CFR 50.24: Exception from Informed Consent (EFIC) Requirements for Emergency research](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm)
* [FDA Website: Protection of Human Subjects; Informed Consent and Waiver of Informed Consent Requirements in Certain Emergency research](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118995.htm)
* [FDA Guidance on Exception from Informed Consent Requirements for Emergency research](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf)
* [OHRP Guidance: Informed Consent Requirements in Emergency research](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html), for research not subject to FDA regulations

# Medical Record Research Note For Clinical Trials

When a research participant is enrolled into a **clinical trial involving an IND or IDE** at DMC and is also a **patient, or when required by the IRB** a research note must be placed in the electronic medical record (EMR), unless the IRB determines that it is not in the best interest of the patient or when a Certificate of Confidentiality is appropriate to protect the research participants.

# Legally Effective Informed Consent and HIPAA Research Authorization

## Form Requirements for Informed Consent and HIPAA Research Authorization

### Informed Consent Requirements

An investigator shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

**Basic elements:**

* A statement that the study involves **research**, an explanation of the purposes of the research and the **expected duration** of the participant’s participation, a description of the **procedures to be followed**, and **identification of any procedures which are experimental**;
* A description of any **reasonably foreseeable risks or discomforts** to the participant;
* A description of any **benefits to the research participants or to others** which may reasonably be expected from the research;
* A **disclosure of appropriate alternative procedures or courses of treatment**, if any, that might be advantageous to the research participant is required **if alternatives are available**;
* A statement describing the extent, if any, to which **confidentiality of records** identifying the participant will be maintained and that notes the possibility that the **Food and Drug Administration may inspect the records (if the research is FDA regulated**);
* **For research involving more than minimal risk, an explanation as to whether there is any compensation for potential study-related injury and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained**;
* An explanation of **whom to contact for answers to pertinent questions about the research and research participants’ rights**, and **whom to contact in the event of a research related injury to the participant**;
* A **statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled**, and that the **participant may discontinue participation at any time without penalty or loss of benefits** to which the participant is otherwise entitled.
* When seeking informed consent for an **“Applicable Clinical Trial”,** as defined FDA Amendments Act of 2007 (FDAAA); the following statement must be included in the informed consent documents and should be included in the information sheet, when documentation of informed consent is waived by the IRB: **"A description of this clinical trial will be available on** [**http://www.ClinicalTrials.gov**](http://www.ClinicalTrials.gov)***,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."**

When IHII (or PHI) is involved in the study, the required HIPAA authorization language must be included with the informed consent to cover the uses and disclosures of IHII (or PHI). This language is included in the templates in the IRB Application and Reporting System. For additional information see:

* [DMC HIPAA-28 Policy: Uses and Disclosures for Research Purposes](http://www.downstate.edu/hipaa/documents/HIPAA.28.USESANDDISCLOSURESFORRESEARCHPURPOSES.Rev09.13Final.pdf)
* [DMC HIPPA-32 policy: Uses and Disclosures Requiring Patient Authorization](https://www.downstate.edu/hipaa/documents/HIPAA.32.USESANDDISCLOSURESREQUIRINGPATIENTAUTHORIZATION.Rev09.13.pdf).

**Additional elements (when appropriate):**

* A statement that the particular treatment or procedure may involve risks which are currently unforeseeable to the participant (or to the embryo or fetus, if the participant is or may become pregnant);
* Anticipated circumstances under which participation in the research may be terminated by the investigator;
* Any additional costs to the participant that may result from participation in the research;
* The consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation;
* A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant; or
* The number of participants (approved by the IRB) to be involved in the study. For multi-site studies, it is best to indicate both the number that will be enrolled at the local site and all sites.

### Obtaining Informed Consent from Individuals with Limited English Speaking Proficiency

The information that is given to the research participant or the representative shall be in language understandable to the research participant or the representative.

Unless waived by the IRB, the consent form may be either of the following, as approved by the IRB:

* A written consent document that embodies the elements of informed consent required as outlined above. This form may be read to the participant or the participant’s legally authorized representative, but in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed; or
* A short form written consent document stating that the elements of informed consent required above have been presented orally to the participant or the participant’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary, if the entire consent is not read, of what is to be said to the research participant or the representative. The short form itself is to be signed by the participant or the representative. The witness shall sign both the short form and a copy of the summary (or consent form), and the person actually obtaining consent shall sign a copy of the summary (or consent form). A copy of the summary (if used) and the consent form shall be given to the participant or the representative, in addition to a copy of the short form.

For more information, please see IRB Guidance – Legally Effective Informed Consent and HIPAA Research Authorization.

## Informed Consent Process

The IRB evaluates whether or not the informed consent process is adequate and determines whether informed consent is documented and sought in accordance with regulations and policies based on information provided in the IRB application materials, including the IRB application and protocol.

# Waiving the Requirements of Informed Consent or HIPAA Authorization

## Waiver of the Process for Informed Consent

Criteria for waiving informed consent or elements of informed consent are as follows:

* + - 1. The research involves no more than minimal risk to the research participants;
      2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
      3. The research could not practicably be carried out without the waiver or alteration; and
      4. Whenever appropriate, the research participants will be provided with additional pertinent information after participation (e.g., debriefing research participants involved in deception research).

For research or demonstration projects to be conducted by or subject to the approval of state or local government officials (e.g., research approved by the HHS Secretary), the criteria for waiving informed consent or elements of informed consent are as follows:

1. The research or demonstration project is designed to study, evaluate, or otherwise examine:
   1. public benefit or service programs;
   2. procedures for obtaining benefits or services under those programs;
   3. possible changes in or alternatives to those programs or procedures; or
   4. possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

### Waiver of Parental Permission

If the IRB determines that a research protocol is designed for conditions or for a population for which parental or guardian permission is not a reasonable requirement to protect the research participants (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the children participating in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.

### Waivers of Child Assent

A request to waive child assent may be made when the capability of some or all of the children is so limited that they cannot be reasonably consulted regarding consent. The PI must provide justification for this type of waiver.

A request to waive child assent may be made when the intervention or procedure involved in the research holds out a prospect of direct benefit that is important for the health and well-being of the children, and is only available in the context of an FDA regulated clinical investigation (even if the IRB determines the children are capable of assenting). The PI must provide justification for this type of waiver, and the following criteria must be met:

The clinical investigation involves no more than minimal risk to the research participants;

The waiver or alteration will not adversely affect the rights and welfare of the participants;

The clinical investigation could not practicably be carried out without the waiver or alteration; and

Whenever appropriate, the research participants will be provided with additional pertinent information after participation.

The permission of the parent(s)/guardian(s) will be documented in accordance with informed consent requirements.

## Waiver of Documentation of Informed Consent

Criteria to waive the documentation of informed consent:

* The research is no greater than minimal risk and involves no procedures for which written consent is normally required outside of the research context, OR
* The only record linking the participant to the research is the consent document and the primary risk would be potential harm resulting from a breach of confidentiality. Under this condition, each participant must be asked whether (s)he wants to sign documentation linking her/him to the research and her/his wishes will govern.

If the study involves PHI, a HIPAA Authorization with a signature must be included, unless a HIPAA alteration (see below) is approved by the IRB. A HIPAA Authorization may be combined with the Information Sheet.

## Waiver of Required Elements of Informed Consent

A waiver can be requested to waive certain required elements of informed consent. This is requested when the PI does not wish to include all the required elements in the informed consent document (i.e., cannot disclose purpose of the research, for a project involving deception). The criteria listed to waive the process of informed consent described in this document must be met.

# HIPAA Waivers

The requested waiver must satisfy all of the following criteria:

* The use or disclosure involves no more than a minimal risk to the privacy of the research participants because:
  + There is an adequate plan to protect the “identifiers” from improper use or disclosure (See [Policy HIPAA-6 on De-Identification of Information](http://downstate.edu/hipaa/documents/HIPAA.6.DEIDENTIFICATIONOFINFORMATION.2013.pdf) for the types of information considered to be identifiers;
  + There is an adequate plan to destroy the identifiers at the earliest opportunity, unless there is a health or research justification for retaining the identifiers or their retention is required by law; and
  + There are adequate written assurances that the protected health information (PHI) will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study or for other research for which the use or disclosure of PHI is otherwise permitted.
* The research could not practicably be conducted without the waiver- research involving treatment will almost never be eligible since most clinical trials could practicably be conducted without a waiver; and
* The research could not practicably be conducted without access to and use of the PHI- If de-identified information or a limited data set can practicably be used, a waiver of authorization should not be granted.

There are three types of HIPAA Waivers (full, partial, and alteration). Each are described below.

## Full HIPAA Waiver

A *Full HIPAA Waiver* removes the requirement to obtain a HIPAA research authorization from research participants for the use and disclosure of their PHI to conduct a study. Examples where this is appropriate include:

* Retrospective chart reviews
* Exempt research involving PHI, when it is impracticable to obtain a HIPAA research authorization

## Partial HIPAA Waiver

When a *Partial HIPAA Waiver* is granted to review PHI for recruitment purposes, a HIPAA research authorization is generally required at the time of consent.

## HIPAA Alteration

A *HIPAA Alteration* is a type of HIPAA waiver that when approved permits the use of a research authorization that does not contain all of the required elements or statements (e.g., signature or another element), or that otherwise deviates from the format or process prescribed by the HIPAA regulations. This may be useful, for example, when a PI is also seeking waiver of documentation of informed consent, when the only link of a participant to a study is their signature on a consent form and HIPAA research authorization, if it can be considered impracticable to the study’s completion to obtain a signed research authorization form as such a requirement might prevent study completion.

There also may be other circumstances where a simplified consent and authorization document are appropriate given the nature of the population enrolling in the research and in these cases a request to waive certain but not all elements or required statements of the authorization would be made.

# Additional Requirements For Trials Following ICH-GCP Requirements

Some sponsors require certain studies follow the standards of the International Conference on Harmonization (ICH) Good Clinical Practice (GCP). For more information see the [International Council for Harmonisation (ICH) Harmonized Guideline: Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2).](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf) You may wish to consult with the following CITI training module regarding these standards: GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus)-GCP. In addition to FDA requirements the following standards go above and beyond the FDA requirements:

* 3.1.2
* 3.1.8
* 3.3.7
* 3.4
* 4.3
* 4.3.3
* 4.5.3
* 4.8.10(c)
* 4.8.10(e)
* 4.8.10(h)
* 4.8.10(i)
* 4.8.10(k)
* 4.8.10(n)
* 4.8.11
* 4.8.12
* 4.8.13
* 4.8.14
* 4.8.15
* 4.8.8
* 4.8.9
* 4.9.0
* 5.11(b)
* 5.15.2
* 5.18.3
* 5.18.6
* 5.18.7
* 5.2.2
* 5.20.1
* 5.20.2
* 5.25(a)(5)
* 5.5
* 8.1
* 8.2.7
* 8.3.2
* 8.3.3

# References

* [CITI](https://www.citiprogram.org/) Module: GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus)-GCP
* [DMC Office of Compliance and Audit Services HIPAA Policy](http://www.downstate.edu/compliance/policies.html)
* DMC Policy AD-1, Guidelines for Preparation Format, Review, Distribution and Retention of Hospital Policy
* [DMC Policy HIPAA-28: Uses and Disclosures for research Purposes](http://www.downstate.edu/hipaa/documents/HIPAA.28.USESANDDISCLOSURESFORRESEARCHPURPOSES.Rev09.13Final.pdf)
* [DMC HIPPA-32 policy: Uses and Disclosures Requiring Patient Authorization](https://www.downstate.edu/hipaa/documents/HIPAA.32.USESANDDISCLOSURESREQUIRINGPATIENTAUTHORIZATION.Rev09.13.pdf)
* DMC’s [Investigational Drug Dispensing and Utilization Policy (PHA-11)](http://www.downstate.edu/regulatory/pdf/policies/PHA-11.pdf)
* [FDA regulations (21 CFR 50, 56, 312, 812) for clinical trials and device studies](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm)
* [Federal Privacy Act](https://www.justice.gov/opcl/privacy-act-1974)
* [HHS 42 CFR Part 50, Subpart F – Promoting Objectivity in research](https://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm)
* [HHS 42 CFR Part 50; HHS 42 CFR Part 94 - Responsibility of Applicants for Promoting Objectivity in research for which Public Health Service Funding is Sought and Responsible Prospective Contractors](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0ahUKEwil28n8j5nMAhXIVj4KHVVzDGMQFggsMAI&url=https%3A%2F%2Fwww.gpo.gov%2Ffdsys%2Fpkg%2FFR-2011-08-25%2Fpdf%2F2011-21633.pdf&usg=AFQjCNEeQblIuCETRXpzp6IeEQRVIYdUOw&sig2=rHVwXEUeojwWm1NQwSYH5Q)
* [HHS 45 CFR 2 –Confidentiality of Alcohol and Drug Abuse Patient Records](http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A1.0.1.1.2)
* [HHS Office for Civil Rights (OCR) Health Insurance Portability and Accountability Act of 1996 (HIPAA) or 45 CFR Parts 160, 162, and 164](http://www.hhs.gov/hipaa/for-professionals/)
* IRB-01 Policy (Downstate Medical Center)
* [New York Codes, Rules and Regulations, Title 14, Department of Mental Hygiene, Part 527, Rights of Patients](https://www.omh.ny.gov/omhweb/policy_and_regulations/)
* [New York Mental Hygiene Law, Article 81](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjwycbpkJnMAhUJyj4KHT7bCe0QFggdMAA&url=http%3A%2F%2Fwww.nycourts.gov%2Fip%2Fgfs%2FArticle_81_Law_2008.pdf&usg=AFQjCNGmFr_gaA9epXmzFloU15Dx64xxzg&sig2=qSaQIg4wUbezAn7tvoMMLQ)
* [New York State Public Health Law, Article 24A –Protection of Human Research Participants](https://www.nysenate.gov/legislation/laws/PBH/A24-A) [New York’s Family Health Care Decisions Act (FHCDA) (Public Health Law §29-CC)](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=0ahUKEwi66OqIlJnMAhVLeT4KHTdOA2AQFgg7MAQ&url=https%3A%2F%2Fwww.health.ny.gov%2Fdiseases%2Faids%2Fproviders%2Fregulations%2Ffhcda%2Fai_fact_sheet.htm&usg=AFQjCNG7kzcFNmDCA1qa5g5VW7b21L9gjQ&sig2=dyxkL-ZTSjxcoErVnoF5eg&cad=rja)
* [New York State's Public Health Law 18: Access to Patient Records](http://www.douglasandlondon.com/docs/New-York-State-Public-Health-Law-18.pdf)
* [New York’s Family Health Care Decisions Act (FHCDA) (Public Health Law §29-CC)](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=0ahUKEwi66OqIlJnMAhVLeT4KHTdOA2AQFgg7MAQ&url=https%3A%2F%2Fwww.health.ny.gov%2Fdiseases%2Faids%2Fproviders%2Fregulations%2Ffhcda%2Fai_fact_sheet.htm&usg=AFQjCNG7kzcFNmDCA1qa5g5VW7b21L9gjQ&sig2=dyxkL-ZTSjxcoErVnoF5eg&cad=rja)
* [NIH Guidance: Protecting PHI in research: Understanding the HIPAA Privacy Rule](https://privacyruleandresearch.nih.gov/pr_02.asp)
* [NY State Department of Health HIPPA Preemption Charts](http://www.health.ny.gov/regulations/hipaa/preemption_charts.htm)
* [NYS 10 NYCRR Part 63 (HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information](http://www.health.ny.gov/professionals/ems/pdf/srgpart63.pdf)
* [NYS 1-2.13 NY Estates Powers and Trusts Law](http://www.nysl.nysed.gov/libdev/excerpts/ept11-23.htm)
* [NYS Civil Rights Law Section 79-L (Confidentiality of genetic tests)](http://codes.findlaw.com/ny/civil-rights-law/cvr-sect-79-l.html)
* [NYS DOH HIPAA Preemption Charts](http://www.health.ny.gov/regulations/hipaa/preemption_charts.htm)
* [OCR Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009](http://www.hhs.gov/hipaa/for-professionals/special-topics/HITECH-act-enforcement-interim-final-rule/index.html)
* [U.S. Department of Commerce, Bureau of Industry and Security, Export Administration Regulations (EAR) 15 C.F.R. §§730-774](https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear)
* [U.S. Department of Education, Family Educational Rights and Privacy Act (FERPA), (20 U.S.C. § 1232g; 34 CFR Part 99)](http://www2.ed.gov/policy/gen/reg/ferpa/index.html)
* [U.S. Department of Education, Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98)](http://familypolicy.ed.gov/ppra)
* [U.S. Department of Education, Title 34 Part 350: Disability and Rehabilitation Projects and Centers Program](http://www.ecfr.gov/cgi-bin/text-idx?SID=9117e0b7886817d491bfcb863916aef0&node=34:2.1.1.1.4&rgn=div5)
* [U.S. Department of Education, Title 34 Part 356: Disability and Rehabilitation research](https://www.gpo.gov/fdsys/granule/CFR-2000-title34-vol2/CFR-2000-title34-vol2-part356/content-detail.html)
* [U.S. Department of Health and Human Services (HHS) Regulations for Protection of Research Participants under 45 CFR 46 (including Subparts A, B, C, D, and E)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)
* [U.S. Department of State, Directorate for Defense Trade Commission, International Traffic in Arms Regulations (ITAR) 22 C.F.R. §§120-130](https://www.pmddtc.state.gov/regulations_laws/itar.html).

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