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| **REVIEWER FORM – EXPEDITED REVIEW** | | |
| **PRO #:** Click or tap here to enter text. | **AME #:** Click or tap here to enter text. | **CPR #:** Click or tap here to enter text. |
| **Principal Investigator:** Click or tap here to enter text. | | **Department:** Click or tap here to enter text. |

**INSTRUCTIONS**:

Use this form for review of:

* **New Protocols** which qualify for review under *Expedited* categories.
* **New Protocols** which are requesting approval under *45 CFR 46.118*.
* **Amendments** to *Exempt* or *Expedited* projects, where new/revised activities still qualify as minimal risk.
* **Amendments** which move *Expedited* projects to the *Exempt* pathway, or vice versa.
* **Amendments** to projects approved under *45 CFR 46.118* or the *Registration* pathway which now require review under *Expedited* categories.
* **Continuing Progress Reports** for *Expedited* projects.
* **6-Year Renewals** for *Expedited* projects.

**DO NOT** use this form for review of New Protocols which qualify for review under *Exempt* categories.

You can jump to each section using the links here. Note that you may have to hold the “Ctrl” button when you click in order for the jump to work:

[**NEW PROTOCOL**](#newprotocol)

[**AMENDMENT**](#amendment)

[**CONTINUING PROGRESS REPORT**](#cpr)

Typically, only the checklist which matches the type of review you have been assigned needs to be completed. See notes within checklists for special rules regarding situations when sections different than the item type may need to be completed.

This checklist also contains an [**APPENDIX**](#_APPENDIX) containing detailed information regarding the determinations you are making in this checklist. Links in this document link within this document only. No links in this document connect to outside documents/websites. Everything is located here for easy reference.

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| **NEW PROTOCOL** | | | | |
| Complete NEW PROTOCOL checklist for:   * All New Protocols. * Amendments to projects approved under 45 CFR 46.118 which are now seeking to begin human research activities. * Amendments to projects approved as Registration projects that now require review under HHS/FDA regulations. | | | | |
| If this project is only seeking approval under [**45 CFR 46.118**](#oneeighteen) at this time, STOP HERE, check this box, jump to [DETERMINATION](#PROdeterm) section, and enter comments (if any) and signature. | | | | |
| **VULNERABLE POPULATIONS** | | | | |
| Complete this section only when vulnerable populations are involved. | | | | |
| Subject population includes vulnerable population(s). When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons or non-English speaking individuals, additional safeguards have been included in the study to protect the rights and welfare of these subjects.  Check the following if vulnerable populations include:   * Pregnant women, fetuses, neonates. **COMPLETE SUBPART B CHECKLIST (embedded below)**. * Minors. **COMPLETE SUBPART D CHECKLIST (embedded below)** * Prisoners.**STOP and notify IRB Coordinator. The MCW IRB does not review research involving prisoner subjects on the Minimal Risk Committee**. * Non-English speaking subjects:   + Is there a plan or procedures to ensure ongoing consent, data collection & subject communication including translated documents and/or interpreter services? *(Refer to section 12.2, section 52.1 for uploaded documents)*   Yes  No  Comments: Click or tap here to enter text.  *NOTE: A separate reviewer with Subpart B or Subpart D expertise may be assigned, in which case the Primary Reviewer should not complete these separate checklists*. | | | | |
| **CONSENT** | | | | |
| Many projects feature multiple activities requiring distinct consent determinations. If necessary, please use comments section to make clear your determinations for each specific research activity. | | | | |
| Project utilizes MCW ICF templates, which is appropriate and satisfies all [consent criteria](#Consent).   * For Federally Funded projects (only):   Contains Certificate of Confidentiality language  Contains Data Sharing (DMP) language (for new grants awarded after 01/25/2023) | | | | |
| [Waiver of Informed Consent](#waiveralteration) granted. | | | | |
| [Alteration of Informed Consent](#waiveralteration) granted and consent material (e.g. informational letter) is appropriate. | | | | |
| [Waiver of Documentation of Informed Consent](#docwaiver) granted. | | | | |
| Project is an In Vitro Diagnostic Project which qualifies for Approval without the requirements of Informed Consent, per [2006 FDA Guidance](#IVD). | | | | |
| Consent process has already been determined and no new consent determinations are needed (e.g. material received from an IRB-approved bank, from another institution, etc.). | | | | |
| Project is an In Vitro Diagnostic Project which qualifies for Approval without the requirements of Assent and Parental Permission, per [2006 FDA Guidance](#IVD). | | | | |
| Parental Permission/Assent process has already been determined and no new determinations are needed (e.g. material received from an IRB-approved bank, from another institution, etc.). | | | | |
| **HIPAA** | | | | |
| The IRB also functions as the privacy board for research projects. While HIPAA determinations will likely mirror consent determinations, they are separate in order to address this dual IRB function. | | | | |
| Project utilizes MCW ICF templates which contain HIPAA Authorization (Section E).   * Consent/HIPAA recruitment waiver is granted to scan records and identify subjects prior to consent. | | | | |
| Waiver of HIPAA Authorization granted. | | | | |
| All subjects are deceased and access to this decedent data is granted. | | | | |
| Limited Data Set would be utilized, and any necessary data agreements are provided. | | | | |
| Only de-identified data is utilized. | | | | |
| HIPAA process has already been determined and no new determinations are needed (e.g. material received from an IRB-approved bank, from another institution, etc.). | | | | |
| Project does not access or create Personal Health Information. | | | | |
| **DETERMINATION** | | | | |
| Only complete this section if this project qualifies for Expedited Approval.   * All research activities must qualify as minimal risk under an HHS/FDA Expedited Review category. If any research activity does not qualify, the project cannot be considered for Expedited Review. * An Expedited Reviewer cannot alone disapprove a project. If you have serious concerns about this project that are not effectively addressed by the Project Team via modifications, notify IRB Coordinator to discuss further action. | | | | |
| All [criteria of IRB approval](#Criteria) are satisfied. | | | | |
| The proposed management and possible reporting of information relevant to the protection of human subjects is adequate. | | | | |
| Approval is granted for this project, under the following regulations. Select all that apply: | | | | |
|  | | 45 CFR 46.111 (HHS)  21 CFR 56.111 (FDA) | | |
| [Expedited category(ies):](#categories) | | 1a  1b  2a  2b  3  4  5  6  7 | | |
| Approval length: | | 6 year (HHS) | 1 year (FDA or CW projects) | Other (Describe in Comments and give reason) |
| Comments: | Click or tap here to enter text. | | | |
| Reviewer Name: | Click or tap here to enter text. | | | |
| Date of Review: | Click or tap to enter a date. | | | |

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| **AMENDMENT** | |
| Please complete NEW PROTOCOL checklist for:   * Amendments to projects approved under 45 CFR 46.118 which are now seeking to begin human research activities. * Amendments to projects approved as Registration projects that now require review under HHS/FDA regulations. | |
| **VULNERABLE POPULATIONS** | |
| Complete this section only when vulnerable populations are involved. | |
| Subject population includes vulnerable population(s) and Amended activities include/maintain safeguards to protect the rights and welfare of these subjects.  Check the following if vulnerable populations include:   * Pregnant women, fetuses, neonates. **COMPLETE SUBPART B CHECKLIST (embedded below)**. * Minors. **COMPLETE SUBPART D CHECKLIST** **(embedded below)** * Non-English speaking subjects:   + Is there a plan or procedures to ensure ongoing consent, data collection & subject communication including translated documents and/or interpreter services? (Refer to section 12.2, section 52.1 for uploaded documents)   Yes  No  Comments: Click or tap here to enter text.  *NOTE: A separate reviewer with Subpart B or Subpart D expertise may be assigned, in which case the Primary Reviewer should not complete these separate checklists.* | |
| **CONSENT/ASSENT** | |
| No changes to currently approved consent/assent methods or forms.   * Can also select this box if only change is to answer new question in section 40 that is required per revised Common Rule. | |
| Project utilizes **consent/assent form**(s) and revisions were made. Revised ICF is appropriate.   * For Federally Funded projects (only):   Contains Certificate of Confidentiality language  Contains Data Sharing (DMP) language (for new grants awarded after 01/25/2023) | |
| Project utilizes a **shortened/altered consent/assent** (e.g. informational letter) and revisions were made. Revised material is appropriate. | |
| Project proposes changing consent/assent method on already-approved activities, and this change is approved.   * For example, project featured signed consent for record review and now requests a waiver of consent for that activity. Describe further in comments as needed. | |
| New activities have been added that require new consent/assent determinations.   * For example, new survey has been added requesting an alteration of consent via informational letter. Describe further in comments as needed. | |
| **HIPAA** | |
| No changes to currently approved HIPAA pathway. | |
| Project utilizes consent form containing HIPAA authorization (section E) and this section was revised. | |
| Project proposes changing HIPAA method on already-approved activities, and this change is approved.   * For example, project featured signed HIPAA authorization on record review and now requests a waiver of HIPAA. Describe further in comments as needed. | |
| New activities have been added that require new HIPAA determinations.   * For example, new survey has been added requesting an alteration of consent via informational letter. Describe further in comments as needed. | |
| **DETERMINATION** | |
| Only complete this section if this project still qualifies as minimal risk under Exempt or Expedited categories. | |
| Protocol remains no greater than minimal risk and still qualifies for Exempt or Expedited review.  If not, please notify C2 to discuss further action. | |
| Approval is granted for this Amendment, and:  (Check only 1)   * No change to approval pathway or categories * Changes require approval under new pathway/categories. See Comments and/or C2 checklist.   (Check only 1)   * No change to Subpart D approval category * Subpart D approval category impacted by amendment changes. **STOP** **– Reach out to C2 to discuss next steps.** | |
| Comments: | Click or tap here to enter text. |
| Reviewer Name: | Click or tap here to enter text. |
| Date of Review: | Click or tap to enter a date. |

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| **CONTINUING PROGRESS REPORT** | | |
| Please complete the following PROJECT STATUS section for all CPRs | | |
| **PROJECT STATUS** | | |
| Cumulative enrollment, withdrawals, unanticipated problems, reportable events, and amendments have been reviewed. | | |
| All [criteria of IRB approval](#Criteria) remain satisfied. | | |
| Project remains no greater than minimal risk, and benefits outweigh risks. | | |
| Project does not need verification from sources other than the researchers that no unapproved changes have occurred since previous IRB review. | | |
| * If this is a **Final Report**, jump to the CPR “DETERMINATION” section below. You do not need to complete sections regarding vulnerable populations and consent/assent. * If this is a **6-Year Renewal CPR that DOES NOT move the project to the Registration pathway**, please now go back and complete the NEW PROTOCOL checklist, including the DETERMINATION section there. The IRB re-assesses the entire project during 6-Year Renewal Review. If project is closed to enrollment, no new patient material needs to be requested. However, the review should consider all activities that occurred during the life of the project in order to re-confirm that all activities qualified as minimal risk and were captured appropriately. * If this is a **6-Year Renewal CPR that DOES move the project to the Registration pathway,** jump to the CPR DETERMINATION section below, enter comments including Registration approval categories, and sign. | | |
| **VULNERABLE POPULATIONS** | | |
| Complete this section only when vulnerable populations are involved. | | |
| Subject population includes vulnerable population(s) and project maintains safeguards study to protect the rights and welfare of these subjects.  Check the following if vulnerable populations include:   * Pregnant women, fetuses, neonates. **COMPLETE SUBPART B CHECKLIST (embedded below).** * Minors. **COMPLETE SUBPART D CHECKLIST (embedded below)**.   NOTE: A separate reviewer with Subpart B or Subpart D expertise may be assigned, in which case the Primary Reviewer should not complete the determination. | | |
| **CONSENT/ASSENT** | | |
| Project is closed to enrollment. | | |
| Project is open to enrollment and consent/assent method remains appropriate. | | |
| Project is open to enrollment and consent/assent form(s) have been migrated to our newest templates (6-Year renewal) | | |
| **DETERMINATION** | | |
| Only complete this section if this project still qualifies as minimal risk under Expedited categories. | | |
| Final Report accepted. Jump to comments/signature. | | |
| Approval is granted for this project, under the following regulations. Select all that apply: | | |
|  | | 45 CFR 46.111 (HHS)  21 CFR 56.111 (FDA) |
| Expedited category(ies): | | 1a  1b  2a  2b  3  4  5  6  7 |
| Approval granted for 6 years. Approval granted for 1 year (FDA and CW) Other. Give proposed approval period and reason in comments. | | |
| Comments: | Click or tap here to enter text. | |
| Reviewer Name: | Click or tap here to enter text. | |
| Date of Review: | Click or tap to enter a date. | |

# Minors (Subpart D)

**Subpart D (children) Determinations (45 CFR 46 or 21 CFR 50)**

Check the allowable category below that best represents the degree of risk and benefit to which the children in this project will be exposed and explain your choice.

**Note: More than one category may be indicated. If multiple categories are indicated, please answer the additional question after each marked category.**

Category 1 (404 or 50.51): The proposed research poses risks no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk).

Category 2 (405 or 50.52): The proposed research poses a greater than minimal risk with the potential for direct benefit to subjects, i.e., the benefit to the subject is at least as favorable as alternative approaches.

Category 3 (406 or 50.53): The proposed research poses a greater than minimal risk with no potential for direct benefit to individuals, but likely to yield vital generalizable knowledge about the subjects’ conditions.

Category 4 (407 50.54): The proposed research does not meet the criteria in the above categories but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children. **Research which meets this category cannot be approved by the IRB and must go for review by Secretary of HHS or the Commissioner of Food and Drug to make a determination as outlined per 50.54.**

Explain your choice of category: Click or tap here to enter text.

1. **What permission will be obtained from the parents?**

Permission from only one parent is being requested

Permission will be obtained from both parents where possible.

Note: ***2 parent signatures are required for any project which meets category 3 (406 or 50.53).***

A waiver of parental permission is being requested

Informed Consent/Parental Permission has already been obtained

(i.e., previously IRB approved bank, incoming data from another institution, etc.)

None of the Above – the project qualifies for exempt review. Select the level of contact

Project will not have direct contact with subjects, and an informed consent process or document is not required

Project will have direct contact with subjects, and an informational letter will be provided

1. **Please indicate whether the children in this project are generally capable of providing assent; evaluate age, maturity and psychological state of the children involved. Please be specific:**

All are capable

None are capable; explain: Click or tap here to enter text.

Some are capable; explain: Click or tap here to enter text.

1. **For subgroups of children capable of assent, how will assent be solicited?** Click or tap here to enter text.
   1. A waiver of assent is being requested
   2. Project is an In Vitro Diagnostic Project which qualifies for Approval without the requirements of Assent and Parental Permission, [per 2006 FDA Guidance](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf).
2. **For subgroups of children capable of assent, how will assent be documented?** Click or tap here to enter text.
   1. A waiver of assent is being requested
   2. Project is an In Vitro Diagnostic Project which qualifies for Approval without the requirements of Assent and Parental Permission, [per 2006 FDA Guidance](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf).
3. **Has the project team developed a plan to consent subjects who reach the age of majority?**  Yes  No  N/A
   1. **Describe the proposed plan:** Click or tap here to enter text.

# Pregnant Women, fetuses, neonates (Subpart B)

This project involves the following (check as many as apply):

[Section: Pregnant women or fetuses (45 CFR 46.204](#Pregnant_Women_204)):

[Section: Neonates of Uncertain Viability (45 CFR 46.205 (a) and (b))](#Neonates_205a)

[Section: Nonviable neonates (45 CFR 46.205 (c))](#Neonates_205c)

Reviewers must then complete the corresponding section(s) below, along with [final comments and recommendations.](#Final_Recommendations)

**Section: Pregnant women or fetuses (45 CFR 46.204):**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

If yes, pregnant women or fetuses may only be involved in the project if the following 10 elements are satisfied.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. Does the application identify 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?

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. 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;

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Any risk is the least possible for achieving the objectives of the research;

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. If the research holds 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 45 CFR 46.116 and 117

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. If the research holds the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accord with 45 CFR 46.116 and 117, 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.

Yes  No  N/A  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Each individual providing consent under items 5 or 6 is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

Yes  No  N/A  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of 45 CFR 46 subpart D; *See IRB Member Form: Research Involving Children (subpart D) Checklist*

Yes  No  N/A  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. 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

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Individuals engaged in the research will have no part in determining the viability of a neonate.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

**[☐ Section: Neonates of Uncertain Viability (45 CFR 46.205 (a))](#Neonates_205a)**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

If yes, neonates of uncertain viability and non-viable neonates may only be involved in the project if the following 4 elements are satisfied.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Each individual providing consent under paragraph [45 CFR 46.205(b)(2) or (c)(5)](http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.205) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Individuals engaged in the research will have no part in determining the viability of a neonate.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The requirements of paragraph [45 CFR 46.205(b) or (c)](http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.205) of this section have been met as applicable.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

**Section: Neonates of uncertain viability (45 CFR 46.205 (b))**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

If yes, 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 2 conditions have been met.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. (i) 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

(ii) 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;

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The legally effective informed consent of either parent of the neonate or, if neither parent can consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accordance with subpart A of 45 CFR 46, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

**Section: Nonviable neonates (45 CFR 46.205 (c))**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

If yes, nonviable neonates may only be involved in the project if the following 5 elements are satisfied.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. Vital functions of the neonate will not be artificially maintained

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The research will not terminate the heartbeat or respiration of the neonate

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. There will be no added risk to the neonate resulting from the research.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The legally effective informed consent of both parents of the neonate is obtained in accordance with 45 CFR 46 subpart A except that the waiver and alteration provisions of 45 CFR 46.116(e) and (f) do not apply.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

# APPENDIX

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| NOTE: This Appendix is a work-in-progress. We may continue to add to it, and please let us know if you find it helpful.  We attempt to keep all information here up-to-date but please do not use this in lieu of federal regulation primary sources. |
| 45 CFR 46.118 Applications and proposals lacking definite plans for involvement of human subjects. |
| 45 CFR 46.118:  *Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal.* These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency. |
| Criteria for IRB approval |
| 45 CFR 46.111:  (1) *Risks to subjects are minimized*: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.  (2) *Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.* In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should 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.  (3) *Selection of subjects is equitable*. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.  (4) *Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required.*  (5) *Informed consent will be appropriately documented, in accordance with and to the extent required.*  (6) *Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.*  (7) *Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.* |
| Elements of Informed Consent |
| 45 CFR 46.116:  (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;  (2) A description of any reasonably foreseeable risks or discomforts to the subject;  (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;  (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;  (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;  (6) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and  (7) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.  When appropriate, one or more of the following elements of information shall also be provided to each subject:  (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.  (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.  (3) Any additional costs to the subject that may result from participation in the research.  (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.  (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.  (6) The approximate number of subjects involved in the study. |
| Requirements to Grant a Waiver or Alteration of Consent |
| 45 CFR 46.116:  *An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:*  (1) The research involves no more than minimal risk to the subjects;  (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;  (3) The research could not practicably be carried out without the waiver or alteration; and  (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation |
| Requirements to Grant a Waiver of Signed Consent Documentation |
| 45 CFR 46.117:  *An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:*  (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or  (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.  (*3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.* (NOTE: This third criteria is drafted for the New Rule implementation but not yet in effect.)  In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research. |
| In Vitro Diagnostic Exception from Informed Consent |
| FDA’s *Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable:*  The FDA intends to exercise enforcement discretion as to the informed consent requirements for  clinical investigators, sponsors, and IRBs if an in vitro diagnostic device investigation is performed and all of the following are true:  a) The investigation meets the IDE exemption criteria at 21 CFR 812.2(c) (3).  b) The study uses leftover specimens, that is, remnants of specimens collected for routine clinical care or analysis that would have been discarded. The study may also use specimens obtained from specimen repositories or leftover specimens that were previously collected for other research purposes.  c) The specimens are not individually identifiable, i.e., the identity of the subject is not known to and may not readily be ascertained by the investigator or any other individuals associated with the investigation, including the sponsor. If the specimen is coded, it will be considered to be not individually identifiable if neither the investigator(s) nor any other individuals associated with the investigation or the sponsor can link the specimen to the subject from whom the specimen was collected, either directly or indirectly through coding systems.  d) The specimens may be accompanied by clinical information as long as this information does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor.  e) The individuals caring for the patients are different from and do not share information about the patient with those conducting the investigation.  f) The specimens are provided to the investigator(s) without identifiers and the supplier of the specimens has established policies and procedures to prevent the release of personal information.  g) The study has been reviewed by an IRB in accordance with 21 CFR Part 56, except as  described in section 7 of this guidance document. |
| Expedited Review Categories |
| Federal Register, as cited in 45 CFR 46.110:  (1) *Clinical studies of drugs and medical devices* only when condition (a) or (b) is met.  (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)  (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.  (2) *Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture* as follows:  (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or  (b) from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.  (3) *Prospective collection of biological specimens for research purposes by noninvasive means.*  Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.  4. *Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves*. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)  Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.  5. *Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).* (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)  6. *Collection of data from voice, video, digital, or image recordings made for research purposes.*  7. *Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social* *behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.* (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.) |
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