Establishment of a Quorum

- **>50% of voting membership** present.
  - For example, an IRB of 10 must have 6, not 5.
  - For example, an IRB of 9 must have 5.
- **At least one non-scientific member** present.

- In-person or through bi-directional communication (speaker/videophone).
- No email/fax/proxy votes.

- **Does anyone have a conflict of interest?**
  - Must leave the room during deliberations and voting.
  - Not counted towards a quorum (i.e. different from "abstaining", as those who "abstain" are eligible to vote but choose not to; those with a conflict are not eligible to vote).
- **Did somebody leave the room?**
  - Re-establish if you still have a quorum.

Checklist For Meeting Minutes

- **Date** of Meeting.
- **Voting Members Present/Absent** and Guests (including whom/**when an alternate member replaces a voting member**, if applicable).
- Members listed in minutes **match those listed in current roster**.
- **Separate deliberations, actions, and votes** for each protocol (no block voting).
- **Exactly what was discussed/approved** (i.e. protocol with version number/date, informed consent with version number/date, list of other documents etc.).
- A written summary of the **discussion of controverted issues and their resolution** (not just a summary of the protocol but specifically the issues germane to human subject protection).
- **How various criteria for approvals were met** (or not met).
- The **basis for requiring changes** in or disapproving research.
- Votes indicate **# For, # Against and # Abstaining** (i.e. not "unanimous" or just "motion passed")**.**
- Notation that those with a **conflict of interest were absent from the room** during deliberations and voting.
- If approved, **how long the protocol was approved for** (i.e. one year, six months etc.).
- For contingent approvals**, how will the changes be verified.**
- List of **expedited reviews** (if any) since last meeting
- Informational items/**training** activities.

Eight Criteria Required to Approve Research

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 from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. **Selection of subjects is equitable**. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. **Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45CFR46.116/21CFR50.
5. **Informed consent will be appropriately documented**, in accordance with, and to the extent required by 45CFR46.117/21CFR50.27.
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, handicapped, 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**. *(NOTE: FDA has additional criteria for children. OHRP has additional legal criteria for Protections for Pregnant Women, Human Fetuses, Neonates, Prisoners and Children. An OHRP governed study is essentially either 1) research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency or 2) if you have a Federal-Wide Assurance and you chose the option to apply your FWA to all studies, regardless of funding source. Federal and State regulations are the minimum protections for vulnerable populations and the IRB may desire additional protections for these populations or determine other populations as requiring additional protections as well.)*

Source: 45CFR46.111, 21CFR56.111 (Note, items in red are 45CFR46 (OHRP) only and items in blue are 21CFR56 (FDA) only)

Informed Consent (Placemat 1 of 3)

Required Elements of Informed Consent

1. A statement that **the study involves research**;
2. An explanation of the **purposes of the research**;
3. The expected **duration of the subject's participation**;
4. A **description of the procedures** to be followed;
5. Identification of **any procedures which are experimental**, including a description of administration of any study drugs;
6. The **probability for random assignment** to each of the protocol's arms (i.e. research group, placebo group, control group etc);
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** which may reasonably be expected from the research;
    i. Even if the benefit is solely limited to a sense of helping the public at large, it must still be mentioned.
    ii. Payments or other reimbursements to the subject are not considered to be expected benefits.
    iii. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
9. A disclosure of appropriate **alternative procedures or courses of treatment**, if any, that might be advantageous to the subject;
10. A statement describing the extent, if any, to which **confidentiality of study data identifying the subject will be maintained**;
    i. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) has certain language required to disclose information for research purposes. This information may be utilized in a separate form or combined with the consent form. In the event a separate form is not used, the elements required by that form are to be included in this informed consent document.
    ii. If the investigational product is governed by the FDA, **then this section must note the possibility that the Food & Drug Administration may also inspect the records**.
11. For research involving more than minimal risk (which includes risk of non-physical injury), an explanation as to **whether any compensation is available if injury occurs** and, if so, what it consists of and who will be responsible for paying, and where further information may be obtained;
12. For research involving more than minimal risk (which includes risk of non-physical injury), **an explanation as to whether any medical treatment available** if injury occurs and, if so, what it consists of and who will be responsible for paying, and where further information may be obtained;

(Continued on Next Page)

Informed Consent (Placemat 2 of 3)

Required Elements of Informed Consent (Continued)

13. An explanation of i)whom to contact for answers **to pertinent questions about the research**; ii) whom to contact **for questions concerning research subjects' rights**; and iii) whom to contact **in the event of a research-related injury to the subject**;
    i. All three areas must be addresses in the document.
    ii. One person cannot be the contact for all three areas. There must be at least two names (e.g. Primary Investigator for area 1 and IRB contact for areas 2 and 3) with local telephone numbers (or toll free for those out of the area) for contacts to answer questions in these areas.
14. A statement that **participation is voluntary;**
15. A statement that **refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled** (NOTE: use of that exact phrase is preferred as opposed to "not affect your treatment at this facility" or other phrase that may imply other limitations);
16. A statement that the subject **may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled** (NOTE: use of that exact phrase is preferred as opposed to "not affect your treatment at this facility" or other phrase that may imply other limitations);
17. Information that is given to the subject or the representative shall be **in language that is understandable to the subject or the representative**;
18. **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;
19. **For applicable clinical trials (see FDA guidance), this EXACT statement (NO DEVIATIONS ALLOWED)**: *"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*

Additional Elements. When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure **may involve risks to the subject, or to the embryo or fetus, if the subject is or may become pregnant,** which are currently unforeseeable;
2. Anticipated **circumstances under which the subject's participation may be terminated by the investigator** without regard to the subject's consent;
3. Any **costs to the subject** that may result from participation in the research, including procedures or services not covered by insurance and copayments and deductibles;
4. The **consequences of a subject's decision to withdraw from the research and procedures for orderly termination** of participation by the subject;
5. A statement that **significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided** to the subject;
6. The **approximate number of subjects to be involved in the study**;
7. For studies involving remuneration to subjects, the form shall have **BOTH the amount and schedule of remuneration**.

Informed Consent (Placemat 3 of 3)

Waiver of Some or All of Elements of Informed Consent

1. **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.

Waiver of Documentation of Informed Consent

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.

Waiver of HIPAA Authorization

1. The use or disclosure of the PHI involves **no more than minimal risk* to the privacy** of individuals based on, at least, the presence of the following elements:
   i. An **adequate plan to protect health information identifiers** from improper use and disclosure.
   ii. 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) **AND**
   iii. 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.
2. The research **could not practicably be conducted** without the waiver or alteration.
3. The research **could not practicably be conducted without access to and use of the PHI**.
4. Required Documentation of IRB Approval of a Waiver: The IRB must provide the Principal Investigator specific documentation of its approval of a HIPAA Waiver. The documentation must include:
   i. The name of the IRB or Privacy Board (not the names of individual members of the board);
   ii. The date on which the waiver was approved;
   iii. The signature of the IRB or Privacy Board chair, or other member designated by the chair;
   iv. A statement that the IRB or Privacy Board has determined that the waiver satisfies the required criteria;
   v. A brief description of the PHI that the IRB or Privacy Board has determined is necessary for research purposes; and
   vi. A statement that the waiver has been reviewed and approved under either normal or Expedited Review procedures and that all applicable procedures were followed.

***"Minimal risk"** means the probability and magnitude of harm or discomforts anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests of healthy individuals.*

Requirements of a HIPAA Authorization

An Authorization differs from an informed consent in that an Authorization focuses on privacy risks and states how, why, and to whom the PHI will be used and/or disclosed for research. An informed consent, on the other hand, provides research subjects with a description of the study and of its anticipated risks and/or benefits, and a description of how the confidentiality of records will be protected, among other things. An Authorization can be combined with an informed consent document or other permission to participate in research. Whether combined with an informed consent or separate, an Authorization must contain the following specific core elements and required statements:

- Authorization Core Elements:
  - **A description of the PHI to be used or disclosed**, identifying the information in a specific and meaningful manner.
  - The names or other specific identification of the person or persons (or class of persons) **authorized to make the requested use or disclosure**.
  - The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
  - A description of **each purpose of the requested use or disclosure**.
  - Authorization **expiration date or expiration event** that relates to the individual or to the purpose of the use or disclosure (**"end of the research study" or "none" are permissible for research**, including for the creation and maintenance of a research database or repository).
  - **Signature** of the individual **and date**. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.
- Authorization Required Statements:
  - A statement of the individual's **right to revoke his/her Authorization and how to do so**, and, if applicable, the exceptions to the right to revoke his/her Authorization or reference to the corresponding section of the covered entity's notice of privacy practices.
  - Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on Authorization, **including research-related treatment** and consequences of refusing to sign the Authorization, if applicable.
  - A statement of the **potential risk that PHI will be re-disclosed** by the recipient. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.
- The authorization must be written in **plain language**.
- The facility **must provide the individual with a copy** of the signed authorization.

Special Documentation for Device Studies

Significant Risk (SR) vs. Non-Significant Risk (NSR) Device Determination At Initial Review

1) The sponsor of a proposed study makes an initial determination of SR or NSR. Significant Risk Device studies can only be conducted under an FDA approved Investigational Device Exemption (IDE). If a sponsor classifies a study as SR, the sponsor is responsible for obtaining FDA approval for the use of the device in the study.
2) Required of the IRB at all initial reviews of devices. **The risk determination is based on the proposed use of the device in an investigation and not on the device alone.**
    i. A Significant Risk ("SR") Device Study is defined as a study of a device that:
        i. Is intended for use as an implant and presents a potential for serious risk to the health, safety or welfare of the subject; or
        ii. Is used in supporting or sustaining human life and presents a potential for serious risk to the health, safety or welfare of the subject; or
        iii. Is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health and presents a potential for serious risk to the health, safety or welfare of the subject; or
        iv. Otherwise presents a potential for serious risk to the health, safety or welfare of a subject.
    ii. A Nonsignificant Risk ("NSR") Device Study is one that does not meet the definitions for a Significant Risk study. NSR device studies should not be confused with the concept of minimal risk.
3) *If the IRB agrees with the sponsor's initial assessment of NSR status,* the submission of an IDE application to the FDA is unnecessary. The IRB proceeds to review the study, applying requisite criteria for review and approval.
4) *If the IRB disagrees with the sponsor's initial NSR assessment*, it informs the Investigator and the sponsor in writing, and the sponsor must notify the FDA that a SR determination has been made and submit an IDE application.

When Does Research With A Significant Risk (SR) Device NOT Need an IDE for Human Studies?

- A legally marketed device when used in accordance with its labeling; OR
- A diagnostic device if it complies with the investigational use labeling requirements and if the testing:
    - is noninvasive;
    - does not require an invasive sampling procedure that presents significant risk;
    - does not by design or intention introduce energy into a subject; and
    - is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure; OR
- Consumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) [that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510(k)] AND if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

Do you have a copy of the FDA's IDE approval letter from the Sponsor/investigator?

Humanitarian Use Devices (HUDs) / Humanitarian Device Exemption (HDE)

Note: An HUD is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year. Humanitarian Device Exemption (HDE) approval is the FDA's approval process for HUDs.

- IRB Approval For The **Treatment Use** of HDEs
  - **Initial IRB approval should be performed at a convened IRB meeting** (i.e. NOT via expedited review).
  - The IRB does not need to review and approve individual uses of an HUD, but rather the IRB may approve use of the device as it sees fit. That is, **the IRB may approve use of the HUD without any further restrictions, under a protocol, or on a case-by-case basis**.
  - IRBs **may approve the use of the device for a period of time, not to exceed one year**. In some higher risk cases, IRBs have approved HUDs for a specific number of patients and have required a summary report before approving the use in additional patients.
  - Continuing review should follow the usual requirements and may be conducted using the expedited review procedures unless the IRB determines that full board review should be performed (**FDA believes that the expedited review procedures are appropriate for continuing review** since the initial review would have been performed by the full board and use of the HUD within its approved labeling does not constitute research).
  - Because an HDE provides for marketing approval, **use of the HUD does not constitute research or an investigation which would normally require consent from the study subjects**.
- IRB Approval For The **Research Use** of HDEs:
  - Sometimes a physician or HDE holder may develop a research protocol designed to collect safety and effectiveness data to support the existing use of the device. In that case, an **IDE is not needed if the research is within the approved labeling; however, IRB approval for the investigational study must be obtained** before the research may begin. Informed consent must also be obtained from the subjects participating in the study. If the research is for a **new use, the IDE regulation must be followed and IRB approval for the research activity must be obtained.**
  - Approving the "use" of a HUD/HDE for diagnosis and treatment does not mean the IRB approved the use of the HUD/HDE in a clinical investigation. Essentially, the collection of safety and efficacy information for research purposes for the HDE approved indication OR the clinical investigation of a new indication for the HUD may require 2 separate IRB approvals.

De-Identified Data

(De-Identified Data does not need Individual Authorization or IRB Waiver of Authorization to be Used/Disclosed)

- **OPTION 1:** The "Safe Harbor" option may be achieved by eliminating the following fields:
  - Names.
  - All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, 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 geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
    - The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
  - All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge 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.
  - Facsimile 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 fingerprints and voiceprints.
  - Full-face photographic images and any comparable images.
  - Any other unique identifying number, characteristic, or code however a covered entity may assign to, and retain with the health information a code or other means of record identification if that code is not derived from or related to the information about the individual (i.e. Initials) and could not be translated to identify the individual. The covered entity may not use or disclose the code or other means of record identification for any other purpose and may not disclose its method of re-identifying the information.

The covered entity also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information.

- **OPTION 2:** The covered entity may obtain certification by "a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable" that there is a "very small" risk that the information could be used by the recipient to identify the individual who is the subject of the information, alone or in combination with other reasonably available information. The person certifying statistical de-identification must document the methods used as well as the result of the analysis that justifies the determination. A covered entity is required to keep such certification, in written or electronic format, for at least 6 years from the date of its creation or the date when it was last in effect, whichever is later.

"Limited Data-Set" Requirements

(A "Limited Data-Set" does not need Individual Authorization or IRB Waiver of Authorization to be Used/Disclosed)

Requirement #1: Removal of the Following Fields

- Names
- Postal address information, other than town or city, state, and ZIP Code
- 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 fingerprints and voiceprints
- Full-face photographic images and any comparable images

Requirement #2: A written "Data Use Agreement", even with employees, stating the following:

- Specific permitted uses and disclosures of the limited data set by the recipient consistent with the purpose for which it was disclosed (a data use agreement cannot authorize the recipient to use or further disclose the information in a way that, if done by the covered entity, would violate the Privacy Rule).
- Identify who is permitted to use or receive the limited data set.
- Stipulations that the recipient will
  - Not use or disclose the information other than permitted by the agreement or otherwise required by law.
  - Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the covered entity any uses or disclosures in violation of the agreement of which the recipient becomes aware.
  - Hold any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the data use agreement with respect to the information.
  - Not identify the information or contact the individuals.

Exemption From IRB Review

[Note: To save IRB resources for more higher risk studies, federal law allows for exempt determinations to be done outside of the IRB meetings by individual(s) designated by the institution. In accordance, HCA policy allows its institutions to designate individual(s) by name, role or position (which cannot be the investigator or other person with a financial conflict of interest) to make exempt determinations. These determinations must state the criteria met as indicated below. Also, any HCA facility may rely on the written exempt determination made by the corporate Responsible Executive for Clinical Research.]

Research protocols that fit exclusively within one of the following categories may be exempt from IRB review. *Federally funded studies that involve prisoners, fetuses, pregnant women or human in vitro fertilization do not fall into these categories nor does studies of investigational therapies governed by the FDA.*

1. Research conducted in established or commonly accepted **educational settings**, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving 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; AND
    ii. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; AND
    iii. For studies involving children, observation of public behavior is not eligible for Exempt Status if the investigators participate in the observed behavior.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), **survey procedures**, **interview procedures, or observation of public behavior** that is not exempt under paragraph (b) above, **if**: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. 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.
5. Research and **demonstration projects** which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate or otherwise examine: (i) 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.
6. **Taste and food quality evaluation** and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Services of the U.S. Department of Agriculture.

Expedited Review (For Studies of No Greater Than Minimal Risk*) (Placemat 1 of 2)

[Note: Expedited Reviews are done by the Chair or their designee (without a conflict of interest) between meetings. The board does not participate in them but must be informed of any approvals via this mechanism at the next proximal meeting. The Expedited Reviewer documents which of the below criteria was met.]

"Minimal risk" means** the probability and magnitude of harm or discomforts anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests of healthy individuals.*

1. Clinical studies of drugs and medical devices only when one of the following is met:
    - i. **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.)
    - ii. **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:
    - i. 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
    - ii. 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.
3. Prospective **collection of biological specimens for research purposes by noninvasive means**. Examples:
    - i. Hair and nail clippings in a nondisfiguring manner;
    - ii. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
    - iii. Permanent teeth if routine patient care indicates a need for extraction;
    - iv. Excreta and external secretions (including sweat);
    - v. 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;
    - vi. Placenta removed at delivery;
    - vii. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
    - viii. 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;
    - ix. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
    - x. Sputum collected after saline mist nebulization.

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Expedited Review (For Studies of No Greater Than Minimal Risk*) (Placemat 2 of 2)

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:
    i. 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;
    ii. Weighing or testing sensory acuity;
    iii. Magnetic resonance imaging;
    iv. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;
    v. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research not otherwise exempt from IRB review **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).
6. Collection of **data from voice, video, digital, or image recordings** made for research purposes.
7. Research not otherwise exempt from IRB review 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.
8. NOTE: Humanitarian Use Devices (HUD/HDE) cannot receive initial approval via expedited review.
9. NOTE: **Minor changes** to previously approved research may also be considered by Expedited Review, but only if the minor change is requested during the period for which approval is authorized (i.e., the study is not yet due for reapproval). ***"Minor changes"* are defined as not affecting the relationship of likely subject risk to benefit relied upon to approve the protocol; or the rights, safety, or welfare of the human subjects involved in the investigation.**

Eligibility Criteria for Expedited Review of Request for Reapproval (Continuing Review)

A request for reapproval (Continuing Review) may, in general, only be reviewed by Expedited Review only if the initial review was eligible for Expedited Review. In the following limited situations, Expedited Review may also be used.

1. The research is **permanently closed to the enrollment** of new subjects, **all subjects have completed all research-related interventions** and the research remains active **only for long-term follow-up of subjects**; OR
2. Where **no subjects have been enrolled and no additional risks have been identified**; OR
3. Where the **remaining research activities are limited to data analysis**; OR.
4. Continuing review of research, not conducted under an Investigational New Drug application or Investigational Device Exemption, where the above categories 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.

Special Documentation for Pediatric Studies

Assigned To One of Four Risk Categories	# Parents Consent Required
1) Research not involving greater than minimal risk	1 or both parents[1]
2) Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects	1 or both parents[1]
3) Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition	Both parents required[2]
4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (thus needing approval from the FDA/DHHS Secretary).	Both parents required[2]

[1]*Consistent with State law*
[2] *Unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child if consistent with State law*

Assent of Child

- Adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent and whether/how assent must be documented. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.
- Waiver of Assent
  - The assent of the children is not a necessary condition for proceeding with the clinical investigation if the IRB determines:
  - The capability of some or all of the children is so limited that they cannot reasonably be consulted
  - The intervention or procedure involved in the clinical investigation holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the clinical investigation.
  - Other circumstances where the IRB finds and documents that:
    - The clinical investigation involves no more than minimal risk to the subjects;
    - The waiver will not adversely affect the rights and welfare of the subjects;
    - The clinical investigation could not practicably be carried out without the waiver; and
    - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Wards of the State

- Children who are wards of the State or any other agency, institution, or entity can be included in clinical investigations only if such clinical investigations are: (1) Related to their status as wards; or (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
- If the clinical investigation is approved, the IRB must require appointment of an advocate for each child who is a ward.
  - The advocate will serve in addition to any other individual acting on behalf of the child as guardian or in loco parentis.
  - One individual may serve as advocate for more than one child.
  - The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the clinical investigation.
  - The advocate must not be associated in any way (except in the role as advocate or member of the IRB) with the clinical investigation, the investigator(s), or the guardian organization.