# IRB Review Checklist

Attached are checklists to assist IRB members in their review of:

1. Protocols
2. Consent forms
3. Assent
4. Consent forms for research involving genetic testing – additional requirements
5. HIPAA authorization
6. Waiver of consent and/or authorization
7. Monitoring
8. Obtaining Consent and Capacity Assessments
9. Level of review required

These checklists supplement regulations and guidance. [[1]](#footnote-1):

1. The Belmont Report (statement of Ethical Principles) <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
2. 45 CFR 46 <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
3. 21 CFR 50 and 56 for FDA regulated research <http://www.cfsan.fda.gov/~lrd/cfr50.html>

<http://www.cfsan.fda.gov/~lrd/cfr56.html>

1. OHRP Policy and Guidance <http://www.hhs.gov/ohrp/policy/index.html>
2. FDA Guidance for IRBs <http://www.fda.gov/oc/ohrt/irbs/default.htm>
3. DMH/RFMH Manual which includes regulatory requirements, sample consent language, HIPAA guidance. <http://corporate.rfmh.org/research_compliance/index.asp?page=irb_table>
4. 21 CFR 54 (FDA) Financial Disclosure by Clinical Investigators <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54>
5. 21 CFR 600 (FDA) Biologic Products: General <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=600>
6. 21 CFR 312 (FDA) Investigational New Drug Application <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312>
7. 21 CFR 812 (FDA) Investigational Device Exemptions <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812>
8. 14 NYCRR 633.13. Research Involving Persons in OMRDD Facilities <http://weblinks.westlaw.com/result/default.aspx?cnt=Document&db=NY%2DCRR%2DF%2DTOC%3BTOCDUMMY&docname=342048282&findtype=W&fn=%5Ftop&ifm=NotSet&pbc=4BF3FCBE&rlt=CLID%5FFQRLT69363921085&rp=%2FSearch%2Fdefault%2Ewl&rs=WEBL9%2E04&service=Find&spa=nycrr%2D1000&vr=2%2E0>
9. 42 CFR 2. Confidentiality of Alcohol and Drug Abuse Patients

<http://www.access.gpo.gov/nara/cfr/waisidx_02/42cfr2_02.html>

**REVIEW CHECKLISTS**

Study Title:

P.I.:

Sponsor, if any:

**1. Protocol Review**

|  |  |
| --- | --- |
| **Requirement** | **Reviewer Notes and Concerns** |
| The proposed research design is sound and will not unnecessarily expose subjects to risk |  |
| Risks to subjects are reasonable in relation to the anticipated benefits to subjects, if any, and the importance of knowledge that may reasonably be expected to result. |  |
| Risks to subjects are minimized by using procedures consistent with sound research design, do not unnecessarily expose subjects to risk, whenever appropriate use procedures already being performed on the subjects for diagnostic or treatment purposes. |  |
| Legally effective informed consent is obtained from research subjects or their legally authorized representative(s). Consider: method, timing and process of consent; consent and assent requirements for adults lacking consent capacity; and parental/guardian permission and assent for children. |  |
| Additional safeguards required to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence, e.g. persons who are developmentally disabled, economically or educationally disadvantaged, or otherwise have diminished consent capacity. |  |
| Research plan makes adequate provision for monitoring data to ensure safety of subjects |  |
| Adequate provisions to protect subject privacy and confidentiality. Review to include paper and electronic records. |  |
| Conflict of Interest   * Positive disclosures have been referred to the Conflict of Interest Committee * Findings of the COI Committee have been considered by the IRB * If appropriate, additional requirements have been imposed by the IRB to manage or eliminate any conflict |  |
| **SPECIAL CATEGORIES OF RESEARCH** |  |
| Study involves CHILDREN:   * Category under which study is being approved (45 CFR 46.404, 405, 406, or 407) ***Specify*** * If research is conducted in a school, have the requirements of the Family Educational Rights and Privacy Act and the Protection of Pupil Rights Amendment been met? |  |
| Study involves PRISONERS:   * Category under which study is being approved (45 CFR 46.306 (a)(2)(i), (ii), (iii) or (iv) ***Specify*** * Criteria in 46.305(a) 1-7 have been met. * If DHHS funded, report to the Secretary required |  |
| Study involves administration of a DRUG  IND required?  If yes, IND obtained? |  |
| Study involves an INVESTIGATIONAL DEVICE:   * IDE obtained? * SR/NSR determination made? |  |
| Study involves PREGNANT WOMEN, HUMAN FETUSES OR NEONATES  Have the requirements of 45 CFR 46 Subpart B been reviewed and satisfied? |  |

2. **CONSENT FORM(S) REVIEW**

Consent Form Version/date:

|  |  |
| --- | --- |
| **Requirement** | **Reviewer Notes and Concerns** |
| Name(s) and Affiliation(s) of the Principal Investigator and Co-Investigators |  |
| Consent will be sought under circumstances that provide sufficient opportunity to consider whether or not to  participate and minimize possibility of coercion or undue influence. |  |
| Consent documents are in language understandable to the subject or representative. |  |
| No exculpatory language. |  |
| Statement that study involves research |  |
| Explanation of the purpose of the research -  When appropriate include approx. number of subjects in the study |  |
| Expected duration of the subject’s participation |  |
| A description of the procedures to be followed |  |
| Identification of any procedures which are experimental |  |
| Description of any foreseeable risks or discomforts to the subject |  |
| A description of any benefits to subjects 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 subject. |  |
| Confidentiality – Description of how confidentiality of records (paper and electronic) will be maintained. Include legal advocacy group access (unless all records are de-identified or there is a Certificate of Confidentiality) |  |

|  |  |
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| For all covered clinical trials: "A description of this clinical trial will be available on *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." |  |
| Information on payment for participation and, when appropriate, any additional costs associated with participation. |  |
| Statement that participation is voluntary, refusal or discontinuation will involve no penalty or loss of benefits to which subject is otherwise entitled. |  |
| If research involves more than minimal risk: availability of treatment and compensation in the event an injury occurs.   * Facility/RFMH * Sponsor |  |
| Who and how to contact the IRB for questions about rights as a subject. |  |
| Who and how to contact a research team member for answers to questions about the research and in the event of an injury. |  |
| Statement that person will get a copy of the consent form |  |

|  |  |
| --- | --- |
| When appropriate:   * Statement that the treatment or procedure may include risks to the subject (or embryo or fetus) which are currently unforeseeable. * Anticipated circumstances under which the investigator may terminate subject participation * Statement that significant new findings which may relate to subject willingness to participate will be provided. * If prisoners are involved:   + a statement that parole boards will not take research participation into account when making decisions about parole   + a statement about any follow up examination or care following participation |  |

**3. Assent: Child or Adult Lacking Consent Capacity**

|  |  |
| --- | --- |
| Is there an adequate process for informing the subject: age and ability appropriate |  |
| Assent form required? If yes, specify age range or other criteria for determining which children or adults who lack consent capacity will be asked to sign an assent form |  |
| Assent in language understandable to subjects |  |
| Voluntary participation, ability to stop, basic procedures and purpose explained |  |
| Other consent elements appropriate for age and ability. |  |

1. **Research Involving Genetic Testing – Additional Elements of Consent** (NY Civil Rights Law 79-1)

|  |  |
| --- | --- |
| Description of the test and its purpose |  |
| A statement that the individual may wish to obtain professional genetic counseling prior to signing consent form. |  |
| A statement that a positive test result is an indication that the person may be predisposed to or have the disease or condition being tested for (IRB may modify this requirement if research does not permit this level of specificity). |  |
| Description of each disease or condition (IRB may modify this requirement if research does not permit this level of specificity). |  |
| Level of Certainty that a positive result serves as a predictor. (IRB may modify this requirement if research does not permit this level of specificity). |  |
| Statement that only authorized tests will be performed on the sample and that it will be destroyed after not more than 60 days – unless the IRB has approved a longer retention and the consent form is clear about retention. |  |
| State the name of the person or categories of persons/organization to whom the test results will be disclosed. |  |
| *Anonymous specimens* may be used for future research if written consent for future use is obtained and no restrictions have been placed on retention or use. |  |
| Future use - include:   * Samples will be used for future genetic tests * Specific time period or as long as deemed useful for research purposes. * Description of confidentiality measures , including explanation of the coding system * Right to withdraw consent and who to contact * Consent to future contact to seek consent for future research, and to provide information about the test or test results * Benefits and risks of consenting to future contact. |  |
| Description of whether access to test results will be given |  |
| Disclosure of potential risks of disclosure of genetic information |  |
| Address commercialization of samples and whether subjects will share in financial benefits |  |

**5. HIPAA Authorization for studies involving access to PHI.**

|  |  |
| --- | --- |
| Research Consent Form Addendum: Authorization to Access PHI under the Health Insurance Portability and Accountability Act (HIPAA)   * Authorization submitted, complete and accurate, or * All elements of HIPAA Authorization are included in the consent document. |  |

**6. Waiver of Consent and/or Authorization** for all or part of study requested:

|  |  |
| --- | --- |
| Waiver application submitted |  |
| Application complete |  |
| Conditions satisfied |  |

**7. Monitoring**

|  |  |
| --- | --- |
| Monitoring required by IRB |  |
| Special Conditions, if any |  |

**8. Obtaining Consent and Assessment of Capacity**

|  |  |
| --- | --- |
| Persons approved to obtain consent |  |
| Persons approved to assess capacity |  |

**9. Level of Review Required**

|  |  |
| --- | --- |
| Does the research fall within one of the exempt categories (45 CFR 46.101(b)? | Yes ⁯ No ⁯  Specify 45 CFR 46.101(b) \_\_\_\_\_\_\_\_ |
| Does the study involve no more than minimal risk ***and***  fall within one of the categories eligible for expedited review  (1) – (9)? | Yes ⁯ No ⁯  ***Specify*** Expedited category \_\_\_\_\_\_\_\_\_ |
| If yes to either of the questions above, the study is eligible for expedited review. | Expedited Review ⁯  Convened Review Requested/Required ⁯ |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of IRB Member Date

(required when member is conducting expedited review or is serving as the primary or secondary reviewer for convened meeting review)

1. Note this is not a complete list of regulatory/policy requirements [↑](#footnote-ref-1)