

**Ohio Department of Mental Health and Addiction Services**

# **Institutional Review Board Guidelines**

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**Department of Mental Health and Addiction Services.**

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### GUIDELINES FOR THE INSTITUTIONAL REVIEW BOARD

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#### I.A. Purpose

1. The Institutional Review Board of The Ohio Department of Mental Health (ODMH) operates under the US Department of Health and Human Services regulations for the Protection of Humans Research Subjects: Title 45 of the Code of Federal Regulations, Part 46 (CFR 46). The IRB also is guided by the ethical principles regarding all research involving humans as subjects as set forth in the April 18, 1979 report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," commonly referred to as The Belmont Report.

The mission of the ODMH IRB is to ensure that vital, department research can be conducted in full compliance with both the letter and spirit of regulations designed to protect the rights and welfare of human subjects. The IRB also monitors research to ensure that human subjects are protected from undue risk and from deprivation of personal rights and dignity. This protection is assured by consideration of three principles that are the basis of ethical research:

- a. That voluntary participation by the subjects, indicated by free and informed consent, is assured by the investigators;
- b. That an appropriate balance exists between potential benefits of the research to the subject or to society and the risks assumed by the subject; and
- c. That there are fair procedures and outcomes in the selection of research subjects.

The IRB Chair and Committee share authority over ODMH IRB policy and procedure in collaboration with the Chief of the Office of Research and Evaluation.

#### I.B. Institutional Assurance of Compliance

To certify that ODMH complies with these federal regulations, the Office of Research and Evaluation has filed a five-year Institutional Assurance of Compliance with DHHS Regulations with OHRP. The assurance includes a statement of ethical principles and institutional policy, a detailed identification of ODMH responsibilities, ORE general procedures, The Institutional Review Board's policies and procedures, and the general responsibilities of the research investigator. As a part of its assurance, ODMH IRB reviews all research involving human subjects regardless of sponsorship. The current Institutional Assurance of Compliance at ODMH is in effect until \_\_\_\_\_. The Assurance number assigned to ODMH is \_\_\_\_\_ and the IRB Registration Number is 8342.

#### I.C. Jurisdiction

All staff and researchers using ODMH data or hospital patients (human subjects) or any identifiable, private information about human subjects to conduct research are required to have prior approval from the IRB before research is initiated. Projects must be approved by the ODMH IRB regardless of the source of funds. This policy also applies to interns and students who are conducting research at state facilities under the supervision of University faculty. All research proposals must be reviewed by the IRB and no individual other than the IRB Chair or Chief of the Office of Research and Evaluation may exempt a proposal from review.

Research is defined as: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities" (Code of

Federal Regulations, 45 CFR 46.102f)

A Human Subject means: “A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” (Code of Federal Regulations, 45 CFR 46.102f)

**I.D. Composition of the Board**

The IRB is composed of:

1. One Chairman of the Board.
2. At least 5 members of sufficiently diverse backgrounds, including consideration of race, sex, and cultural backgrounds, to promote complete and adequate review of research activities commonly conducted by ODMH and ODMH grantees;
3. Persons who are able to ascertain the acceptability of research applications in terms of institutional commitments, applicable law, and professional standards;
4. One member from each Ohio RPH campus.
5. At least two members who are researchers in the behavioral/social sciences;
6. At least one member whose primary concerns are in non-scientific areas (e.g., law, policy).
7. A member who is not affiliated with or related to a person who is affiliated with ODMH; and
8. The Chief of the Office of Research and Evaluation who serves as a non-voting, ex-officio member of the Committee.

No IRB may have a member participate in the IRB’s initial or continuing review of any project, in which the members has a conflicting interest, except to provide information requested by the IRB. When needed, an IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB Committee. For example, when research involves vulnerable subjects (i.e., prisoners, children, institutionalized individuals, mentally handicapped), the IRB will ensure that at least one board member has expertise in the area or will invite an outside individual to assist in the review. Invited persons provide information and feedback to the IRB; however, they may not vote with the IRB.

IRB members are appointed by the Director annually. The Chief of the Office of Research and Evaluation (or his/her designees) serves as an ex-officio (non-voting) member.

**I.E. Responsibilities of the IRB**

The IRB will:

1. Review and have authority to approve, exempt, require modifications (to secure approval), or disapprove all research activities covered by this policy;

2. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research;
3. Review proposed changes in research activities to insure that changes in approved research doesn't negatively impact patients and safety during the period for which IRB approval has been given, has not been initiated without IRB review and approval;
4. Require that information given to subjects as a part of informed consent is in accordance with policy;
5. Require or waive documentation of informed consent;
6. Notify, in writing, investigators and ODMH of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person or in writing;
7. Monitor additional safeguards when vulnerable subjects (minors, mentally incompetent, prisoners, economically disadvantaged, pregnant females) are involved in the research in order to protect against coercion or undue influence;
8. Conduct its review of research (except when an approved exempt or expedited review procedure is used) at convened meetings where a majority of the members of the IRB are present;
9. Approve research only with the concurrent of a majority of those members in attendance;
10. Report to the institution and OHRP any continuing or serious matters of non-compliance with the IRB's determinations or whether a researcher or research project has been associated with unexpected serious harm to subjects.

#### **I.F. IRB Records**

The Director of Research Integrity will maintain:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany proposals, approved sample consent documents, approved advertising or other solicitations for subjects, progress reports and injuries to subjects;
2. Minutes of all IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution;
3. Records of continuing review activities;
4. Copies of all correspondence between the IRB and investigators;
5. A list of all IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the department (for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant);
6. A compendium of written procedures; and
7. Statements of significant new findings provided to subjects.

Any applicable records shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department at reasonable items and in a reasonable manner. All records will be maintained by the Chief of the Office of Research and Evaluation.

## II. CATEGORIES OF REVIEW AND THE APPLICATION/APPROVAL PROCESS

Specific criteria for IRB approval of research are discussed in more detail in the following sections; however, the following elements are central to IRB decision. The IRB will consider whether:

1. Risks to subjects are minimized;
2. Risks are reasonable in relation to anticipated benefits;
3. Selection of subjects is equitable;
4. Informed consent is sought from each subject; and
5. Informed consent is appropriately documented.

There are five categories of review for projects involving human subjects in research settings, each with its own application process. The categories include:

1. Exempt
2. Expedited
3. Full Board Review
4. Continuing or annual renewal
5. Student Classroom assignments

### II.A. EXEMPT REVIEW

#### II.A.1. Definition of Exempt Categories:

1. Certain types of research are exempt from this policy. According to the Department of Health and Human Services (DHHS) regulations for protection of human subjects in 45 CFR 46.101, research may qualify as exempt if:
  - a. The research is conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
  - b. The research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures or observation of public behavior, unless
    - i. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; or
    - ii. Any disclosure of this information outside the research could reasonably place the subject at risk

of criminal liability or civil liability or be damaging to the subject's financial standing, employability or reputation. "When children are involved in survey or interview procedures or observations of public behavior they are NOT exempt unless the research involves observation of public behavior by children when the investigator(s) do not participate in the activities being observed" [45 CFR 46.401(b)].

- iii. The research involves the use of educational tests, survey or interview procedures, or observations of public behavior when the human subjects are elected or appointed officials or candidates for public office.
- iv. The research involves the use of educational tests, survey or interview procedures, or observations of public behavior and federal statutes require without exception that the confidentiality of the personally identifiable information will be managed throughout the research and thereafter.
- v. The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
  - 1) There are several classifications of research that may involve human subjects but are exempt from IRB's policies and jurisdiction. All of the types of research listed below are exempt and do not require IRB applications or approvals.
    - a) ODMH supervisor, trainer, or intern evaluations;
    - b) Program evaluation research to benefit ODMH and carried out by ODMH administrative officials and/or their designees;
    - c) Projects designed to enhance or improve the quality of services;
    - d) ODMH employee performance evaluations;
    - e) State of Ohio mandated program evaluations;
    - f) Marketing research (designed to market ODMH and its services as a product).

Except for the examples above, all other research involving human subjects MUST complete an application to be deemed exempt. Exempt categories of research do not require a full IRB hearing, but must be reviewed by the IRB Chair or his/her designee. Funding agencies (e.g., DHHS) do not allow investigators to make this determination on their own, nor does the Ohio Department of Mental Health.

The IRB Chair must approve the exempt status of any proposal before the proposed research may proceed and the investigator must receive a letter from the Chief of the Office of Research and Evaluation confirming this decision. There is no such thing as an emergency exemption and no ODMH official other than the IRB Chair may designate research as exempt.

### II.A.2. Application Process

1. If an investigator believes his or her study qualifies as exempt from IRB review, a Form A should be completed. The Form A requires the investigator to discuss the purpose/objectives of the research, the subject population, methods/procedures, experimental design/methodology, and justification for exemption. Submit the completed form, consent forms (if applicable), and any research instruments to the Chief of the ODMH Office of Research and Evaluation via electronic submission to [IRB.application@mh.ohio.gov](mailto:IRB.application@mh.ohio.gov). Application forms and contact information for the Chief of the Office of Research and Evaluation can be found on the ODMH website (<http://www.mh.ohio.gov>). They also are on file at the Office of Research and Evaluation.

Exempt applications may be submitted at any time (i.e., there are no deadlines or specific time frames). Electronic submission is required.

### II.A.3. Review Process

1. The review process typically takes two weeks from the time the application is received by the Chief of ORE. If the proposal is approved by the IRB Chair, the Chief of ORE will send an email notification and a hard copy letter of approval to the principal investigator noting that the research is exempt from the IRB policy. If the information on the application seems incomplete or raises any concerns (e.g., regarding eligibility for exempt status, invasion of the subjects' privacy, or confidentiality of research records), the applicant will receive an Action Form. The Action Form will outline the additional information required and/or the concerns that must be addressed in order to continue to the review process. It also may indicate that the research does not qualify as exempt and ask the investigator to submit an application for either Expedited or Full Board Review.

### II.A.4. Conditions of Approval

1. Once a project is approved as exempt, no further action is needed. There are no annual reviews required for exempt applications.

### II.A.5. Changes to the Research Project

1. If substantial changes are planned, the investigator should submit a new IRB application. For minor changes (e.g., a change in principal investigator, minimal changes in working of the survey instrument, or increasing the sample size from the same sample pool), the investigator must fill out and receive approval of a Form C outlining the modifications. Prior to making any changes that will affect the information given on a previously approved exempt application, the IRB Chair must approve changes and the Form C must be on file with the Office of Research and Evaluation. The Chief of ORE and/or his or her designee will contact the investigator regarding approval of the Form C or to inform the investigator that the changes outlined on the Form C are not acceptable.

## II.B. Expedited Review

### II.B.1. Definition of Expedited Categories

1. Federal regulations and institutional policy allow for expedited review of certain types of research that have been determined to place a human subject at minimal risk in a research setting (45 CFR 46.110 and 21 CFR 56.110).
2. Investigators may apply to the IRB for expedited review if their research falls into one of the nine categories discussed in the following section although the activities listed should not be deemed to be of minimal risk simply because they are included on the list. Inclusion merely means that the activity is eligible for review through the expedited review procedure when the proposed research involves minimal risk to human subjects. Both the Applicability and the Research Categories sections of the regulations need to be considered in order to qualify for expedited review; however, if subjects will be randomized to treatment and control groups, then the study does not qualify for expedited review.

### II.B.2. Applicability

1. The categories in this list apply regardless of the age of subjects, except as noted.
2. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be stigmatizing, unless

reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are not greater than minimal.

3. The expedited review procedure may not be used for classified research involving human subjects. Classified research is defined as research, knowledge of the procedures and results of which, is restricted to individuals with United States government security clearances. The Ohio Department of Mental Health does not approve federal classified research. ODMH will not approve such research contracts for which the identity of the sponsor and the general nature of the research cannot be revealed to the public.
4. Standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of type of review-expedited or convened-utilized by the IRB.
5. Categories one (1) through five (5) pertain to both initial and continuing IRB review.

### II.B.3. Research Categories

1. A very limited number of studies of approved drugs and devices: Clinical studies of drugs and medical devices 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 marketing 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 (1) an investigational device exemption application (21 CFR Part 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

*NOTE: The drug or device must be approved and used exactly according to its labeling. All study procedures other than use of the drug or device must themselves be of minimal risk for the study to qualify for expedited review. Very few studies fit this category.*

2. Blood sampling: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. From healthy, non-pregnant 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, 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.
  - c. Children as defined in the HHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted” 45 CFR 46.402(a).
3. Noninvasive specimen collection: Prospective collection of biological specimens for research purposes by non-invasive means. Examples: (a) hair and nail clippings in a non-disfiguring 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 gumase 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. Noninvasive clinical procedures: 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 give the age, weight, and health of the individual.
5. Use of data or specimens collected for non-research purposes: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research 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 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.

*NOTE: (a) this category refers to materials collected for "non-research purposes." but can be used to cover research materials if the investigator's role is simply to analyze them. That is, if an investigator is receiving materials from colleagues who have separate approval to collect them, and the materials are handled with code numbers and other protections for confidentiality, he or she may apply for expedited review for the analysis; (b) this type of research is exempt from review only if the data collected has no link whatsoever to identifiers (not even a code number).*

6. Use of recordings: Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Low risk behavioral research: Research on individual or group characteristics or behavioral (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.

*NOTE: Only very specific types of behavioral research are exempt from review. Again, there usually must be no link whatsoever to identifiers [not even a code number].*

8. Renewal of inactive research protocols or protocols that are essentially complete: Continuing review of research previously approved by the convened IRB as follows:
  - a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow up of subjects; or
  - b. Where no subjects have been enrolled and no additional risks have been identified; or
  - c. Where the remaining research activities are limited to data analysis.
  
9. Renewal of other minimal risk research protocols: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The IRB Committee must approve any expedited proposal before the proposed research may proceed and the investigator must receive a letter from the Chief of the Office of Research and Evaluation confirming this decision. There is no such thing as an emergency exemption and no ODMH official other than the IRB Committee may grant approval.

#### **II.B.4. Application Process**

Investigators who believe their study qualifies for expedited review should complete a Form B and check the box marked Expedited. The Form B requires the investigator to discuss the purpose/objectives of the research; background and rationale for the study; the subject population; methods/procedures; incentives; risks and benefits; and privacy/confidentiality. The Form B, consent forms, and any special attachments (including questionnaires or surveys if applicable) must be submitted to the Chief of the Office of Research and Evaluation via electronic submission to [IRB.application@mh.ohio.gov](mailto:IRB.application@mh.ohio.gov). Application forms and contact information for the Office of Research and Evaluation can be found at the ODMH website (<http://www.mh.ohio.gov>). They are also on file at ORE. Expedited applications may be submitted at any time (i.e., there are no deadlines or specific time frames). Electronic submission is required.

#### **II.B.4.a. Additional Special Requirements or Attachments to the Application**

If the study involves any of the following items, they must be included in the application packet.

1. (IND) (Investigational New Drug) Number and Investigator's Brochure

When a study involves use of an unapproved drug, or an approved drug for a new use, the investigator must submit an IND number obtained from the FDA, and one copy of the Investigator's Brochure for the drug, which provides background information such as information from animal research and toxicity data.

2. (IDE) (Investigational Device Exemption) Number and Investigator's Brochure

When a study includes an unapproved device, or an approved device for a new use, and a "significant risk" device is involved, the investigator must submit an IDE number obtained from the FDA, and one copy of the Investigator's Brochure for the device. If the investigator believes that the device poses a non-significant risk, FDA regulations allow the option of requesting a "non-significant risk" IDE determination

from the local IRB. The Investigator must submit this request to the IRB with an explanation of why the study should be considered of non-significant risk, and other supporting information. This request and justification should be presented separately or distinctly from the application for approval of the protocol. The IRB will make a determination based on the criteria described in the FDA “Guidance on Significant and Non-Significant Risk Device Studies”. Depending on the circumstances of the study, additional safety or liability assurances may be required on an individual, case-by-case basis.

3. Approvals from other IRBs

Cooperative research projects involve research that involves more than one institution. In these instances, federal law holds each institution responsible for safeguarding the rights and welfare of human subjects and for complying with federal policy; therefore, ODMH IRB applications must be made even if there is another institution conducting a review of the same project.

When a study is being carried out at a non-USA site, approval from other institutional review boards at the foreign site must be sought. The IRB recommends that a copy of the IRB approval be submitted.

4. Questionnaires/Other Instruments

Any questionnaires, tests, survey instruments or data collection sheets which are not standard and well known must be submitted as part of the application. Structured interview questions and outlines for unstructured interviews also must be included.

5. Advertisements/Notices/Recruitment Flyers

The text of any advertisement, video display, notice, sign, brochure or flyer used to recruit subjects also should be included as an attachment.

#### **II.B.4.b. Review Process**

The review process for expedited review typically takes two to four weeks from the time the application is received by the Chief of the Office of Research and Evaluation (provided there are no modifications or clarifications needed to the application).

An expedited review will normally be processed by two or more IRB committee members who will be assigned by the Chief of ORE. Expedited reviews will be rotated among IRB committee members based on expertise and workload. Under certain circumstances, the IRB Chair alone may conduct the expedited review. If both reviewers indicate approval at the expedited level, the IRB Chair will approve the application and the Chief of ORE will send a letter of approval to the principal investigator or the faculty advisor noting that the research has been approved. (In some cases, reviewers may provide feedback regarding their evaluation of the research project that is not related to the approval process. This information is intended only as feedback and the investigator is not required to make modifications to the study.)

If the information on the application is incomplete or raises any concerns (e.g., regarding eligibility for expedited status, invasion of the subjects’ privacy, or confidentiality of research records) on the part of either reviewer, the applicant will receive an Action Form from the Chief of ORE. The Action Form will outline the concerns that must be addressed in order to continue the review process. If the investigator does not agree with the comments of the reviewer or feels that any suggested changes conflict with the investigators vision of the research project, s/he may request a hearing by the full board. Likewise, the Chief of the ORE, the IRB Chair or any reviewer may refer the

application to the Full IRB for review. If the reviewers or the IRB Chair have concerns about an application, they must refer it to the full board for a hearing. An application cannot be denied at the expedited level without a full board hearing.

#### **II.B.4.c. Conditions of Approval**

Approval is valid for one year. At that time, investigators must file a Form C noting the project is complete or request a renewal. (See section on annual review). Projects approved under the expedited process are eligible for continuation and do not have to complete a Full Board Review.

#### **II.B.4.d. Changes to the Research Project**

If substantial changes are planned, the investigator should submit a new IRB application to the Chief of the Office or Research and Evaluation. A new application will be treated in accordance with any other IRB application and the process outlined elsewhere in the policy will apply. Minor changes (e.g., a change in principal investigator, minimal changes in working of a survey instrument, or increasing the sample size from the same sample pool) may be approved by submission of a Form C. The investigator must fill out and receive approval of a Form C outlining modifications prior to making any changes that will affect the information given on a previously approved expedited application. The Form C must be submitted to the Chief of ORE. Once the changes are approved by the IRB Chair, the investigator will receive notification of approval. The Chief of ORE will contact the investigator in writing if the changes outlined on the Form C are not acceptable.

### **II.C. Full Board Review**

#### **II.C.1. Definition of Full Board Review**

This type of application is used for studies that do not meet requirements to be exempt from review or to qualify for expedited review and/or involve more than minimal risk to the subjects and require review by the full IRB committee membership. Please note that the types of research conducted at ODMH usually will not require full board hearings so investigators are encouraged to contact the Chief of ORE prior to submitting a full board application. In most cases, expedited review is possible.

The IRB Chair must approve any full board application before the proposed research may proceed and the investigator must receive a letter from the Chief of ORE confirming this decision. There is no such thing as an emergency exemption and no OMDH official other than the Chief of ORE may provide official notice of the IRB approvals.

#### **II.C.2. Application Process**

Investigators who believe their study qualifies for full board review should complete a Form B and check the box for that category. Consent forms, and any special attachments (including questionnaires or surveys if applicable) must be submitted prior to the full board review. The Form B requires the investigator to discuss the purpose/objectives of the research; background and rationale for the study; the subject population; methods/procedures; incentives; risks and benefits; and privacy/confidentiality. Any special requirements and/or attachments also must be included.

Full Board applications may be submitted at any time (e.g., there are no deadlines or specific time frames). Electronic submission is required for Full Board applications.

### **II.C.2.a. Review Process**

The IRB full-board meets on a monthly basis; therefore, investigators should consult the Chief of the Office of Research and Evaluation to ensure that they are scheduled for a review. The full IRB membership will review applications during their meetings. Every attempt will be made to schedule a meeting to hear these applications within 3-5 weeks from the time the application is received by the Office of Research and Evaluation (provided there are no modifications or clarifications needed to the application).

Votes are taken and recorded at the meeting of the full board after a discussion of a proposal. A quorum (a majority of members present) is required to hear applications and a committee member with primary focus on non-scientific areas must be present. If the majority of the members vote to approve the proposal, it is considered approved at the meeting. The Chief of the ORE will promptly notify the investigators in writing of the decision. If the IRB committee has unanswered questions or concerns about the proposal, a majority vote may result in a request for additional information, clarification, or changes to the application. The Chief of ORE will issue a letter explaining the issues or problems as discussed in the meeting. (These comments also will be reflected in the IRB Committee minutes). The principal investigator must then address a response and/or revise the application in order to obtain approval. The investigator also may request to meet, in person, with the Committee.

On very rare occasions, the IRB may encounter major difficulty in making a risk/benefit assessment, and an outside reviewer may be asked to consider the protocol and provide input based on their specific expertise; however, this reviewer will not be allowed to vote under any circumstances. The IRB Committee also may request the principal investigator to attend a full board meeting to discuss or clarify issues with the application.

### **II.C.2.b. Conditions of Approval**

Approval is valid for one year. At that time, investigators must file a Form C noting the project is complete or request a renewal. Projects approved under the Full Board Review process require an annual review by the full board committee membership.

### **II.C.2.c. Changes to the Research Project**

If substantial changes are planned, the investigator should submit a new IRB application to the Chief of the Office of Research and Evaluation. A new application will be treated in accordance with any other IRB application and the process outlined elsewhere in the policy will apply. Minor changes (e.g., a change in principal investigator, minimal changes in working of a survey instrument, or increasing the sample size from the same sample pool) may be approved by submission of a Form C. The investigator must fill out and receive approval of a Form C outlining modifications prior to making any changes that will affect the information given on a previously approved expedited application. The Form C must be submitted to the Chief of ORE. Once the changes are approved by the IRB Chair, the investigator will receive notification of approval. The Chief of ORE will contact the investigator in writing if the changes outlined on the Form C are not acceptable.

## **II.D. Changes, Annual Review, or Final Reports**

### **II.D.1. Definition of Changes (Minor vs. Major)**

Minor project changes have no impact upon the original goals and protocols outlined in the original application. Minor changes include those that do not adversely alter the overall harm-benefit profile of the study or would not potentially affect the willingness of current subjects to remain or enroll in the study. Examples include: change of project title, minimal changes in wording of a survey instrument, minor grammatical changes to an informed consent

an/or child's assent form, addition or deletion of collaborators and/or co-PIs, change in student advisor, additional sites for the performance of the research (include a letter from the authorized individual for a new location).

Major changes involve significant changes to the research protocol including changes in the purpose or process of the research project. Examples might include changes in: sampling population, survey instruments, interview protocols, administration of a treatment of any kind, and/or the informed consent process. Any research, by definition, that increases the level of risk to the participant relative to the initial application MUST assume that the changes are major.

The initial evaluation as to whether an addendum/modification is major or minor starts with the principal investigator, who should assess the degree of change in procedures and risks. The IRB Chair may change the status of that designation if they deem the designation inappropriate. The IRB Chair must approve proposed changes to the full board application before any modifications may proceed and the investigator must receive a letter from the Chief of ORE confirming this decision. There is no such thing as an emergency exemption and no university official other than the IRB Chair may grant approval.

### **II.D.2 Application Process**

Investigators who believe their changes involve minor modifications should complete a Form C and submit it to the Chief of ORE.

Major modification/change requests require that the investigator complete a new Form B noting the modifications to the project. Investigators should send the new Form B to the Chief of ORE.

As is the case with all other levels of review, forms are available at the ODMH website, or through the Office of Research and Evaluation.

### **II.D.3. Review Process**

The review process for minor changes and modifications typically takes two weeks from the time the application is received by the Chief of the Office of Research and Evaluation (provided that there are no modifications or clarifications needed to the application). The review process for major changes typically takes about three to five weeks.

The IRB Chair will review requests for minor changes. However, unless the proposed minor modification may be deemed to be a major change. Major changes will be reviewed by committee members assigned by the IRB Chair, consistent with expedited review processes. Consistent with that procedure, any reviewer or the IRB Chair may request a full board hearing to review requests for changes. In addition, any major change proposed to an application that was initially approved by a full board hearing will require another full board hearing to approve any modifications.

If a full board hearing is required to hear major changes, the Committee will follow the procedures that govern full board hearings.

### **II.D.4. Definitions of Annual Review**

The Department of Health and Human Services (DHHS), The Food and Drug Administration (FDA) and the Ohio Department of Mental Health require annual review of all projects involving human subjects. The annual review date is the anniversary date that is one calendar year later than the date on the original IRB formal letter of approval.

The investigator must receive a letter from the Chief of the Office of Research and Evaluation stating that the research approval has been renewed prior to the anniversary date or the research must be suspended pending an approved renewal notice. Again, there is no such thing as an emergency approval and no ODMH official other than the IRB Chair may grant approval for the research to continue past the anniversary date.

#### **II.D.5. Annual Review Process**

Investigators are required to complete and submit a Form C to the Chief of the Office of Research and Evaluation at least four weeks before the anniversary date. It is the investigator's responsibility to initiate a renewal application, allowing sufficient time for the review and re-approval process to be completed before the current approval expires. ***If any project activity occurs or continues after the expiration date, the investigator is out of compliance with both federal regulations and ODMH policy.***

Like the forms for initial review of protocols, Annual Review forms are classified as exempt, expedited, or full board reviews and requires different levels of review. The Chief of ORE will review all renewal requests/applications and determine the appropriate level of review. If exempt or expedited review status is granted, the forms will be forwarded to the IRB Chair for approval. The IRB Chair may simply sign off on the Form C provided there have been no changes to the project. ***All IRB applications that were originally approved as a result of a Full Board Hearing also require a hearing of the full committee for renewal. The Chief of ORE will schedule these meetings.***

If the IRB Chair determines if a full IRB review is warranted, e.g. because of the on-going nature of the research or because of major changes outlined in the update, she/he will notify the Principal Investigator in writing and request that a new Form B be completed for review by the full IRB Committee.

#### **II.D.6. Conditions of Approval**

Approval of renewal applications is valid for one year. At that time, investigators must file an additional Form C noting the project is complete or request renewal. Unless major changes have been made and approved (necessitating a new Form B), the anniversary date of the project will always remain the date of the original IRB formal letter of approval.

Projects which are found to be continuing without IRB approval are out of compliance with ODMH policy and federal regulations. In these circumstances a non-compliance report will be sent to the Director of the Ohio Department of Mental Health for further action.

#### **II.D.7. Definitions of Termination/Completion**

Projects are considered completed when the study is officially closed to new participants and follow up, and all data collection is complete. If the investigators continue to actively follow research participants, the study is not considered closed and requires annual renewal. Normally, projects may be considered complete during the process of analyzing data, unless the data contains identifiable private information that can be linked to specific individuals. In these cases, the project is considered complete when data analyses are completed.

Projects are considered terminated if they received IRB approval and are abandoned for any reason (regardless of whether or not the project actually began the research process).

#### **II.D.8. Termination/Completion Process**

The Principal Investigator must complete and submit to the Chief of ORE a Form C within four weeks of

termination/completion of a project. The Investigator should indicate the project is completed or that the project will not be conducted at all by marking the appropriate box on Form C.

For thesis/dissertation research: IRB-approved projects should NOT be terminated until the thesis/dissertation committee has approved and signed off on the final submission.

### **II.E. Class Assignments for Students**

In some instances, students participate in research projects in order to learn about the process of conducting research. These projects do not meet the definition of research as outlined in the IRB policy unless the research is intended to contribute to the generalized body of knowledge in the field. There is a need to ensure that these assignments do not compromise any of the principles outlined in the ODMH policy. It also is essential that students be socialized to the ethical and procedural concerns associated with institutional review practices and the need to protect human subjects.

Student projects may be exempt from IRB review if the assignment meets the criteria outlined below. This procedure for review of student classroom assignments does not include honors projects, theses, or dissertations. These types of research require normal review according to the ODMH IRB policy.

ODMH staff supervising a student may elect to use the procedure outlined in this section of the policy for student projects that meet all the following criteria:

1. The assignment is part of a class and is conducted under faculty supervision;
2. The purpose of the assignment is for students to learn about the process of engaging in research or applying a pedagogical technique as opposed to engaging in research which is intended to be used for publication, formal reports, or presentations at professional conferences;
3. The project is eligible for exempt or expedited review (i.e., no project requiring full board approval may be dealt with under this procedure);
4. The student has completed the on-line training and has filed their certificate of completion with the Chief of ORE (available at <https://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>).

Staff using this procedure must:

1. Submit a Form D to the Chief of ORE indicating the semester, title of class, instructor name and a listing detailing each project completed. Signature of instructors are required certifying that all human subject projects have been met (including informed consent, anonymity, and minimal risk). This form must be approved by the IRB Chair prior to any projects proceeding;
2. Require students to submit the appropriate Form A or B for approval by the Chief of ORE; and
3. Review and approve the exempt and expedited review forms submitted by the student to the instructor.

These files must be maintained for no less than three years by ORE and may be periodically audited by the Chief of ORE and/or his/her designee.

## II.F. IRB Approval Involving Externally Funded Applications

Investigators are encouraged to submit IRB applications prior to securing funding; however, if there is insufficient time to do so, proposals may be submitted with the assurance that IRB approval will be sought and received prior to pursuing any research related activities. In these cases, the researchers must articulate the specific portion of the grant that will require IRB approval in the funding application and provide an anticipated start date for these activities. For example, a researcher might apply for a grant with a funding cycle that begins in January; however, there are no activities that require human subjects' approval until June. From January to June the investigators might be engaged in planning activities, drafting questionnaires, or offering direct services. In these types of cases, the investigator would use the following type of language in the grant application:

Any necessary IRB approvals will be secured prior to engaging in any research involving human subjects. If funded, the project will require IRB approval for (specify purpose here-such as: questionnaires that will be used to evaluate the efficacy off the grant activities). It is anticipated that IRB approval would be secured no later than June 1, 20XX).

When a grant is funded, the Principal Investigator will notify the Chief of the ORE in writing that the grant was approved, the activities requiring IRB approval, and the anticipated start date for IRB activities.

## III. INFORMED CONSENT

### III.A. Purpose of the Consent Document

Informed consent is a process, not just a form. Information must be presented to enable people to an informed and voluntary decision whether or not to participate as research subjects. It ensures respect for people by providing the opportunity for thoughtful consent to ensure that participation is voluntary. The procedures used to obtain informed consent should be designed to educate the subject population in terms that they can understand to ensure that research participants understand the consent they have provided. As a result, the IRB will seek to ensure that the following general requirements of informed consent are satisfied in all studies:

- Informed consent must be obtained prospectively from the participants or their legally authorized representatives;
- 
- Information must be conveyed in understandable language;
- 
- Subjects must be given sufficient opportunity to consider whether they want to participate;
- 
- Consent must be given without coercion or undue influence; and
- 
- Subjects must not be made to give up legal rights or be given the impression that they are being asked to do so.

### III.B. Elements of Consent

Except as provided elsewhere in this policy, no investigator may involve a human subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject 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 subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is

made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

### III.B.1 Basic Elements of Consent

Federal regulations on informed consent stipulate eight basic required elements of consent, and note six additional elements that may be added to a standard consent form when appropriate (see Title 45, Code of Federal Regulations, Part 46.116). The following information shall be provided to each subject when seeking informed consent (except as provided in section IIIC. below):

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 reasonable 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. For research involving more than minimal risk, an explanation as to whether any compensation 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;
7. 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
8. 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.

### III.B.2. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall 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 related to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

### **III.C. Exceptions to Required Elements of Consent**

#### **III.C.1. Public Benefit Exception**

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 above (in Sections III.B.1 and III.B.2), or waive the requirement to obtain informed consent provided the IRB finds the documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in methods or levels of payment for benefits or services under those programs; or (iv) 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.

#### **III.C.2. Other Exceptions**

An IRB also may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above (in Sections III.B.1. and III.B.2.), or waive the requirement 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.

The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

### **III.D. Documentation of Informed Consent**

Except as provided in Section III.E. below, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent outlined previously in this policy (See Section III.B). This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
2. A short form written consent document stating that the elements of informed consent required by this policy have been presented orally to the subject or the subject'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 of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

### **III.E. Exceptions/Waivers for Documentation of Informed Consent**

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.

The IRB will usually waive the requirement of signed consent in the following situations:

1. When the identities of subjects will be completely anonymous if the consent form is not signed, and there is minimal risk involved in the study;
2. When obtaining a signed consent is not appropriate or feasible according to the cultural standards of the population being studied, and there is minimal risk involved in the study;
3. When there is a possible legal, social, or economic risk to the subject entailed in signing the consent form, e.g., for HIV antibody-positive individuals who might be identified as such by signing the consent form.
4. Retrospective chart review or use of pathological specimens where the patients need not be contacted as part of the study, and appropriate precautions to protect the confidentiality of the data are described;
5. Use of extra blood which is taken at the time of a venipuncture being done for clinical reasons; or
6. Use of leftover biological material taken from another study for which consent was obtained.

If an investigator does request a waiver of signed consent, then the application should provide a written justification for doing so and cite one of the above bases for the waiver.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. The IRB is likely to require use of such a written statement, in the form of an information sheet, which includes most or all of the same elements as a consent form, but does not require the signature of the subject.

### III.F. General Information to be Considered when Constructing Informed Consent Forms

Consent forms should be simple and straightforward so that all subjects will have an easily understood form that outlines the proposed research. As such, investigators should consider the following elements when constructing consent forms:

**Reading Level:** For most studies, it is recommended that the consent forms be written at an eighth grade reading level

**Lay Language:** Unless the subjects are themselves medical professionals, scientific or technical terms should either be replaced with or defined in lay language.

**Legal terms:** Legalistic language should not be used. These phrases interfere with a subject's comprehension of the consent form and lend the appearance of a legal document to the consent form. (Examples include: "You hereby agree," "You certify that," "You, the undersigned, do acknowledge that," "You understand that," "You realize that," "You have been told that," or "It has been explained to you that.")

**Proofreading:** The entire form should be carefully proofread for correct spelling and grammar before it is submitted for IRB review.

#### III.F.1. Elements of a Consent Form

When constructing a consent form, the investigator should review the following items and include them when appropriate to ensure they are addressing the elements of consent as outlined by federal law and ODMH Policy. Research participants must be told about the purpose, procedures, risks and benefits of a particular study, the subject's rights in participating in research, the freedom to decline to participate without any jeopardy. If applicable, the alternative treatments available will be explained. The individual will also be given the opportunity to obtain further information and answers to questions related to the study. Sample consent forms are included in Appendix A and are available on the ODMH web site.

**Investigators who are requesting exempt status normally will not need to use a signed informed consent form when the identities of subjects will be completely anonymous and there is minimal risk involved in the study. Investigators in these instances, however should be conscious of the ethical principles guiding the process of informed consent and ensure that they have provided sufficient information to satisfy the basic elements of informed consent (see Appendix A for sample notifications.)** At a minimum, they should either provide a cover letter or introductory remarks (e.g. at the beginning of a survey) that provide: a reference to ODMH and the title of the research project; the identity of the principal investigator(s) and their contact information; an introduction to the study; the aims of the study; a brief summary of the background or reason for the project; a summary of why the individual has been asked to participate in the study; a description of the type of participation requested and any procedures; an outline of any risks; an overview of how confidentiality will be maintained; an discussion of any benefits; a description of any alternatives to participation; a discussion of any costs and/or benefits; and a method of securing additional information or asking questions.

1. **Heading and Title:** Reference to the Ohio Department of Mental Health and notification that a research project is being discussed should be included in the heading of all consent forms. The study title also should be included in the heading of the form. (If the official title is technical and difficult to understand, a simplified non-technical title should be used in addition to the official title.) If a study has more than one consent form, each form should be labeled or titled appropriately, and the same references used within the application, in order to avoid confusion.

Example Heading:

**OHIO DEPARTMENT OF MENTAL HEALTH INFORMED CONSENT FORM**  
**Attitudes toward Cartoon Violence and its Real or Perceived**  
**Impact Upon Children**

2. **Identify Principal Investigator(s):** This section should indicate who is conducting the research. The first and last names of the principal investigator(s) should be used and the investigators identified with titles and department and other pertinent contact information at the beginning of the form, so that it is clear who is carrying out the study.
3. **Purpose and Background:** This section should introduce the study, state the aim of the study, give a brief summary of the background or reason for the project, discuss the number of subjects expected to participate in the study, and explain why the individual has been asked to participate. The reason a person has been asked to participate should be simply but specifically stated (e.g., “because you have tried to quit smoking in the past but have not been successful,” “because you’re undergoing surgery and will be given a general anesthetic,” “because you are a healthy person”) and should not include a discussion of the inclusion/exclusion criteria. If the study is sponsored research, the sponsor should be named.

If an investigational drug or device is being used in the study, this should be mentioned in this section and the drug or device should be named. The name of the drug or device referred in this section should be used consistently throughout the form. This section should not begin with such phrases as “You agree to participate...” since the prospective subject has not yet had a chance to read the form and, thus, could not yet make an informed decision about whether or not to participate.

4. **Procedures:** To emphasize the voluntary nature of participation in research, this section should begin with a phrase like, “If I agree to be in this study, the following will happen.”

Each procedure should then be listed, preferably in the order in which it occurs, and discussed. If the study involves screening procedures, these should be mentioned first and identified as tests that will determine eligibility to continue in the study. The Procedures section should clearly state what will be done to the individual as a result of participation in the study, and, where appropriate, how this differs from standard treatment or what would happen to the individual if he/she did not participate in the study.

When a study involves randomization, it should be described as a study procedure, and the term “randomization” explained in lay language. Information about the probability of assignment to each treatment or condition should be given. Other terms, which might not be familiar to the average layperson (e.g. “placebo”) should be defined the first time they are mentioned in the form or use a lay term.

If a standard medical procedure is being done as part of the study, it should not be referred to as “standard” or “routine,” since this could easily imply that the procedure would be done anyway for

clinical reasons. Rather, what should be conveyed is that this procedure is an extra laboratory test that is commonly done for clinical purposes, but is being done here for research purposes.

If patient records will be reviewed for purposes of the study, this study should be listed as a procedure. Amounts of blood or tissue to be taken for study purposes should be specified, using lay equivalents (e.g., teaspoons, ounces) for metric terms.

The number of times a procedure will be done, the time involved for each procedure, and the total amount of time for participation in the study should be specified. The location(s) where the procedures will be done should also be stated.

5. Risks and/or Discomforts: The risks and/or possible discomforts of all study procedures should be listed and explained in this section. It is usually best to describe the risks of each procedure in a separate point. Risks should be arranged and described according to their severity and the likelihood of their occurrence. Where appropriate, it should be indicated what precautions will be taken to avoid certain side effects or outcomes from occurring, and what will be done should they occur. A statement should be included that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

To the extent possible, consent forms should characterize the likelihood of risks using words like "likely," "frequent," "occasional," and "rare." The first time these words are used in a form they should be defined using percentages, as follows:

Likely events: Expected to happen to more than 50% of subjects

Frequent events: Will probably happen to 10 – 50% of subjects

Occasional events: Will happen to 1 – 10% of subjects

Rare events: Will happen to less than 1% of subjects

For studies involving investigational agents, or experimental doses or combinations of drugs and/or treatments, subject should be warned that there may be as yet unknown risks associated with the drug/ treatment but that they will be advised if any new information becomes available that may affect their desire to participate in the study.

6. Confidentiality: Since one of the risks of participating in research is a loss of privacy, a discussion of confidentiality issues should be included in the Risks section. It should describe briefly how the confidentiality will be protected, i.e., coding of records, limiting access to the study records, not using any individual identifiers in publications or reports resulting from the study.

Food and Drug Administration regulations also require a statement about the extent of confidentiality of records be included in the consent form. For studies involving investigation of drugs or devices, both officials from the sponsoring company and the FDA have at least some limited right to review individual records; subjects in such studies must be forewarned about this intrusion into their privacy.

For all statements regarding confidentiality of research records, it should be kept in mind that there is no legal privilege between investigator and subject as there is between physician and patient or counselor and client. Thus, a guarantee of complete confidentiality, or "strictest confidentiality," should not be given or implied. One should always state instead that confidentiality will be protected "as far as is possible" or "as far as is possible under the law."

NOTE: The one way to protect research records from subpoena is through a Federal Certificate of Confidentiality. More information about this Certificate may be obtained by contacting the federal funding agency (see web-link <http://grants1.nih.gov/grants/policy/coc/index.htm>) or by calling the IRB Compliance Specialist (460-6308). If such a certificate is obtained, it is recommended that the consent briefly discuss the added degree of protection that this certificate provides.

7. **Benefits:** Any potential direct benefits to the subject should be described first, followed by potential general benefits (e.g. the group of patients to which the individual belongs, to medical knowledge, etc.). It is usually recommended that the description of possible direct benefits be qualified with the phrase, "... but this cannot be guaranteed." If there is no direct benefit to the subject anticipated from the study, this should be stated at the beginning of the section.

The FDA recommends that possible benefits such as medical or societal benefits resulting from a research study be considered separately from payment for participation in the study. Thus, the discussion of payment of reimbursement should be separated from the benefits statement and placed in its own separately labeled section.

8. **Alternatives:** This section should discuss the various alternatives to participation in the study. This can be a short statement, but it should make clear the possible choices (e.g., no treatment, standard therapy, other experiential treatments, or some or all of the protocol treatment, but without participating in the study) that are available if the individual chooses not to participate in the study. When alternative therapies are available, brief objective descriptions of their important benefits and risks should be included.

When the only alternative is to decline participation in the study (e.g., if the study involves only normal, healthy volunteers), this need not be mentioned in a separate section, since the individual's right to choose not to participate will be made clear in the last section of the form.

9. **Costs/Financial Considerations:** When there are no costs at all to be charged to the subject, this should be clearly stated in the form. However, a simple statement that there are no costs is usually not sufficient and could be misleading. The more typical situations are that the subject will have to pay for the usual costs of his or her medical care but will not be charged any extra for participating in the study or the cost of the study medication will be covered by the study but the subject will have to pay all other charges.

When participation in the study may result in any costs whatsoever to subjects, clear information must be provided in the consent form regarding these costs. Special attention must be paid to this issue in studies in which the subjects are also patients. In such cases, where individuals may be undergoing various procedures, tests, or hospitalizations that are part of their clinical diagnosis and treatment, and others that are part of the research study, the costs sections of the consent form should clearly distinguish which costs will be charged to the patient or his third party carrier, and which costs will be covered by the study. In addition, when appropriate, a statement should be included, warning subjects that because the therapy is experimental, the insurance carriers may not cover the costs involved.

Whenever substantial costs to the subject are involved (e.g., for many oncology, cardiology, and MRI studies) you may wish to consider referring subjects to a financial counselor. The consent form, then, should state that such a counselor is available and ask that subjects take advantage of this service.

10. **Reimbursement/Payment:** When referring to money that subjects will receive in return for participation in a study, either "reimbursement" or "payment" may be used. However, the term "compensation"

should not be used, since it is used on consent forms to designate compensation for injury. Investigators should avoid connotations of undue influence to participate or that the subject is being employed by the investigator. Rather, the sense should be that subjects will be reimbursed for their time, travel expenses, and the inconvenience of being a research subject. However, unless the subject has actual receipts (e.g., parking, taxi, babysitting), the person is not being reimbursed in the strictest sense of the word, for either accounting or tax purposes.

This section should state the total dollar amount that the subject will be paid for participation in the study, and should give any other relevant information such as pro-rating if a subject does not complete the study, or bonus payment at the end of the study. If appropriate, a payment should be included in this section. Subjects should not be required to complete the entire study in order to be reimbursed and bonus payments for study completion should be modest.

Subjects should be informed how payment will be made (e.g., in cash, by check) and when they will be paid (e.g., immediately after the interview, approximately six weeks after individual completion of the study).

Payments for research participation in excess of certain amounts may be considered taxable income. Subjects who will be paid should be advised in the Reimbursement section that the organization will report this income to the IRS.

If there will be no payment or reimbursement of subjects for the study participation, this information should be so stated in this section.

11. Questions: This section should provide contact information for the investigator(s) in case of questions about the study. At least one permanent name and telephone number of one investigator, usually the principal investigator, must be typed into this section as submitted. Blank lines to be filled in later may be included for additional contact persons. If the principal investigator is a student, the faculty advisor's name and phone number should be included in this section as subjects often wish to contact the person who is supervising the project.

If the person explaining the study and obtaining consent is not the principal investigator, a blank line in this section may be filled in with the person's name, and telephone number, if different, at the time consent is obtained.

12. Tissue and/or blood banking or storage: Some studies include the option to have tissue specimens or blood stored (or banked) for studies that may come available in the future, future diagnostic testing, or other purposes not yet determined. Subjects should have the option to participate in the study whether or not they agree to tissue banking.
13. Consent: This section should state that the subject has been given (not just "offered") a copy of the consent form.

This section should then state the information that participation in research is voluntary, and explain the individual's right to decline to participate, or withdraw from the study at any time. If the subjects are patients, students, or employees, a phrase may be added indicating that refusal or withdrawal will be without jeopardy to status or care.

The investigator may also advise subjects that they may be withdrawn from the study if the investigator deems it in the best interests of the subject or for other reasons that should be specified (e.g., medical interests, failure to keep appointments).

The IRB discourages such wording as “You have read this form and understand it; based on this understanding, you hereby agree to participate,” since this does not guarantee an individual’s comprehension, legally, or otherwise. Rather it is recommended that investigators simply state that if the person wishes to participate in the study, he or she should sign the form; signature will then indicate agreement to participate.

14. Signature Section: Unless waiver of signed consent is approved by the IRB, this section should include lines for the subject’s signature and the date of signature. The consent form also should include a signature line for the specific individual that secured or was present to obtain consent so that subjects have a record of who explained the study to them.

If the study involves subjects who cannot give consent for themselves (e.g., minors, unconscious patients, individuals with Alzheimer’s disease), and the IRB accepts the justification for their inclusion in the study, a separate signature should be obtained for the purpose of third party consent. For studies involving minors, this signature line will be for parent(s) or guardian(s). In other studies where a legally authorized representative will give consent for the subject, an appropriately labeled signature line should be used. Note, only parents, guardians, conservators or those who have power of attorney for health care are so authorized.

If the study involves minors, an assent line also should be included for minors to sign when appropriate.

#### IV. ADVERSE EVENTS REPORT

All investigators conducting research on human subjects must report two types of incidents if there are: 1) any injuries or adverse events associated with the study procedures and/or problems involving the conduct of individuals associated with the study which occur during the course of their research project and 2) any possible breach of human subject protections that an investigator becomes aware of associated with research activities at ODMH conducted by other investigators.

As the standard approval letter for the IRB applications states, “All problems involving risks and adverse events must be reported to the IRB immediately.” Specifically, the following must be reported, in writing:

- All serious adverse events associated with the study procedures,
- Any incidents or problems involving the conduct of the study or participation by research subjects, including problems with the recruitment and/or consent process, and/or
- Any breach of confidentiality or security related to subjects.

The information below is provided to clarify IRB policy regarding reporting of adverse events as well as problems involving the conduct of the study. The “Adverse Event Report Form” (see Form E) should be used for reporting such events. All reports should be signed by the Principal Investigator.

#### **IV.A. Adverse Events that Require a Report**

All serious adverse events associated with the study procedures must be reported. All deaths, whether or not they are directly related to study procedures, must be reported. However, common sense must play a large role in deciding what to report; not every bruise or rash needs to be reported. If there is a question, investigators are encouraged to err on the side of “over-reporting.”

In general, any serious or recurring problem, any unanticipated side effect, any adverse event reported to a study sponsor and/or to the FDA, any adverse event requiring treatment, or any side effect about which a subject is concerned, should be reported to the Chief of the Office of Research and Evaluation.

Any problems involving the conduct of the study or patient participation, including problems with the recruitment and/or consent processes also require reporting. For example, if a person who is contacted, either in writing or in person, about participating in a study becomes upset about the recruitment process, this should be reported.

Any deviations from the approved protocol should be reported in writing. Examples of a more serious nature include incidents of a person being enrolled in a study before signed consent has been obtained, an investigational drug being given prior to signed consent, or a subject being given a higher or lower dose of the drug than stated in the approved protocol.

#### **IV.B. Definition of an Adequate Adverse Event Report**

The ODMH IRB Adverse Event Report Form was created to help ensure that sufficient information concerning an adverse event is submitted. Adverse event reports submitted to study sponsors and/or to the FDA may not be sufficient in that they rarely include an assessment of whether changes in the protocol or consent form should be made as a result of the adverse event.

If a study sponsor sends updated drug or device brochures, safety reports or other summaries of adverse effects please forward to the Chief of the Office of Research and Evaluation (ORE). The Principal Investigator should include an appropriate analysis and assessment.

#### **IV.C. The effect of Reporting an Adverse Event Report**

A report is not an admission of any liability. However, for adverse events, the investigator should make an initial determination as to whether any changes are needed in the discussion of the risks and/or benefits in the consent form. In response to incidents, the investigator may need to re-evaluate the recruitment or consent process and modify existing procedures appropriately.

#### **IV.D. The Review Process for Adverse Events and/or Incident Reports**

The full IRB Committee will review all adverse event reports and/or incident reports in order to re-evaluate the risks/benefits of the study and/or the appropriateness of the recruitment/consent process to determine if any changes should be made in the protocol or consent form. If the investigator has already modified the protocol or consent form in response to these events, the appropriateness of these changes are also reviewed.

The IRB is responsible for continuing review of all human subject research. This is done through the annual renewal process required for any ongoing study. Thus, all reported adverse events should also be included when a renewal application is submitted for the study, so that the IRB may consider renewal of the protocol in light of such information.

Serious adverse events or incident reports are forwarded to the Director of ODMH who must be informed in case of inquiries, institutional liability, or publicity. If the FDA or DHHS is involved, and if the problem is of sufficient magnitude, the appropriate agency officials will be informed. The Chief of ORE will be responsible for notification in all of these instances.

#### **IV.E. The Effect of Failing to Report Adverse Events**

Failure to report adverse events is a breach of the conditions under which IRB approval is given, and could result in suspension or revocation of approval. Suspension or revocation of approval could result in loss of support by funding agencies and loss of right to publish.

#### **IV.F. Incident Reports Related to Research Activities**

The Chief of ORE will conduct an inquiry following any report of possible misconduct related to human research activities that may come from subjects, study personnel, staff, or students/interns. If, for instance, a research project is being conducted without IRB approval, or an improper method of recruiting subjects is being used, or undue influence is being placed upon prospective subjects to participate in a study, the IRB has no means of learning about such situations and rectifying them unless it is informed that they are taking place. Thus, in order to fulfill its obligation to protect human subjects in research, the institution depends upon concerned individuals, including investigators, to inform the Chief of ORE of any possible misconduct related to research activities of which they become aware.

Such incidents are usually reported by telephone or in writing to the Chief of ORE. An inquiry is made to the investigator conducting the research activity, maintaining requested anonymity of the individual submitting the report whenever possible. Depending upon the outcome of the initial inquiry, information about the incident may be forwarded to the Director of ODMH for appropriate resolution.

### **V. THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)**

Federal guidelines establish the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes [45 CFR §§ 164.501, 164.508(f), 164.512(i)]. The Privacy Rule outlined in HIPAA defines the means by which individuals/human research subjects are informed of how medical information about them will be used or disclosed, and their rights with regard to gaining access to information about them when such information is held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time, ensuring that researchers continue to have access to medical information necessary to conduct vital research.

In the course of conducting research, researchers may create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose PHI for research with individual authorization, or without individual authorization under limited circumstances.

All research involving health information and/or records of the same should complete a Form G and attach it to any relevant IRB proposal.

#### **V.A. Disclosure with Authorization by the Research Subject**

The Privacy Rule permits researchers to use and disclose PHI for research when participants authorize the use or disclosure of information about themselves. Typically, a research participant's authorization will be sought for clinical trials and some research involving records. In these instances, specific elements must be included in the informed consent form.

**V.A.1. Informed Consent under HIPAA**

Certain language is required to ensure HIPAA compliance with respect to informed consent and PHI. This language is reproduced in the Authorization Template attached in the Appendix. This template must be inserted into the confidentiality section of the informed consent form exactly as written in the Appendix.

A valid authorization for the release of PHI for research also must contain the following required elements in the informed consent form:

1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful manner.
2. The name of the covered entity or person(s) authorized to make the requested use or disclosure;
3. The name or other specific identification of the person(s) or entities, which may include the covered entity itself, to whom the covered entity may make the request for use or disclosure;
4. An expiration date and a signature and date;
5. The authorization must be written in plain language;
6. If the authorization is executed by a legal representative authorized to act for the individual, a description of his/her authority to act for the individual must be specified as well as the relationship to the individual.
7. A statement that the individual acknowledges that he/she has the right to revoke the authorization except to the extent that information has already been disclosed under the authorization;
8. A statement that the individual acknowledges that information used or disclosed to any entity other than a health plan or health care provider may not longer be protected by the federal privacy law.
9. A description of the purpose(s) of the requested use or disclosure;
10. A statement that the individual may inspect or copy the protected health information to be used or disclosed; and
11. A statement that the individual may refuse to sign the authorization.
12. Consent forms for actual or potential subjects in a research study must be retained for at least six years from the date permission is granted.

**V.B. Research Use: Disclosure Without Authorization by the Research Subject**

There are four circumstances that allow researchers to use and disclose PHI for research purposes without authorization by research subjects. These are:

1. Waiver of authorization through an IRB or Privacy Board.
2. Review of PHI preparatory to research.

3. Research involving a decedent's information
4. Use involving limited data sets

*All of these situations require IRB approval.*

### **V.B.1. Application Process for Disclosure of PHI Without Authorization by Research Subjects**

All applications for disclosure of PHI without authorization by research subjects will require a full board hearing. At such time the IRB will consider the type of PHI which is being considered for waiver and whether the investigators have met the criteria for waiver outlined in the following sections. Normal procedures for full board hearings will be used in hearing waiver applications (see Section II.C.). Investigators should submit applications to the Chief of ORE. Application forms and contact information for the Chief of ORE can be found at the IRB Website (<http://www.utc.edu/irb>). Electronic submission is required.

The IRB full-board meets on a monthly basis; therefore, investigators should consult the Chief of ORE to ensure that they are scheduled for review. Every attempt will be made to schedule a meeting to hear these applications within 3 – 5 weeks from the time the application is received by the Chief of ORE (provided there are no modifications or clarifications needed to the application). The Chief of ORE will notify the applicant in writing of all decisions. The IRB approval letter will include the identification of the IRB and the date on which the waiver of authorization was approved.

A covered entity is permitted to disclose PHI for research purposes without a written authorization from the research subject if approval is obtained from the IRB. A covered entity also may use or disclose PHI without individuals' authorizations for the creation of a research database, provided they have documentation that an IRB has determined that the specified waiver criteria were satisfied.

#### **V.B.1.b. Criteria to Determine if a Waiver is Authorized**

A waiver of authorization application form is attached in the Appendix (Form F). The investigator must provide information about the research study that enables the IRB to determine that three requirements are satisfied:

1. There must be no more than minimal risk to the privacy of individual subjects based on the presence of the following elements:
  - a. An adequate plan to protect the identifiers from improper use and disclosure;
  - b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law);
  - c. An adequate written assurance that the PHI will not be reused or disclosed to any other person or entity (except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure is permitted without authorization).
2. It must not be practicable to conduct the research without the waiver of alteration of the authorization requirement; and
3. It must not be practicable to conduct the research without access to and use of the PHI.

**V.B.1.c. Documentation Required to Secure a Waiver**

An investigator may use or disclose PHI for research purposes pursuant to a waiver of authorization by the IRB based on adequate documentation of all of the following:

1. The use or disclosure of PHI involves no more than minimal risk to the individuals;
2. The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;
3. The research could not practicably be conducted without the alteration or waiver;
4. The research could not practicably be conducted without access to and use of the PHI;
5. The privacy risks to individuals who PHI is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;
6. There is an adequate plan to protect the identifiers from improper use and disclosure;
7. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research or justification for retaining the identifiers or such retention is otherwise required by law; and
8. There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except as required by law for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this subpart.

Investigators seeking a waiver of authorization for PHI disclosure without consent of subjects must complete a Form F and submit it to the Chief of ORE who will schedule a full board review.

**V.B.2. Reviews Preparatory to Research**

Investigators may review PHI without authorization to prepare a research protocol (i.e., limited to designing a study and/or determining the feasibility of completing a study). Neither recruitment nor patient contact is considered preparatory activity. Under this provision of the regulations, the investigator must provide the following assurances to the covered entity:

1. The investigator shall not remove any protected health information from the covered entity;
2. The use/disclosure of PHI is sought solely for the purpose of preparing a research protocol; and
3. The PHI for which use or access is sought is necessary for research purposes.

In addition, reviews preparatory to research must not involve making copies of PHI or making notes that include PHI. However, medical records of interest to investigators in preparing a study may be flagged for future reference.

Investigators seeking to use PHI in preparation for research must complete a Form H and submit to the Chief of ORE who will schedule a full board review. Investigators must certify that they have complied with the provisions outlined above.

### V.B.3. Research on Decedent's Information

An investigator is not normally required to secure IRB approval for research involving deceased individuals, unless other living persons (such as family members) could be affected (i.e., genetic markers of certain diseases). If the research has no impact upon other living individuals, the investigator may use PHI of deceased individuals without authorization from decedent's estate. If the research has an impact upon other living individuals, IRB review is necessary. Investigators who are not sure about this determination should err on the side of caution and submit an application for IRB approval.

Qualifications under this provision require that the researcher provide the covered entity:

1. Assurance that the use or disclosure is being sought solely for research on the PHI of decedents;
2. Documentation, at the request of the covered entity, of the death of such individuals; and
3. Assurance that the PHI is necessary for research purposes.

Investigators may use PHI in research on decedent's information if the investigator certifies they have met the provisions outlined above. Investigators must submit a Form I and submit it to the Chief of ORE who will schedule a full board review.

### V.B.4. Research Involving the Use of Limited Data Sets

Regulations permit covered entities to use or disclose PHI for research purposes without subject authorization if the use or disclosure only involves a "limited data set" and the covered entity enters into a data use agreement with the investigator. A "limited data set" is PHI that excludes the following direct identifiers of the individual and of relatives, employers, or household members of the individual subjects:

1. Names (individual, employer, relatives, etc.)
2. Postal address information, other than town or city, state and zip code
3. Telephone numbers
4. Fax numbers
5. Social Security numbers
6. All elements of dates (except for years)
  - Birth Date
  - Admission Date
  - Discharge Date
  - Date of Death
  - Ages >89 and all elements of dates indicative of such age
7. E-mail addresses
8. Web Universal Resource Locator (URLs)
9. Internet Protocol (IP) address numbers
10. Medical Record numbers
11. Health Plan Beneficiary numbers
12. Account numbers

13. Certificate/License numbers
14. Vehicle Identifiers and Serial numbers (e.g., VINs, License Plate numbers)
15. Device Identifiers and Serial numbers
16. Biometric Identifiers (including finger and voice prints)
17. Full face photographic images and any comparable images
18. Any other unique identifying number characteristic, or code

A limited data set may, however, include other indirect identifiers, especially dates of birth, treatment, discharge, or death.

Investigators may use a limited data set for research without subject authorization if they have completed a Data Use Agreement with the entity releasing the data. Investigators in this situation should complete a Form J and provide it and the Data Use Agreement to the Chief of ORE. (Normally, the entity releasing the data should provide the Data Use Agreement; however, if the entity does not have such a form the investigator should contact the Chief of ORE for examples of acceptable forms.)

### **V.C. Use of De-Identified Data in Clinical Research**

Under HIPAA, PHI can be released freely if it does not contain “individually identifiable information” as defined in the regulations. PHI is not individually identified if the specified eighteen identifiers have been removed and the covered entity has no reasonable basis to believe that the information alone or in combination with other information can be used to identify the individual. Research using De-Identified Data is exempt from the IRB requirements. To be exempt, none of the subject identifiers identified in the can be reviewed or recorded by the research team. In order to de-identify PHI, investigators must comply with one of the two following procedures.

#### **V.C.1. Procedures to De-Identify Datasets**

HIPAA regulations allow researchers to use two procedures to de-identify data sets so that they may conduct research without securing waivers. These procedures are:

##### **V.C.1.a. Use of Statistician**

Researchers may obtain the services of a person with appropriate experience and knowledge who applies generally acceptable statistical and scientific principles and methods to determine that the information is not individually identifiable; there is a very small risk that the information could be used by itself or in combination with other available information by the anticipated recipient(s) to identify the subject with the information; and who will document the methods and results in making such a determination.

##### **V.C.1.b. Removal of Identifiers**

Investigators may ensure that all identifiers specified in the regulations [at 45 CFR 164.514] have been removed and certify that they have no actual knowledge that the information remaining could be used alone or in combination with other information to identify the patient who is the subject of the information.

Investigators who choose to “de-identify” PHI data must complete and submit a Form J to the Chief of ORE who will schedule a full board review. The IRB shall determine if the PHI has been adequately de-identified in accordance with the privacy laws. If so, the IRB will notify the researcher in writing that the research has been approved as a de-identified health information data set. The investigator may then use the IRB approval notice to access and create the de-identified database.

**V.D. Investigators' Responsibilities Maintaining Databases**

If an investigator maintains a database containing PHI, then the investigator has an obligation to ensure that the use and disclosure of PHI is in compliance with policies. The investigator is responsible for:

1. Maintaining reasonable security for the database, including physical security and access control;
2. Controlling and managing the access, use and disclosure of PHI, including verifying appropriate IRB approvals and patient authorizations; and
3. Ensuring that any PHI in the database used for treatment or payment purposes must be a duplicate and the original must be included in the patient's medical record.

In order to use a research database containing PHI, one must have authorization or a waiver from the IRB.

**V.E. Studies and Databases initiated prior to HIPAA Regulations**

Studies involving subjects that have enrolled prior to April 14, 2003 will not be required to re-consent. Investigators may continue to collect and use data gathered from these subjects and no new documentation is required. Investigators must receive annual IRB renewals for these studies.

**V.F. Research Participant's Right of Access to Research Records**

With few exceptions, the Privacy Rule gives patients the right to inspect and obtain a copy of health information about themselves that is maintained in a "designated record set." A designated record set is a group of records that a covered entity uses to make decisions about individuals, and includes a health care provider's medical records and billing records, and a health plans enrollment, payment claims adjudication, and case or medical management record systems. Research records or results maintained in a designated record set are accessible to research participants unless one of the Privacy Rule's permitted exceptions applies.

One of the permitted exceptions, however, applies to PHI created or obtained by a covered health care provider/researcher for a clinical trial. The Privacy Rule permits the individual's access rights in these cases to be suspended while the clinical trial is in progress, provided the research participant agreed to this denial of access when consenting to participate in the clinical trial. In addition, the health care provider/researcher must inform the research participant that the right to access PHI will be reinstated at the conclusion of the clinical trial.

Ohio Department of Mental Health and Addiction Services

# Institutional Review Board Guidelines

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**OR&E** Office of Research & Evaluation  
Ohio Department of Mental Health  
and Addiction Services

**Ohio**

Department of Mental Health and Addiction Services.

John R. Kasich, Governor  
Tracy J. Plouck  
Orman Hall

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