

GUIDELINES FOR DETERMINING “EXEMPT” AND “EXPEDITED” ELIGIBILITY

Instructions and guidelines: Study the application and make sure that every requirement is documented within the application. If a fact is not documented in writing, then it cannot be counted upon for a determination. Extrapolation or a phone conversation with the investigator is not sufficient confirmation. **MARK EVERY CRITERION THAT IS SATISFIED TO REACH YOUR DETERMINATION.**

A. MINORS – In Wisconsin, virtually everyone under the age of 18 years (even young mothers) is considered a minor. In other states and other countries, other laws will apply. If any minor subjects are involved in a proposed project (or: medical records of minors; biospecimens of minors), do not review the application and send it back to the IRB Coordinator with a note flagging the involvement of minors.

B. RISK LEVEL – “Minimal risk” means that “the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in the daily life, or during the performance of routine physical or psychological examinations or tests.” Here the standard should be the daily life or routine physicals of a normal healthy person. The “minimal risk” threshold cannot increase just because the subject is sick and faces greater-than-average risks due to illness or expected interventions.

There is no risk level for a study lower than “minimal risk” (per federal regulations). When an application makes the claim of “no risk” or “less than minimal risk,” the reviewer must point out the relevant risks (perhaps privacy or confidentiality risks, in the case of behavioral or social science research) and require the investigator to correct the application.

C. FDA-REGULATED STUDIES – FDA regulations do not provide for any EXEMPT categories of research, and do not provide for any waivers of “informed consent” or “documentation of informed consent.” A study is FDA regulated if it involves a drug, device, biologic, or in vitro diagnostic device; or if the data might be used to support an FDA application.

D. VULNERABLE POPULATIONS – Studies that include the following vulnerable groups are NOT eligible for EXEMPT status:

- Minors (children or adolescents)
- Decisionally impaired persons
- Nursing home residents
- Homeless people
- Prisoners

E. RECRUITING AND SCREENING ACTIVITIES – All recruiting and screening activities are (by regulation) integral to the research activity, and so screening ordinarily requires prior informed consent and HIPAA authorization.

Recruiting rules

- All recruiting materials (e.g., posters or flyers, TV or radio ads in their broadcast form, internet solicitations) must be reviewed and approved by the IRB prior to use.
- In response to advertising or “Dear Colleague” letters to other physicians, it is permissible for potential subjects to contact the research team and submit to verbal or written screening procedures to determine eligibility without signing a consent form or HIPAA authorization, so long as:
 - The screening procedure has been detailed in the IRB application;
 - The screening procedure does NOT involve physical examinations, biological testing (e.g., blood or urine samples), or clinical procedures; and
 - All information about the identity of the potential subject and his/her screening results are destroyed when he/she proves ineligible or declines to sign a study consent form and HIPAA authorization.
- It is not permissible for other physicians to provide the research team with the names, contact information, and/or eligibility information of potential subjects without first obtaining a signed consent form and HIPAA authorization -- or -- a documented waiver of these requirements from the IRB.
- It is not permissible for any member of the study team to review clinical or medical records to identify potential subjects without first obtaining a signed consent form and HIPAA authorization – or – a documented waiver of these requirements from the IRB. An investigator may review his/her own patient records and discuss study participation with these patients, but the investigator does not have the same privilege with respect to other patients seen on the same service or in the same clinic or practice group. The test of “legitimate access to patient records for research screening purposes” is – Would the patient in question recognize the physician or nurse as their personal caregiver?

Screening rules

- Study applications should make a clear distinction between “screening” and “study procedures,” even though the eIRB application may not ask (in its present form) for a clear distinction. “Screening procedures” determine whether or not a potential subject is eligible for a study, and should be completed before enrolling subjects in the study. Sometimes second-level screening procedures (e.g., does the subject tolerate withdrawal from prior medication during a washout period?) are embedded in the study design; this discussion is focused on initial screening to determine eligibility.
- There are three permissible ways to screen potential subjects:
 - The Investigator may seek the patient’s consent before beginning any screening activity, using a consent document that includes a description of the screening procedures and the entire study;

- The Investigator may seek the patient’s consent before beginning any screening activity using an abbreviated “screening consent document” that is simpler and different than the “study consent form.” A screening consent document should identify the purpose of the overall research, describe all the screening procedures, and make it clear that the subject will have an opportunity to learn more about the study before deciding whether or not to participate. This approach is not appropriate when the screening procedure involves physical examination, biological testing (e.g., blood or urine samples), or clinical procedures; or
- The Investigator may ask the IRB to waive informed consent and waive HIPAA authorization for recruitment purposes. In this case, the reviewer should always be clear that the two waivers are issued ONLY “for recruitment purposes,” and do not extend to the study itself. These waivers are not necessary if subjects will be contacting the research team in response to advertisements or referral. Waivers are not appropriate when the screening procedure involves any physical examination, biological testing (e.g., blood or urine samples), or clinical procedures. In some situations, recruitment waivers for screening medical records may be judged inappropriate (e.g., cancer patients, AIDS patients).

Also: Expedited reviewers should not grant recruitment waivers for screening medical records unless the Investigator documents that he/she also has administrative approval for access to the records in question. The investigator should submit a letter from the administrative head of any hospital, department, division, program or clinic overseeing those records, providing administrative approval for record access.

Pools of potential subjects for future recruitment

- Investigators may NOT save names, contact information, and screening data to build a database of potential subjects for future studies unless the Investigator has received IRB approval for this purpose, and developed a banking consent form and HIPAA authorization (see IRB Banking policy).

F. IDENTIFICATION AND DE-IDENTIFICATION OF DATA -- There are four possible relationships that identifiers can have with data, images, tracings, or biospecimens:

- a. IDENTIFIED data (data/specimens are labeled with an identifier)
- b. CODED data (data/specimens are labeled with a code that the PI can decode)
- c. DE-IDENTIFIED data (data/specimens are labeled with a code that is unknown to the investigator at the time of the study, but is capable of being decoded with the appropriate key)
- d. ANONYMIZED data (no linkage exists, potential or otherwise, between data/specimen and their source)

How can a reviewer decide whether the research plan satisfies the criteria for Exemption category # 4?

- The investigator should provide a list of variables or a data coding sheet, so the reviewer has sufficient information to rule out the presence of any identifiers; and
- It is the investigator's responsibility to detail all the steps and details of any proposed de-identification process in writing, so the reviewer can determine whether an exemption is appropriate.

Studies using CODED data (as defined above) and most using DE-IDENTIFIED data (as defined above) are NOT eligible for Exemption.

Data may be considered “de-identified” for purposes of Exemption category # 4 only if one of the following conditions are met:

- The investigator receives data in truly anonymized form and no other party has the potential to re-identify data (i.e., no code key exists anywhere in the world);
- The investigator receives data stripped of all identifiers but bearing a code, AND none of the parties with the potential to re-identify data have a work or student relationship with MCW/Froedtert/Children's Hospital/Zablocki VA, AND the investigator files with his/her IRB application an agreement, signed by the investigator and all persons holding code keys, attesting that the investigator and his/her staff will never have access to any identifiers;
- The investigator plans to access identified information, images, tracings, or biospecimens from existing clinical (not research) records, AND plans to strip the data of all identifiers quickly and irreversibly, so that the data becomes anonymized and incapable of re-identification. “Quick stripping of identifiers” means that less than 24 hours will lapse from the point of access to completion of the anonymization process for that record.

What is an IDENTIFIER, exactly?

All the following variable types are considered **identifiers** of the individual, including those referring to relatives, employers, or household members of the individual; presence of any one example in the dataset dictates that the reviewer must consider the **entire dataset to be identified**:

- Names;
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census –
 - The geographical unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, service or treatment date,

date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

- Telephone Numbers;
- Fax Numbers;
- Electronic Mail Addresses;
- Social Security Numbers;
- Medical Record Numbers;
- Health Plan Beneficiary Numbers;
- Account Numbers;
- Certificate/License Numbers;
- Vehicle Identifiers and Serial Numbers, including License Plate Numbers;
- Device Identifiers and Serial Numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) Address Numbers;
- Biometric Identifiers, including Finger and Voice Prints;
- Full Face Photographic Images and any Comparable Images; and
- Any other unique identifying number, characteristic, or code.

EXEMPT CATEGORIES

1. “Normal educational practices” (Exemption 1 may apply if all three conditions are satisfied, unless the subjects are minors, decisionally impaired persons, nursing home residents, homeless persons, or prisoners):

- a. Research takes place entirely within an established or commonly accepted educational setting (i.e., within officially recognized school or training program); and
- b. Research involves only normal educational practices (i.e., instructional strategies or techniques, curricula); and
- c. There are not any other elements to the research study (beyond educational practices).

Note: Research studies involving medical students, residents, fellows, or continuing medical education for physicians often do not qualify for this exemption. A study that involves evaluation of a radically new instructional strategy or use of random assignment to different instructional methods is not exempt, because the methods employed deviate from normal educational practices.

Necessary permissions and HR policy restrictions:

Unless the research is exempt-eligible and is conducted by the official curricular instructor, the investigator must document having obtained permission from the relevant Medical College administrator:

- For MCW medical students:
 - Richard Holloway, Ph.D., Associate Dean for Student Affairs

- For MCW residents and fellows:
 - Mahendr Kochar, M.D., Senior Associate Dean, Graduate Medical Education
- For continuing medical education:
 - Michael O'Donnell, Director, Continuing & Professional Education

In addition, there are MCW Human Resources policies that limit access to students, residents, fellows, faculty, and employees for research purposes. These policies forbid non-exempt research with persons in all these categories during school or working hours; and forbid research by an investigator who is in a supervisory or evaluative relationship (broadly defined) with persons in these categories. To explore the possibility of an exception to these MCW HR policies, contact the Assistant Dean for Clinical Research (dclark@mcw.edu).

2. Interviews, questionnaires, surveys, and focus groups (Exemption 2 may apply if the following conditions are satisfied, unless the subjects are minors, decisionally impaired persons, nursing home residents, homeless persons, or prisoners):

- a. The research is limited to educational tests, survey procedures, interview procedures, or observation of public behavior (no other data); and EITHER
 1. The information obtained is recorded in such a way that human subjects cannot be identified (directly or through identifiers or through codes) -- OR --
 2. While the information obtained is identified or coded, disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

Note: Exemption 2 reflects concern about protecting the subject's privacy and avoiding any risks associated with breach of confidentiality. The IRB should consider all potential risks associated with research on sensitive and private aspects of the subject's behavior (e.g., sexual preferences, substance abuse, or illegal conduct) in determining exempt status. For the examples given, there may be more than minimal risk involved even in the absence of subject identifiers. Such surveys often contain invasive questions that may cause the subject to experience emotional distress or discomfort while answering them. Thus, although the research technically qualifies for exemption because there are no study identifiers, the potential risks of the research may negate the exemption.

[Exemption # 3 is almost never used]

4. Chart review and biospecimen studies (Exemption 4 may apply if the following conditions are satisfied, unless the subjects are minors, decisionally impaired persons, nursing home residents, homeless persons, or prisoners):

a. Research involving 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.

“Existing” means that all the records or biospecimens were created before the study application date. The investigator cannot use records or specimens created after that date, and cannot “refresh” the database with clinical follow-up records dated after the study application date.

“Publicly available” means available to the general public, or available to any investigator (whether or not there is a fee).

“Recorded so that subjects cannot be identified” – see exempt guidelines above, “**F. IDENTIFICATION AND DE-IDENTIFICATION OF DATA.**”

[Exemptions # 5 and 6 are almost never used]

EXPEDITED CATEGORIES

Instructions:

- First, decide whether the study presents any more than minimal risk to human subjects; “any greater than minimal risk” disqualifies a study from Expedited consideration. Study activities should not be deemed “minimal risk” simply because they are included on the list of Expedited-type studies. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- Second, decide whether the study procedures fit entirely within one or more of the following categories.

The Expedited categories 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 damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, -- unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Remember that the standard requirements for informed consent (or its waiver, alteration, or exception) apply to Expedited review studies.

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met:

- (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with

the use of the product is not eligible for expedited review.)

- (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- (b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging,

doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for 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. This listing refers only to research that is not exempt.)

- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.**

- (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

- (8) 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) 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.**

EXEMPT OR EXPEDITED? DIFFERENTIAL DIAGNOSIS

A. Surveys, interviews, and questionnaires

1. If there are any MINOR SUBJECTS, the application will be forwarded to the Children's Hospital IRB.
2. If any subjects are decisionally impaired persons, nursing home residents, homeless persons, or prisoners, the study cannot be exempted.

3. Would disclosure of the subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation? If yes, perform expedited review and do not exempt the study. If yes, be very reluctant to waive the informed consent process.

B. Existing data or biospecimens

1. If there are any MINOR SUBJECTS, the application will be forwarded to the Children's Hospital IRB;
2. If any subjects are decisionally impaired persons, nursing home residents, homeless persons, or prisoners, the study cannot be exempted.
3. If there is any intention to collect information or specimens directly from subjects, or to collect new information or specimens after the date of the IRB application, or to seek follow-up information on subjects, the study cannot be exempted.
4. Perform an expedited review -- unless the data may be considered "de-identified" for purposes of Exemption category # 4 because the proposal satisfies one of the following conditions:
 - The investigator receives data in truly anonymized form and no other party has the potential to re-identify data (i.e., no code key exists anywhere in the world);
 - The investigator receives data stripped of all identifiers but bearing a code, AND none of the parties with the potential to re-identify data have a work or student relationship with MCW/Froedtert/Children's Hospital/Zablocki VA, AND the investigator files with his/her IRB application an agreement, signed by the investigator and all persons holding code keys, attesting that the investigator and his/her staff will never have access to any identifiers; or
 - The investigator plans to access identified information, images, tracings, or biospecimens from existing clinical (not research) records, AND plans to strip the data of all identifiers quickly and irreversibly, so that the data becomes anonymized and incapable of re-identification. "Quick stripping of identifiers" means that less than 24 hours will lapse from the point of access to completion of the anonymization process for that record.

EVERYTHING ELSE...

(...BEYOND THE EXPEDITED AND EXEMPT CATEGORIES)

Instructions: If the application satisfies the criteria for expedited review, the reviewer must also ensure that the study satisfies the criteria for:

- General approval any research;
- Appropriate informed consent process and document – OR – waiver of informed consent process or documentation; and
- Appropriate HIPAA authorization – OR – waiver of HIPAA authorization

Criteria for IRB approval of research (45 CFR 46.111.a):

In order to approve a research proposal by expedited review or full convened committee review, the IRB shall find and document that all of the following requirements are satisfied:

- (1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result directly from the research.
- (3) Selection of subjects is equitable.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
- (5) Informed consent will be appropriately documented.
- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- (8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, mentally disabled persons, or

economically or educationally disadvantaged persons), additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Criteria for IRB approval of informed consent document (45 CFR 46.116.a,b)

In order to approve a consent document, the IRB shall find and document that all of the following information will be provided to each subject:

- (1) A statement that the study involves **research**.
- (2) An explanation of the **purposes** of the research.
- (3) An explanation of the expected **duration** of the subject's participation.
- (4) The approximate **number of subjects** involved in the study.
- (5) A description of the **procedures** to be followed, and identification of any procedures that are experimental.
- (6) Any **additional costs** to the subject that may result from participation in the research.
- (7) A description of any reasonably **foreseeable risks or discomforts** to the subject.
- (8) A description of any **benefits** to the subject or to others that may reasonably be expected from the research.
- (9) A disclosure of **appropriate alternative procedures** or courses of treatment, if any, that might be advantageous to the subject.
- (11) A statement describing the extent, if any, to which **confidentiality** of records identifying the subject will be maintained.
- (12) 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.
- (13) An explanation of **whom to contact for answers** to pertinent questions about the research and research subjects' rights.
- (14) Any anticipated circumstances under which the **subject's participation may be**

terminated by the investigator without regard to the subject's consent.

- (15) The **consequences of a subject's decision to withdraw** from the research and procedures for orderly termination of participation by the subject.

Criteria for waiving or altering informed consent procedure (45 CFR 46.116.d)

***IMPORTANT:** If any member of the study team or if any person assisting the study team interactst with subjects (in person, or by phone, or by email), or have potential access to subjects (i.e., patients seen in clinic or surgery earlier the same day that biospecimens are collected), there are virtually no grounds for waiving the requirement to obtain informed consent.*

In order to approve alteration or waiver of the requirements to obtain informed consent, the IRB must find and document that all of the following requirements are satisfied:

- (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; [Note: “practicable” refers to a continuum ranging from “do-able” to “impossible,” with “how difficult?” being the operative question; Investigator convenience or preference is not relevant here] and
- (4) Whenever appropriate, the subjects will be provided with **additional pertinent information** after participation.

***IMPORTANT:** If the Investigator seeks waiver or alteration of the requirements to obtain informed consent, then the Investigator will almost always need a parallel “waiver of HIPAA Privacy Rule authorization.” See criteria for this below.*

[Note: Since FDA regulations do not permit waiver of informed consent or waiver of documentation of informed consent, these waivers should never be invoked for FDA-regulated studies]

“Provenance of data,” or how was the data first created or obtained? When an investigator petitions for “waiver of the informed consent procedure,” the reviewer must consider “provenance.” If the medical information or biospecimens were created

or archived for clinical purposes, and reside within the MCW complex (including Froedtert Hospital and Children’s Hospital of Wisconsin), the reviewer may consider a waiver. If the information or biospecimens were created or archived for a research study, however, the reviewer should not consider a waiver unless: (a) the investigator can document that all subjects provided informed consent for their data to be used in “future, unspecified research;” or (b) the data are registered as “Bank” under the IRB Banking Policy. If the data do not reside within the MCW complex, the investigator must document that he/she has approval to access that data from the corresponding institution’s IRB or senior administrator.

Genetic studies almost invariably evoke the IRB Banking Policy, because – even in situations where a specific genetic analysis is proposed – investigators usually intend to save some of the biospecimen or genetic material for “future, unspecified research.” Per the Banking Policy, specimens or genetic material may NOT be collected for “future, unspecified research” unless subjects are presented with two separate consent choices – one for the immediate study (assuming there is one) and one for “future, unspecified research.” If a subject opts to participate in a specific study but declines participation in a genetic data bank, the investigator must state clearly that specimens will not be saved for re-use.

“Banking:” Per the IRB Banking Policy, information or specimens or genetic material may NOT be archived for “future, unspecified research” unless subjects are presented with two separate consent choices – one for the immediate study (assuming there is one) and one for “future, unspecified research.” If a subject opts for the first and declines the second, the Investigator must provide a clear, auditable system for distinguishing between subjects who have and have not opted to participate in the banking activity.

Until special instructions about “banking consent forms” and “banking study applications,” **do not review and approve any application that entails “banking.”** Contact one of the IRB Analysts for assistance.

Criteria for waiving documentation of informed consent (45 CFR 46.117.c)

In order to approve waiver of the requirement to obtain a signed consent form from all subjects, the IRB must find and document that all of the following requirements are satisfied:

- (1) 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) 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.

In cases in which the documentation requirement is waived, the IRB may still require the investigator to provide subjects with a written statement regarding the research.

[*Note: Since FDA regulations do not permit waiver of informed consent or waiver of documentation of informed consent, these waivers should never be invoked for FDA-regulated studies*]

Criteria for waiving or altering HIPAA authorization to use, create, or share protected health information

IMPORTANT: *If the Investigator seeks waiver or alteration of the requirements to obtain informed consent, then the Investigator will almost always need a parallel “waiver of HIPAA Privacy Rule authorization.”*

IMPORTANT: *“Protected health information” refers to all health-related information, even if that information is not related to a clinical diagnosis or treatment. Most MCW-related community surveys of normal subjects, for example, collect health information (health knowledge, health habits, smoking, alcohol intake, sexual behavior, etc.).*

IMPORTANT: *The only segment of the MCW/Froedtert community NOT bound by the HIPAA Privacy Rule is -- the Center for AIDS Intervention Research (CAIR). CAIR studies that do not access Froedtert inpatients or outpatients are free from the requirements for HIPAA authorization or waiver.*

In order to approve waiver of the requirement to obtain HIPAA authorization from all subjects, the IRB must find and document that all of the following requirements are satisfied:

- (1) The use or disclosure of the Protected Health Information (PHI) involves **no more than minimal risk** to the privacy of individuals;
- (2) The investigator has documented the three following plans or assurances:
 - a. An adequate **plan to protect health information identifiers** from improper use and disclosure;
 - b. An adequate **plan to destroy identifiers at the earliest opportunity** consistent with conduct of the research (absent a health or research

justification for retaining them or a legal requirement to do so);

c. Adequate **written assurances that the PHI will not be reused or disclosed** to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule;

(3) The research could not practicably be conducted without the waiver or alteration; and

(4) The PHI sought is necessary to the conduct of the research.
