

Investigator Handbook

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Scope and Purpose of the IRB:

The University of Texas Health Science Center at San Antonio (HSC) has established three Institutional Review Boards (IRBs) responsible for the review and approval of all [human research](#) conducted by faculty, staff, and students, regardless of the location of the research

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activity, or source of funding to foster high ethical standards in the conduct of research and to assure that uniform criteria are applied to protect the human subjects who take part in research.

The IRB is the central element of the HSC's Human Research Protection Program (HRPP). The HRPP encompasses all of the institution's entities that contribute to the mission of protecting the rights and welfare of participants who take part in Health Science Center research. (See [HOP 7.2.1.](#))

All new human research (including research thought to be [exempt](#)) must be submitted to the Office of the IRB (OIRB). The OIRB is responsible for performing an administrative review and forwarding the research to the IRB for review as appropriate.

The HSC has been issued a [Federalwide Assurance](#) (FWA00005928) that signifies the HSC's agreement with the Department of Health and Human Services ([DHHS](#)) that all human research will be reviewed by a properly constituted IRB. The HSC's Federalwide Assurance covers the five schools of The University of Texas Health Science Center at San Antonio and UT Medicine (formerly University Physicians' Group).

IRB's review of research includes new studies ([initial review](#)), re-approval of previously approved research ([continuation review](#)) and modifications ([amendments](#)) to currently approved research. Other issues reviewed by the IRB include reports of: possible unanticipated problems involving risks to subjects or others ([UPIRSO](#)), allegations of [noncompliance](#) with the regulations or policies that govern human research, and complaints. (See [HOP 7.2.2.](#) for a description of the IRB responsibilities).

The HSC also serves as the [IRB of record for all human research](#) conducted at several other [affiliated](#) institutions including: the University Health System (UHS), the South Texas Veterans Health Care System (STVHCS), the University of Texas at San Antonio, the Southwest Foundation for Biomedical Research, and the Southwest Research Institute.

In addition, [limited IRB Authorization Agreements](#) have been established with other institutions that allow the HSC IRB to review a specific subset of human studies. Currently, the agreement with Christus Santa Rosa Health Care (CSRHC) covers (a) HSC faculty, (b) intramural studies conducted by CSRHC staff, and (c) CSRHC Family Practice Residents; (2) UT Austin's agreement covers faculty of Graduate School of Pharmacy assigned to the HSC campus; (3) Wilford Hall Medical Center's (WHMC) agreement covers the Children's Oncology Group research, (4) Baptist HealthCare covers HSC faculty research.

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The IRB reviews research in accordance with current Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations, and with the Good Clinical Practice Guidelines. The IRB charter is established under the HSC Handbook of Operating Procedures (HOP) [HOP 1.6.6](#).

The IRB also serves as the HSC privacy board, acting upon requests for waivers or alterations of the [authorization](#) requirement under the Privacy Rule for uses and disclosures of [PHI](#) for research studies, in compliance with the privacy rules defined in the Health Insurance Portability and Accountability Act ([HIPAA](#)).

Institutional Review Boards

The HSC currently operates three IRBs. Each board is capable of reviewing all types of business items (i.e., new studies ([initial review](#)), re-approval of previously approved research ([continuation review](#)) and modifications ([amendments](#)) to currently approved research, reports of possible unanticipated problems involving risks to subjects or others ([UPIRSO](#)), allegations of [noncompliance](#) with the regulations or policies that govern human research, and complaints). **IRB-1** and **IRB-3** focus on review of new studies (initial review) and **IRB-2** focuses on re-approval of previously approved research ([continuation review](#)).

The Office of the IRB (OIRB)

The OIRB is the administrative support office for the IRB and although many of the office's responsibilities overlap with those of the IRB, the OIRB is separate from the IRB. The office staff provides the administrative support for the IRB, serves as the liaison or communication center between each Board and the investigators, study staff and officials and committees of the institution. The OIRB has the administrative responsibility of documenting the reviews and actions taken by or on behalf of the IRB and that the human research activities approved by the Board were approved in compliance with federal regulations and guidelines and with institutional policy.

Who do I call with questions about Human Research?

Please address all questions regarding human research or IRB actions to the OIRB.

Contact the OIRB Office, either in person in room 2.500U of the HSC Dental Building, by telephone at 567-2351 or e-mail: IRBMAIL@uthscsa.edu. The staff will answer your questions and do all that is possible to facilitate the review process.

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What needs IRB review?

All [human research](#) must be reviewed and approved by the IRB (or a designated reviewer) before the research is started. Human research is defined by the Department of Health and Human Services (DHHS) and the Food and Drug Administration. Each department's definition of human research is unique and both must be considered collectively to determine whether the research is subject to IRB review and approval.

The IRB policy [Determining Whether an Activity is Research Involving Human Participants](#) provides guidance on how these definitions are applied. In addition, the IRB provides a [Human Research Worksheet](#) to assist investigators determine whether the research needs IRB review.

All modifications to previously approved research must be reviewed and approved by the IRB except where necessary to eliminate apparent immediate hazards to the subject is needed to remove an immediate harm. The IRB policy on [Modifications and Amendments](#) provides further guidance.

All requests to continue research (re-approval) nearing the end of the current approval period must be submitted using a [progress report form](#) in sufficient time to allow review and re-approval before the current approval period expires. The IRB policy [Continuation Review](#) provides further guidance.

All unanticipated problems involving risks to subjects or others ([UPIRSOs](#)) must be promptly reported to the IRB. The IRB policy on [UPIRSOs and Unanticipated Adverse Device Effects](#) provides further guidance.

All incidents involving [noncompliance](#) with the regulations governing human research or the IRB requirements to conduct research must be reported to the IRB. The [IRB policy on Noncompliance](#) provides further guidance.

Who Needs HSC IRB Approval?

All [employees](#) or [agents](#) of the HSC who are [engaged in human research](#) must obtain approval from a HSC IRB prior to starting any research activities. Contact the OIRB for clarification of this policy.

For South Texas Veterans Health Care System (STVHCS) employees, the VA requires IRB approval for research activities determined to be [VA Research](#). Contact the [VA R&D Service](#) for clarification of this policy.

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FACULTY, STAFF, and STUDENTS

IRB review is required of faculty, staff, and students who are [engaged](#) in human subject research conducted on or off-campus.

Students engaged in human subject research must have a faculty member as an advisor under whose supervision the research will be conducted.

Please note that when an employee of any type (faculty or staff, full time or part time, permanent or temporary), or a student conducts research at an institution that has its own IRB, approval is may be required from **both** the IRB at the site of the study and from the HSC IRB. HSC faculty, staff and students are required to obtain HSC IRB approval if the research is within the course and scope of their university duties/roles or is conducted in the facilities of any of the institutions that the HSC IRBs serve. In addition, written documentation of the other IRB's approval (or appropriate alternative) is required. The requirement applies equally to research done outside of the United States, carried out by someone affiliated with an institution served by the HSC IRBs. The IRB policy on [Cooperative Off-Site Research](#) provides further guidance.

HSC CLINICAL FACULTY

Research conducted by clinical faculty (paid or unpaid) is subject to review by the appropriate HSC IRB if the research is within the course and scope of their university duties or is conducted in the facilities of any of the institutions that the HSC IRBs serve.

Private physicians, who have clinical or adjunct faculty appointments, often perform important ancillary roles in research [sponsored by the HSC](#), such as: recruitment and preliminary screening of patients, follow-up of patients, adjustment of medications, performance of tests, and collection of blood/urine samples. In cases where a HSC faculty member serves as the principal or a co-investigator in the conduct of the research, a HSC IRB will review the protocol in the standard manner.

Where primary responsibility is to be assumed by the clinical or adjunct faculty member for the conduct of a study in his or her private office or in an outlying hospital or other facility, the research **may** be reviewed by the appropriate HSC IRB if all of the following conditions are met:

1. The department chair certifies that:
 - the research is within the course and scope of university duties;
 - the clinical faculty member is an active participant in the University's programs;
 - the clinical faculty member has agreed to conform to all department and university policies governing research including review and approval by the IRB of the proposed research; and

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- the standards of the private office or other facility where the research is to be conducted are sufficient to assure that adequate facilities and expert professional care are available for a subject in the event of difficulties;
- 2. Approval of the IRB (or administration if there is no IRB) of the institution where the research is to be conducted is documented; *and*
- 3. The investigator:
 - understands his or her responsibilities relating to the conduct of human research and agrees in writing to abide by all requirements imposed by the HSC IRB;
 - certifies that he or she has professional liability insurance which is applicable to the study being performed; and
 - agrees to indemnify and hold harmless the University of Texas System, the System Board of Regents, employees, legal representatives, successors and assignees of the University and the System against all loss or liability, damage, cost or expense arising out of claims and/or suits seeking damages for injury, disease, and other bodily harm to persons, or damage to property, alleged to have been caused directly or indirectly as a result of the research.

Clinical and Adjunct faculty, who are not full time and wish to serve as investigators for research, must submit an appropriate Clinical Investigator Agreement. [[See sample of Investigator Agreements in Forms Table.](#)]

NON-EMPLOYEES

Individuals who are not employees of the institutions regularly covered by the HSC IRBs, but who wish to conduct research involving patients, staff, students or facilities of any of the institutions regularly covered by the HSC IRBs, must have their proposed research reviewed by the appropriate HSC IRB, must obtain HSC IRB approval before beginning the study.

Individuals who are not employees of the institutions regularly covered by the HSC IRBs but who wish to serve in the capacity of an investigator on a research study for which the principal investigator is affiliated.

How are new human research studies reviewed by the IRB (initial review)?

Some human research is [exempt](#) from IRB review and may be reviewed using an **administrative** process. These “exempt” human research studies are reviewed by a member of the IRB and if found to meet the criteria for exempt status are administratively approved (see the IRB policy [Exempt Research](#) for the details). All other human research studies that are not eligible for exempt status are referred to as “non-exempt” human research.

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For non-exempt human research, there are two review processes:

1. **Expedited review** – one or more members of the IRB review the research outside a convened meeting of the IRB
2. **Full Board review** – the research is reviewed during a convened meeting of the IRB

New research may be reviewed using the expedited process if the research is minimal risk and the activities fall into one or more of the defined categories (see the IRB policy on Initial Review of Research by Expedited Process).

All other non-exempt research must be reviewed by the convened IRB (see the IRB policy on Initial Review of Research at a Convened Meeting)

Note: research that is not considered human research is reviewed by the Office of the IRB to confirm that the research does not require IRB approval. If you believe you are either not conducting research or not conducting human research, you can request the IRB review the project by submitting a Non Human Research form.

Is there required education for researchers?

All investigators and research staff conducting human research at institutions using the HSC Institutional Review Board (IRB) must complete research ethics training provided by the University of Miami, Collaborative IRB Training Initiative (CITI). (www.citiprogram.org)

Special note to investigators or study staff conducting VA Research

The VA requires completion of a different investigator training course (VA Course on the CITI website) – regardless of whether you are a VA employee; you must complete the VA training.

The HSC recognizes the VA CITI training – HSC researchers who have completed the VA CITI Course do not have to complete the HSC CITI training. See the IRB Policy on Research Ethics Education for more information.

What is the procedure for submission of new research (initial review)?

EXEMPT RESEARCH

There is **no submission deadline** for research that meets the criteria for exempt research. Follow the directions for completing an exempt application found on the IRB website. Follow the instructions for completing the required forms and attach additional documents as

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applicable. Submit one completed paper copy of the application along with an electronic version (CD) or use the IRB SharePoint to upload your electronic submission package.

For more information, review the IRB policy [Exempt Research](#).

EXPEDITED REVIEW

There is **no submission deadline** for research that meets the criteria for [expedited review](#). Follow the directions for completing an [Expedited Human Research application](#) found on the IRB website. Follow the instructions for completing the required forms and attach additional documents as applicable.

Submission Process - There are two methods for submitting a new expedited study for review by the convened IRB:

1) Option A - Drop off the application at the Office of the IRB (OIRB):

One (1) original submission packet containing: (1) A paper copy of each document submitted (including an original (written) signature – if applicable), and (2) An electronic copy of all documents (either CD or USB drive), or

2) Option B - Upload the application documents using the OIRB's SharePoint site:

Submit an electronic copy of all documents including Form A, with either a scanned copy of the original signatures or electronic signatures

For more information, review the IRB policy [Initial Review of Research by Expedited Process](#).

Note: Please download the IRB forms from the IRB web site **each time** you submit a new application to ensure you are using the most current version of our forms.

The study may be started only after the investigator has received the IRB approval and any other institutional approval (as applicable).

Other committees at institutions serving as study sites, such as the [University Health System's Research Committee](#) and the [VA R&D Committee](#) must also approve the study before the research may start.

FULL BOARD REVIEW

[Guidelines](#) for submissions requiring review by the convened IRB are published on the IRB website and vary from month to month.

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Submission Process - There are two methods for submitting a new study for review by the convened IRB:

1) Option A - Drop off the application at the Office of the IRB (OIRB):

One (1) original submission packet containing: (1) A paper copy of each document submitted (including an original (written) signature – if applicable), and (2) An electronic copy of all documents (either CD or USB drive), or

2) Option B - Upload the application documents using the OIRB's SharePoint site:

Submit an electronic copy of all documents including Form A, with either a scanned copy of the original signatures or electronic signatures

Pre-review process - All new studies considered by the convened IRB must undergo pre-review by members of the IRB and the OIRB staff.

The purpose of the scientific/ethical pre-review by the Board Members and the regulatory pre-review conducted by the OIRB Staff is to determine whether there are major scientific or ethical issues or questions that if left unanswered could result in tabling the study at the convened meeting and delaying the approval process. IRB members document their pre-review questions, comments or concerns using Form Z.

The purpose of the administrative pre-review is to ensure the materials being forwarded for IRB consideration are appropriately completed. Applications will not be placed on an agenda until the materials are deemed complete by the IRB office ("IRB Ready").

It generally takes 8-10 weeks from pre-review to final approval, with all conditions met. This is an estimate and meant to serve only as a guideline for funding deadlines.

Fast Track pre-review allows for an abbreviated administrative pre-review that results in a rapid turn around of comments or corrections to the investigator. If an application does not qualify for Fast Track, a regular pre-review including for example, face-to-face appointments with OIRB staff will be necessary to prepare the application for the IRB. (Depending on the issues identified during the pre-review process, the IRB member and/or OIRB staff may request a meeting with the PI .

Pre-review does not guarantee immediate full board approval. The intent of the pre-review is to assist the investigator to meet IRB requirements and to facilitate review by the full board. The pre-review process has reduced the number of new studies tabled by the IRB to less than 5%.

"IRB Ready" - Determined by the Office of the IRB

- All required forms submitted

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- All required signatures obtained
- All required investigator training completed
- All substantive issues raised by OIRB analyst have been resolved/addressed
- All substantive issues raised by IRB member pre-reviewer have been resolved/addressed
- Approval by the following committees (as applicable): Safety (radiation or bio-); Conflict of Interest; Protocol Review (oncology)

What is the procedure for submission of requests for re-approval (continuation review)?

Continuing review of on-going research by the IRB is just as important as the initial review. It is only after research has begun that the real risks can be evaluated and the actual risk/benefit ratio calculated to determine whether the Board was correct in its initial judgment about the protocol. Further, the risk/benefit ratio may change over time. Unexpected results and effects of the research project itself as well as new knowledge resulting from other research (e.g., alternative treatments now available, newly identified side effects of the study drug) may affect the balance between benefits and risk. Based on its assessment at the time of continuing review, the IRB may require that the research be modified (by imposing special precautions or by relaxing special requirements previously imposed on the research) or halted altogether.

Notification that Continuing Review is Due:

The IRB may only approve research for a period of no longer than one year. All requests to continue research (re-approval) nearing the end of the current approval period must be submitted using a [progress report form](#) in sufficient time to allow review and re-approval before the current approval period expires. The IRB policy [Continuation Review](#) provides further guidance.

It is the Principal Investigator's responsibility to ensure a progress report is submitted in a timely manner to allow sufficient time for pre-review by the OIRB and review by the convened IRB. The PI should establish a reliable procedure that will be a reliable reminder of an upcoming expiration date.

As a courtesy, the IRB Office generates continuing review reminder notices for each study. These notices are sent to the PI allowing adequate time to complete the process prior to the approval expiring. The PI should not rely on these notices as the only reminder of an upcoming expiration date.

The IRB [website](#) provides additional details.

Progress Reports (see [IRB Forms Required After Approval](#)):

There are different progress report forms depending on the type of re-approval needed. Use the Progress Report form for all non-exempt human research studies. The HDE Progress

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Report form is only for Humanitarian Device Exemption studies and the Repository Progress Report is only for repositories.

The progress report is reviewed by the IRB along with the IRB file and evaluated using the same approval criteria used at the initial review. The IRB needs to determine whether any new information has emerged either from the research itself or from other sources that could alter the IRB's previous determinations, particularly with respect to risk to subjects. Of note, information regarding any unanticipated problems involving risks to subjects or others that have occurred since the previous IRB review in most cases will be pertinent to the IRB's determinations at the time of continuing review.

Submission Process - There are two methods for submitting a progress report for review by the IRB:

1) Option A - Drop off the re-approval application at the Office of the IRB (OIRB):

One (1) original submission packet containing: (1) A paper copy of each document submitted (including an original (written) signature – if applicable), and (2) An electronic copy of all documents (either CD or USB drive), or

2) Option B - Upload the application documents using the OIRB's SharePoint site:

Submit an electronic copy of all documents including Form A-1, with either a scanned copy of the original signatures or electronic signatures

Besides the IRB, are there other approvals before research can start?

APPROVAL OF OTHER COMMITTEES

In addition to IRB approval, a research project may need the approval of other committees, officials or institutional offices before it is implemented. The PI is responsible of obtaining approval of other applicable committees or officials of the institution.

Some additional approvals are required **before** a study is reviewed by the IRB, for example:

- The **CTRC Protocol Review Committee** must approval all cancer clinical trials
- The **Biosafety Committee** must approve all studies involving recombinant DNA
- **Radiation Safety Control Committee** and possibly from the **Radioactive Drug Research Committee** if using radiation for research purposes

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Some additional approvals are required **after** a study is reviewed by the IRB, for example:

- ***Veteran's Administration Research & Development (VA R & D) committee*** and the ***CTSA review committee*** for research conducted at the Barter Research Unit (BRU)
- ***Affiliated institution's research committees/officials*** – for example, University Hospital's Research Committee

A chart briefly describing the deadlines and guidelines of some of the other relevant committees is given in the [IRB Forms](#). See the IRB policy [Coordination with Other Committees or Offices](#) for more information.

Occasionally, other committees may require the principal investigator make changes in a protocol or consent documents after they have been approved by the IRB. When such changes are made, the investigator must submit the changes to the IRB for approval. While the protocols and consent documents may vary between the sites, all documents to be used at the various sites must be approved by the IRB. **Initiation of a study without final IRB approval of all modifications constitutes a violation of Federal regulations and institutional policy.**

How do I handle approval by another (non-HSC) IRB?

The approval of faculty, staff or students' research by another institution's IRB cannot substitute for the requirement to have the protocol reviewed by the appropriate HSC IRB. When the research involves a site that has its own IRB, evidence of formal approval by that institution's IRB or equivalent must be submitted to the HSC IRB before the study can begin. This applies to research being done across the street (Methodist Hospital, St. Luke's Baptist Hospital), across the state (MD Anderson, Rio Grande Valley) and outside of this country. When research is being done in other countries, evidence should be provided that the laws governing research in the respective country and institution are also being upheld.

See the IRB policy [Cooperative Off-Site Research](#) for more information.

Informed Consent

No investigator may involve a human being as a subject in research unless the investigator has obtained the [legally effective informed consent](#) of the subject or from the subject's [legally authorized representatives](#). See the IRB policy [Informed Consent](#) for more details.

Investigators may seek consent only under circumstances that provide the prospective subject or his or her representative sufficient opportunity to consider whether or not to participate,

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and that minimize the possibility of [coercion](#) or [undue influence](#). Furthermore, the information must be in language that is understandable to the subject or representative. The person obtaining consent must assess the capacity of the potential subject to give consent. If the subject appears to be cognitively impaired, the consent discussion should be postponed. If the impairment is not likely to resolve, the appropriateness of including the subject, or obtaining consent from a legally authorized representative must be evaluated. When a study targets a population, condition or situation where the likelihood exists that subjects will be impaired, the protocol should include a strategy to formally assess the subjects' capacity to give consent.

The **consent process** is expected to be conducted by an investigator. It is permissible to have other study personnel involved in the consent process, however if someone other than an investigator is to obtain consent, it should be within the person's credentials or [research scope of practice](#), specified in the protocol (Form B-2) and approved by the IRB. The consent process involves assessing the subject's mental and physical state and other factors that may effect the person's ability to give informed consent. For research likely to enroll subjects will [limited or diminished autonomous decision making capacity](#) (e.g., [incapacitated](#), [incompetent](#), children, pregnant women and fetuses, etc.) review the additional protections required in the IRB policy [Research Involving Individuals with Diminished Autonomous Decision Making Capacity](#)). The consent process should in provide sufficient time to explain the study to the prospective subject, ensuring that the individual understands the information, giving the person adequate opportunity to consider all options, responding to questions, and obtaining the individual's voluntary consent to participate. To be effective, the consent process must provide an opportunity for the person obtaining consent and the prospective subject to exchange information and ask questions--both at the time of recruitment and throughout that person's participation. It may involve the use of charts, models, video tapes and other audio visuals that may assist in communicating the procedures and processes that will be part of the study. For complex protocols, incorporation of diagrams and flow charts into the consent document itself is encouraged to improve the clarity and description of the research procedures and possible treatment assignments.

The **consent document** is a legal document containing sufficient information to allow the prospective research subject to make an informed decision about whether or not to participate in the research and ensures that adequate information is given to the subject in the process of obtaining consent. It is not intended to be a protection for the investigator and does not constitute any waiver of liability. Neither the consent process nor the consent document may involve the use of exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence. The signed consent document provides documentation of the information provided to a subject to serve as a basis for consent to participate in a study.

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When protected health information ([PHI](#)) is to be collected, used and/or disclosed in the course of the research study, the consent document will also contain a valid authorization, outlining the planned uses and disclosures of the PHI. For more information on valid authorizations, see [the HSC Compliance Office webpage on HIPAA](#) or view information provided in the IRB policy [HIPAA in Research](#) or review the information provided by the NIH website [HIPAA Privacy Rule Information for Researchers](#).

The IRB must approve all consent documents before they are used. Approval must also be obtained from the IRB for **each modification** made in the form thereafter, before instituting the change. The version of the consent document being used should match exactly with the version given final IRB approval in the protocol file. The IRB will stamp and date each approved version of the consent document. The investigators are strongly encouraged to use the stamped and dated copies to assist them in assuring the appropriate version is in use.

While federal regulations have a provision for use of a **short form**, this approach is generally not permitted locally, except when a non-English speaking subject is to be enrolled without a complete consent form being available in the person's own language.

Consent Form FORMAT

The IRB provides [template consent forms](#) for use. These templates include directions and other helpful instructions to completing a consent form that contains the required elements of consent. There are several versions of the consent form templates including: [general research consent](#), [repository consent](#), English and [Spanish](#) versions, and [VA consent](#) templates. Each template includes a separate HIPAA authorization form at the end of the template.

Special Considerations - Informed Consent

Two or More Consent Documents

It may be necessary to use two or more consent documents in a single study when procedures are to be performed on subgroups of subjects or when reasons for subject selection differ. The most common example of this situation is studies which involve both patients and normal subjects or a treated and a control population. If there is more than one consent document, place a label in the upper right hand corner of page 1, or after the title, indicating the subject population to which each consent is addressed.

Witness policy

It is local policy to include the signature of a witness on the consent form. Generally, the signature of the witness attests only to the signature of the subject. There are some occasions, however, in which the witness would be required to witness the entire consent process. The IRB may require this as an additional protection for subjects who are particularly vulnerable or when

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the risk involved in the research warrants it. In the case that the subject does not read and in cases when the IRB has approved the use of a "short form" consent document, FDA regulations and GCP Guidelines require a witness to attest to the consent process undertaken, not only to the signature of the subject. Please note that the use of the short form consent is generally not permitted by this IRB except in special situations – contact the OIRB for guidance or review the IRB policy on [Informed Consent](#).

The witness attesting to the signature of the subject needs to be someone not affiliated with the research; neither an investigator nor study staff. "Study staff" means persons involved in carrying out the particular research protocol for which the subject is signing the consent. In addition, it is preferred that the witness not be associated with the subject either so that s/he may be truly impartial. However, having a completely impartial witness is not always feasible and a family member or friend may serve as a witness if an impartial witness is not available. In some settings, securing the signature of any witness, impartial or otherwise, may not be feasible. This may occur in studies where subjects are enrolled in their homes, for example. The protocol should indicate that this is expected. If the IRB approves omitting the signature of a witness when none is available, when the situation occurs, "none available" will be written on the line for the witness' signature and the person obtaining consent will make a notation in the study record describing the situation.

Commercial Development

When the sponsor or investigators believe that the specimens collected during the research may be used for the development of marketable products, it is important to state this in the consent form and indicate whether there are plans to share the profits with the subjects. If there are no plans to share the profits with the subjects, the following wording is recommended: "It is possible that the experiments being done for this study, using the [specify type of specimens, such as blood or tissue] specimens or future experiments using the specimens, will discover or develop something that can be marketed and sold to make money. Anything that results from these research activities, whether it be information or products, will be owned solely by the investigators and the institution." If there are plans to share the profits, describe those plans. You CANNOT state that subjects waive any of their rights

Biological Specimens

The protocol must include the various tests that will be done using the biological specimens collected in the course of a research study. Unless otherwise specified, biological specimens should be kept no longer than is necessary to accomplish the study objectives of the research for which they were collected. It is not permissible to informally or unofficially keep and reuse biological specimens for purposes that are beyond the scope of what was described in the

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consent document that covered the specimens' collection. When investigators wish to establish a specimen bank as a source of specimens for future, undefined research projects, a banking protocol must be established. See the IRB policy on [Repositories](#) for more information.

Banking or Storing Biological Specimens or Private Information for Future Research Use

When the research includes a plan to [bank](#) biological specimens or private information for future research use, a separate [repository consent](#) and HIPAA authorization must be used. See the IRB policy on [Repositories](#) for more information.

Genetic research

Human genetic research involves the study of inherited human traits. Much of this research is aimed at identifying DNA mutations that can help cause specific health problems, developing methods of identifying those mutations in patients, and improving the interventions available to help patients address those problems. The identification of genetic mutations enables clinicians to predict the likelihood that persons will develop a given health problem in the future or pass on a health risk to their children. For many disorders, however, there will be a considerable time lag between the ability to determine the likelihood of disease and the ability to treat the disease. DNA can be derived from many easily obtained biological specimens, so the risk associated with genetic research is NOT a physical risk. It is a social and psychological risk. Genetic information pertains to the most personal aspects of individuals' lives and may have implications for family members as well. The research protocol and the consent form must clearly state what type of information will be gained about the disease, its treatment, about the people who have the disease, about the individual tested, about their families and about their children. Subjects need to understand what the implications and what the potential consequences are of obtaining the information sought. A subject might very well want to be part of the laudable effort to discover the gene that may cause Alzheimers. However, it may never occur to that subject that if it is determined he/she has the Alzheimers' gene, it might mean that he/she would likely develop the disease. Furthermore, if the results of the genetic research somehow become part of the subject's medical record and the medical record is later reviewed by the health insurance company, and the insurer gives the information to the employer, it could jeopardize the subject's career and insurability. In pedigree studies, non-paternity and non-maternity may also be unexpectedly revealed, changing family relationships forever. Even when DNA is used in research without identifiers, some argue that DNA can never be truly anonymous since each person's DNA is unique, like a fingerprint. Researchers planning genetic research must address the potential risks to the subjects and their loved ones, state how confidentiality will be safeguarded, indicate how results will be handled, specify the disposition of the biological specimen once the immediate research project is complete and clearly state what information will

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or will not be shared with the subject. You are encouraged to seek guidance from the IRB office early in your planning.

Consent from a Legally Authorized Representative

This is an extremely complex issue that can not be summarized here. Please review the IRB policy on [Informed Consent](#) and the policy attachment [Legally Authorized Representatives Under Federal and Texas Law](#) for more details. In addition, you may need to seek legal advice for your institution's legal department.

Assent

Children: Adequate provisions must be made for soliciting the assent of children, when the children are capable of providing assent. The ages, maturity, and psychological state of the children involved should be taken into account. Generally, age 7 is accepted as the age children should give assent. If the procedure involved in the research 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 research, assent of the children is not a necessary condition for proceeding with the research.

Adults: Regarding the involvement of adults who are unable to provide consent (e.g., [incompetent](#), [has impaired decision making capacity](#), etc.), in addition to the consent of a legally authorized representative the feelings and expressed wishes of the participant should still be respected. Investigators should both inform the subject and solicit his/her assent to take part in the study.

Deception

The IRB recognizes that in some cases, informing the subject of the hypothesis being tested may result in a biased response. Under these circumstances, the nature of some studies requires that the full purpose not be revealed to a subject until the study has been completed. Such intentional withholding of information may be permitted if the subject is informed that this is the case and agrees. Plans for when and how complete information will be shared with the subject should be disclosed in the consent document.

Non-English Speaking Subjects

If the research subject does not understand English sufficiently to be able to give informed consent, consent should be obtained in the language readily understood by the subject. Translations of consent documents should be available at the outset of a study if it is anticipated that non-English speaking subjects will be enrolled. (See [IRB Forms](#) for a Spanish language sample of the standard statements used in a consent document.)

Non-English speaking subjects may not be excluded from therapeutic studies, on the basis of language use if there is a possibility that they might benefit by participating in the study.

Enrollment of Non English-speaking subjects without an approved translation of the consent form

A request to enroll a non English-speaking subject using an English consent form must be justified. Generally, such requests should be reserved for situations where the study offers a treatment not available outside of the study and a delay in enrollment would not be in the subject's best interest. This situation will be treated as a protocol deviation.

The request should be written unless the situation is emergent. The request must explain the reason it is not possible to have a translation of the consent prepared and approved prior to the subject's enrollment. State who will perform the verbal translation and obtain consent. Describe plans to have the written translation prepared giving approximate date it will be submitted to the IRB.

The procedure will require that a third party witness the translation of the consent. The subject will choose someone fluent in both languages to be present during the consent process while the written English consent is being verbally translated and explained in the language the subject speaks. Since the witness may become aware of private information shared between the subject and the study personnel in the course of the consent process, it is vital the subject be comfortable with the person witnessing the translation of the consent. A copy of the English consent document must be given to the person who witnesses the translation of the consent so that s/he may follow along during the translation. A copy of the English consent should be given to the subject to keep and a copy of the translated consent should be provided to the subject later, after the translation is approved.

In addition, a **short form consent document, written in the subject's own language** must be used to document the process and the persons involved in the process (contact the IRB office for a template of the short form document.) It will be signed by the subject, by the bilingual witness and by the person obtaining consent. The bilingual witness and the person obtaining consent will also sign a copy of the English consent document to keep on file with the short form (as part of the official study documentation of this subject's enrollment).

The witness is being asked to attest to the following:

- that he/she witnessed the translation process,
- that he/she received a copy of the English version of the consent and that the information given in the subject's preferred language, was an accurate representation of that provided in the English version,
- whether it appeared the subject was given an opportunity to ask questions,
- whether it appeared the subject understood the information provided and
- whether the subject signed the document voluntarily.

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Screening Studies to Identify Eligible Subjects

If a procedure is to be performed solely for the purpose of identifying a population of research subjects, prior consent for the screening test and/or process is required. Often, it is appropriate for the screening to be presented in a separate consent document describing the screening procedure and stating that its purpose is to determine eligibility for participation in further studies. A separate consent document for the actual study would then be signed by individuals found to be eligible. In such situations, at the time the subject is enrolled for the screening procedures, the prospective subjects should be shown the document they will be asked to sign if they prove to meet the criteria for further study.

Emergency ID Card

In some drug or device studies, it is advisable for a subject to be given a card to carry in his or her wallet to be shown in the event of an emergency. An example of such a card is in the [IRB Forms](#).

Distribution and Storage of signed consent forms

A complete, signed copy of the consent document must be given to each subject. A copy with original signatures must be retained in the investigator's file for a minimum of six years after completion of the study (except in the case of the V.A. Hospital, where the original must be in the patient's hospital record and a copy kept in the investigator's file.) If the subject is a patient, a copy of the **signed** consent document must be placed in the subject's hospital or clinic record unless it would be inappropriate (would put the subject at additional risk) to do so.

Guidelines for consent in research using surveys and interviews

Research involving the use of surveys or other self-administered questionnaires or interviews (e.g., telephone or face-to-face interviews) generally involves minimal risk (unless the nature of the questions or topic of the research represents a risk to the individual). Research involving the use of surveys or interviews may be eligible for exempt status (see IRB policy [Exempt Research](#) for more information).

Surveys or interviews that have been determined to be **exempt** should use the following information to guide consent.

Some sources of risks to consider include:

- legal risk if questions involve admitting to illegal activity that has mandatory reporting

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- social risk if questions involving topics that are a possible invasion of privacy, or could be embarrassing (e.g., sexually transmitted diseases, alcohol or drug abuse)
- the risk of psychological discomfort may occur if questions address issues related to previous traumatic events

Consent for Surveys /Self-Administered Questionnaires

Should include written information either in the introduction section of the tool, cover letter or separate information letter addressing the following:

1. Involves research and an explanation of the purpose of the questionnaire
2. A statement of the amount of time the questionnaire will require
3. A description of any stresses associated with sensitive information elicited (if applicable)
4. A description of any benefits reasonably to be expected (if applicable)
5. An offer to answer any inquiries concerning the questionnaire with information as to whom to contact and how
6. An instruction that the subject is free to refuse to fill out the questionnaire or any of the individual questions
7. Information as to how and to what extent confidentiality will be maintained

Consent for Telephone and Face-To-Face Interviews. Whenever possible, a letter containing the elements of consent in an information sheet should precede an interview to inform the subject of the impending interview. (See References for guidelines on recruitment of subjects.) The letter should contain the following information:

1. An explanation of the purpose of the interview and the kinds of questions to be asked
2. An explanation of how and/or why the subject was asked to participate in the study
3. A statement of the amount of time the interview will require
4. A description of any benefits reasonably to be expected
5. An instruction that the subject is free to discontinue the interview at any time without prejudice
6. An assurance of confidentiality
7. Information as to how and to what extent confidentiality will be maintained
8. If the study will involve PHI, include a valid authorization and submit an H-4 form requesting the authorization be valid without a signature and without giving the subject a signed copy.

At the beginning of the interview, the information contained in the letter should be reviewed with the subject.

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Procedures for selection and training of interviewers should be described in the protocol. This should include the number of interviewers to be used, method(s) of recruitment, their familiarity with the community/population to be studied, the language in which the interview is to be conducted, and method of approaching subjects.

In the instance of telephone interviews, and assuming that the information sheet is part of the process, the oral consent of the interviewee to continue the interview will be considered to be informed consent.

In the instance of face to face interviews, the informed consent document should be in writing. Informed consent should be obtained prior to the interview. The signatures of the subject, the interviewer, and the person obtaining consent should be contained in the consent document. Like the letter and spoken introduction, the informed consent document should include the required elements of informed consent and a valid HIPAA compliant authorization if protected health information is being collected.

Waiver of the requirement for a signed consent document

The IRB may waive the requirement of obtaining documentation of (signed) consent (permitting verbal consent) in some circumstances, and may require instead that a written statement describing the research be given to the subject. Such a waiver may be given when one of the following conditions exist:

1. The only record linking the subject and the research would be the consent document and the principal risk would be 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.
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.

See the IRB policy [Informed Consent](#) for more details.

Submit a request for waiver of documentation of consent using the IRB's [Form F](#) .

Waiver of the requirement to obtain consent

In research that is *not* subject to FDA regulations, an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in the DHHS regulations, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

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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.

See the IRB policy [Informed Consent](#) for more details.

Submit a request for waiver of documentation of consent using the IRB's [Form F](#) .

If PHI is to be collected as part of the research, submit a Waiver of Authorization using [Form J](#).

Recruitment and selection of subjects

The Belmont Report describes how the principles of respect for persons, beneficence, and justice are relevant to research involving human subjects. The principle of **respect for persons** demands that subjects' decisions whether to become involved in research must be voluntary and informed. Investigators have a responsibility to recruit subjects in such a manner that they not feel pressured to agree, and that they have ample time to discuss the study procedures and to ask questions.

Justice in particular relates to the selection of research subjects. The selection process needs to be scrutinized in order to determine whether some classes (e.g. welfare patients, racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Whenever research leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

The selection of subjects must be fair and equitable. In assessing whether selection of subjects is equitable, the IRB takes into account the purposes of the research and the research setting. Potentially beneficial research should not be offered only to some patients who are pleasant to work with; likewise, higher risk or research with no potential benefit to the subjects, should not be targeted only at "undesirable" populations. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g. adults before children) and that some classes of potential subjects (e.g.

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the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only under exceptional conditions.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically or educationally disadvantaged, the very sick who may have impaired decision-making capacity, mentally disabled persons and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition. For similar reasons, staff and students are considered vulnerable as well. Guidelines for the inclusion of staff and students are found later in this section. Because the IRB needs to be particularly cognizant of the special problems of research involving these vulnerable populations, the investigator will supply a discussion of the reason for including such groups, how their autonomy will be assured and how risks to these subjects will be minimized. Other vulnerable populations of concern include groups such as children, prisoners, pregnant women. The regulations contain special "Subparts" which define the criteria and conditions that must be met in order to involve pregnant women and fetuses, prisoners and children as research subjects.

See the [Privacy and Confidentiality Policy \(Identification and Recruitment\)](#) for more information.

Staff and students as subjects

Definitions

"*Student*" means any individual who is enrolled at HSC in the School of Medicine, School of Allied Health Sciences, School of Nursing, Dental School or Graduate School of Biomedical Sciences or in the sister schools located on the HSC campuses, such as the Houston School of Public Health and the UT Austin's extension of its Clinical Pharmacy program. It also means those individuals who are in training as Interns, Residents, Fellows, or Postdoctoral trainees, including individuals enrolled at a school or training facility other than the HSC training or work program.

"*Staff*" means all other HSC employees, including faculty.

IRB Policy Guidelines

HSC students and staff have the same rights as any other potential subject to participate in a research project, irrespective of the degree of risk, provided all of the following conditions exist:

1. The research must not bestow upon participating HSC subjects, any competitive academic or occupational advantage over other HSC students or staff who do not

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- volunteer, and the researchers must not impose any academic or occupational penalty on those HSC students or staff who do not volunteer.
2. HSC students and staff must not be systematically treated differently from non- HSC subjects as part of the project.
 3. Due to the potential for perceived or real coercion to participate, HSC students and staff who desire to participate in the research must not be under the direct supervision of the principal investigator or listed research collaborators.
 4. Recruitment of HSC students and staff must be handled through general announcements or advertisements, rather than through individual solicitations. Personal solicitations increase the likelihood that participation will be the result of undue influence, either because of the relationship between the recruiter and the prospective subject, or methods of communication employed by the recruiter that may act to persuade prospective subjects to participate, thus compromising the voluntariness of the agreement to participate.

SCREENING STUDIES TO IDENTIFY ELIGIBLE SUBJECTS

Minor procedures may be performed for the purpose of identifying a pool of eligible research subjects. Consent is required for all study procedures.

SOLICITATION OF SUBJECTS THROUGH ADVERTISEMENTS

The use of advertisements (e.g., notices on bulletin boards, paid and unpaid newspaper solicitations, solicitation by electronic mail, WEB sites, letters to private practitioners, signs, or pamphlets, etc.) to solicit volunteers for research must have IRB approval. Such advertisements are an extension of the informed consent and subject selection process.

The IRB reviews advertisements to determine that (1) they are neither misleading nor coercive to potential subjects; and (2) in treatment protocols, no claims are made, either explicitly or implicitly, that a proposed treatment is safe and effective or equivalent or superior to any other treatment.

Advertisements should contain the following:

1. The name and address of the investigator
2. The purpose of the research
3. In summary form, the eligibility criteria
4. A straightforward, truthful description of the benefits, if any
5. The location of the research and the person to contact for additional information

Submission and approval procedures:

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1. Identify method(s) of advertisement for research subjects in the protocol.
2. Submit bulletin board notices for IRB approval prior to posting. The IRB will return the advertisement with a dated IRB approval stamp. Subsequent changes in the content of an advertisement must be approved by the IRB.
3. If you plan to advertise in a newspaper, a WEB site, or other media advertisements, submit the text or a printed copy of the WEB information or other item for IRB approval. Solicitation of subjects within the context of a published or broadcast "news" release is not appropriate.
4. Submit other forms of advertisement (e.g., electronic mail, letters to private practitioners, letters to potential subjects, etc.) for IRB approval.

(Guidelines and a sample of an appropriate advertisement are found in the [IRB Forms](#).)

FINDER'S FEES

A proposed recruitment method which involves offering cash and/or tangible non-cash incentives to residents, fellows, private physicians, or others (i.e., finder's fees) is not permitted by institutional policy and cannot be approved by the IRB.

Food and Drug Administration Regulations

In addition to the requirements imposed by DHHS which form the basis of these guidelines, the Food and Drug Administration also has regulations requiring IRB review, informed consent and protection of human subjects.

FDA regulations generally apply to the investigational use of a drug, biologic or device in research. (See the IRB policy [Determination of what activities are human research \(HHS & FDA\)](#) for specific information).

In some cases, use of a "test article" such as a drug in research may be subject to FDA research regulations even if the drug is approved for use in clinical practice. For example, the investigational use of an approved drug for an indication or in a population not mentioned on the FDA-approved package label may be subject to FDA. The IRB [Form O](#), [Form O-1](#) and [Form P](#) are designed to assist researchers determine whether the intended use of a drug or device in research is subject to additional regulations such as an investigational new drug (IND) number. Physicians who plan to use "articles" in ways that differ substantially from those identified on the package label should contact the firm that distributes the "article" to see what the manufacturer would either agree to obtain an IND/IDE or permit the investigator to apply for an IND/IDE. Even if FDA regulations are not applicable, research involving investigational practices must conform to IRB guidelines.

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See the IRB policies on [Research Involving a Drug](#) and [Research Involving a Device](#) for more information.

CONSENT FORM

When the study is subject to FDA regulations or to the Good Clinical Practices Guidelines, it is necessary to state the number of subjects who will participate in the study. The statement must be an objective statement of fact, such as `A total of X# of subjects will take part in this study.' Statements like `You will be one of X# of subjects...' or `This pivotal study will include X# of subjects from the United States and X# of countries.` are not permitted.

Subjects must be informed that their medical records may be subject to review by agents of the FDA and, in some cases, by agents of the industrial sponsor.

WAIVER OF CONSENT NOT PERMITTED BY FDA REGULATIONS

FDA regulations do not have a provision for a waiver or alteration of the informed consent requirements except in emergency situations where the use of the test article would be for emergency treatment or for research in an emergency room setting, which is subject to special requirements. Please see the guidance at the following web address:

<http://www.fda.gov/oc/ohrt/irbs/except.html>

SUBJECT PRIVACY

To protect the privacy of the subjects, separate research code numbers should be used to identify individual subjects and only the investigators should have the means to link the code numbers to identifiable patients. There are some exceptions to this principle, such as when an implantable device is being tested, the FDA may require the reporting of the subjects' identity and contact information to sponsors. In most circumstances, if the sponsor's data reporting forms include names, initials or other identifiers, the forms should be modified.

DOCUMENTATION

Investigators working on FDA-regulated studies are strongly encouraged to keep all data, notes, and consent forms as "research records" that are separate from the medical records. When FDA personnel arrive to inspect records, they may -- in the interests of protecting the patient's privacy -- be given these records rather than their having to go to the medical chart to find the documentation. While clearly the subjects' medical records need to include information about research participation that would impact clinical decision making, research records should also be maintained.

HSC record retention policy is that the research records be kept a minimum of six years after the study protocol is inactivated, which satisfies the federal requirements related to the HIPAA privacy rule. FDA regulated study records may have to be kept a longer period. FDA regulations state that an investigator must maintain the records of drug disposition, signed consent documents, case report forms, all correspondence, dates of monitoring visits, and supporting documentation, for a period of two years following the date a New Drug Application is

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approved or until two years following the notification by the sponsor that the clinical investigations have been discontinued. The investigator may withdraw from the responsibility to maintain records and transfer custody of the records to another faculty or staff person who will accept responsibility for them. Notice of a transfer must be given to the FDA not later than 10 working days after the transfer occurs. **A copy of that notice should also be sent to the IRB.**

INSPECTIONS

Various federal agencies such as the FDA, the NCI and others have the authority to inspect medical records of patients or subjects involved in research studies in which these agencies have an interest. The Director of Internal Audit is responsible for coordinating the activities of all external auditors. If a department is contacted by an external audit agency, the agency should be referred to the Director who will contact the appropriate levels of Health Science Center management to schedule the external auditor's visit.

Investigators should also contact the President's Office and the IRB as soon as they receive notice of an inspection or audit by a federal agency.

FDA Defined Expanded Access to Investigational Drugs

Investigational products are sometimes used for treatment of serious or life-threatening conditions either for a single subject or for a group of subjects. The procedures that have evolved for an investigational new drug (IND) used for these purposes reflect the recognition by the Food and Drug Administration (FDA) that, when no satisfactory alternative treatment exists, subjects are generally willing to accept greater risks from test articles that may treat life-threatening and debilitating illnesses. The following mechanisms expand access to promising therapeutic agents without compromising the protection afforded to human subjects or the thoroughness and scientific integrity of product development and marketing approval.

OPEN LABEL PROTOCOL OR OPEN PROTOCOL IND

These are usually uncontrolled studies, carried out to obtain additional safety data (Phase 3 studies). They are typically used when the controlled trial has ended and treatment is continued so that the subjects and the controls may continue to receive the benefits of the investigational drug until marketing approval is obtained. These studies require prospective Institutional Review Board (IRB) review and informed consent.

TREATMENT IND

The treatment IND [21 CFR 312.34 and 312.35] is a mechanism for providing eligible subjects with investigational drugs for the treatment of serious and life-threatening illnesses for which there are no satisfactory alternative treatments. A treatment IND may be granted after sufficient data have been collected to show that the drug "may be effective" and does not have unreasonable risks. Because data related to safety and side effects are collected, treatment INDs also serve to expand the body of knowledge about the drug.

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There are four requirements that must be met before a treatment IND can be issued: 1) the drug is intended to treat a serious or immediately life-threatening disease; 2) there is no satisfactory alternative treatment available; 3) the drug is already under investigation, or trials have been completed; and 4) the trial sponsor is actively pursuing marketing approval.

Treatment IND studies require prospective IRB review and informed consent. A sponsor may apply for a waiver of local IRB review under a treatment IND if it can be shown to be in the best interest of the subjects, and if a satisfactory alternate mechanism for assuring the protection of human subjects is available, e.g., review by a central IRB. Such a waiver does not apply to the informed consent requirement. An IRB may still opt to review a study even if FDA has granted a waiver.

GROUP C TREATMENT IND

The "Group C" treatment IND was established by agreement between FDA and the National Cancer Institute (NCI). The Group C program is a means for the distribution of investigational agents to oncologists for the treatment of cancer under protocols outside the controlled clinical trial. Group C drugs are generally Phase 3 study drugs that have shown evidence of relative and reproducible efficacy in a specific tumor type. They can generally be administered by properly trained physicians without the need for specialized supportive care facilities. Group C drugs are distributed only by the National Institutes of Health under NCI protocols. Although treatment is the primary objective and patients treated under Group C guidelines are not part of a clinical trial, safety and effectiveness data are collected. Because administration of Group C drugs is not done with research intent, FDA has generally granted a waiver from the IRB review requirements [21 CFR 56.105]. Even though FDA has granted a waiver for these drugs, an IRB may still choose to conduct a review under its policies and procedures. The usage of a Group C drug is described in its accompanying "Guideline Protocol" document. The Guideline Protocol contains an FDA-approved informed consent document which must be used if there has been no local IRB review.

PARALLEL TRACK

The Agency's Parallel Track policy [57 FR 13250] permits wider access to promising new drugs for AIDS/HIV related diseases under a separate "expanded access" protocol that "parallels" the controlled clinical trials that are essential to establish the safety and effectiveness of new drugs. It provides an administrative system that expands the availability of drugs for treating AIDS/HIV. These studies require prospective IRB review and informed consent.

Principal Investigator Responsibilities

These responsibilities include:

1. conduct the study only according to the protocol approved by the IRB;

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2. promptly report to the IRB all unanticipated problems. All events, whether related to an adverse event or other non-adverse event problems to meets the definition of an unanticipated problem involving risk to subjects or others ([UPIRSO](#))
3. complete non-prompt reporting of all adverse events provided in the progress report in the form of a summary
4. promptly report any issue involving [noncompliance](#)
5. ensure that only formally designated investigators (as approved by the IRB) enroll subjects using the most current IRB stamped consent form;
6. ensure that only appropriately qualified clinicians make study-related health care decisions (if applicable)
7. protect the confidentiality of all personally identifiable information collected and train study staff and collaborators on policies and procedures for ensuring confidentiality of this information;
8. submit for review and approval by the IRB all [modifications](#) to the protocol or consent form(s) prior to the implementation of the change using the [amendment](#) form (except where necessary to eliminate apparent immediate hazards to the subject is needed to remove an immediate harm);
9. submit a Progress Report for continuing review by the IRB in sufficient time to allow review and re-approval before the current approval period expires;
10. monitor subject safety according to a local data safety monitoring plan (if applicable);
11. notify the IRB when the study has been completed and prepare a final report.
12. For VA research the investigator will:
 1. Inform the pharmacy service of the IRB's and Research and Development Committee's approval through Form 10-1223.
 2. Provide the pharmacy with a signed copy of Form 10-1086 to document each participant's consent to participate in the study.
 3. Inform the Chief, Pharmacy Service, and the Research and Development Committee when a study involving investigational drugs had been terminated.

Emergency Use of an Unapproved Drug or Device

The use of an unapproved (experimental) drug biologic or device for the treatment of a single patient in a life-threatening situation, for which there is no acceptable treatment available, may be undertaken without prospectively obtaining IRB approval *provided an emergency situation exists*. The following conditions should exist for a situation to be considered an emergency:

1. The patient is suffering from a life-threatening condition
2. No acceptable alternative treatment available.
3. Because of the immediacy of the need to use the drug or device, there is not sufficient time to use existing procedures to obtain IRB approval.

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Life-threatening includes the scope of both life-threatening and severely debilitating, as defined below.

Life-threatening means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

Severely debilitating means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

FDA regulations do not provide for expedited IRB approval in emergency situations. Therefore, the terms "interim", "compassionate", "temporary", or any other terms implying an expedited approval process are not authorized and do not apply for emergency use of test articles.

See the IRB policy [Emergency Use of an Unapproved Investigational Drug](#) or [Emergency Use of an Unapproved Investigational Device](#) for details.