
Guide to the Exempt Application

This document provides guidance to the questions found within the exempt sub-form.

(590) Case Study: Is your project solely a case study or series (including NO MORE THAN FIVE CASES) whose only procedures involve the review and analysis of the records of the case(s)?

A case study is an in depth study of an individual or several individuals. In biomedical research, it involves a detailed analysis of a person or persons (no more than five) with a particular disease or condition, noting characteristics of the disease or condition, its treatment and/or outcome. Case studies in biomedical research are often used to call attention to unusual or novel manifestations of disease, unusual responses to treatment or rarely seen side effects. In behavioral research, nearly every aspect of the subject's life and history is analyzed to seek patterns and causes for behavior. In either case, the hope is that learning gained from studying one case or several cases can be generalized to many others.

Sources:

<http://medical-dictionary.thefreedictionary.com/Case+study+research>

<http://psychology.about.com/od/cindex/g/casestudy.htm>

(592) Evaluation for Improvement: Does the project involve performing an internal evaluation of an institutional program or academic course?

This question can be confusing because UTHSC is an educational institution in which researchers are faculty, staff, residents, and students. However, just because one is performing this research as part of an academic program, it does not mean that the research itself involves an internal evaluation of an institutional program or academic course. In this setting, this question is specifically referring to such things as educational programs, academic classes, patient care methods, etc. within an institution. An internal evaluation means that the results are going to be used to improve those educational or other programs within the institution. If it is also the case that the results of the study will be presented at a professional conference or published (i.e. used to contribute to generalizable knowledge beyond the institution), then you should indicate this when answering the follow-up question.

602 Subject Identity: Is it true that the only study procedures involve the analysis of information or specimens from persons whose identities cannot be ascertained by the investigator? (If your study involves surveys or other procedures, you should answer "no" to the question.)

This question is NOT referring to how you will record your data when it is collected. It may be true that data will be collected in such a way that the subject cannot be identified. However, this question is referring to source documents. If the source documents, such as patient charts, have the patients' names, social security numbers, dates of birth or other identifying information, or the research involves contact with subjects, or identification of subjects for recruitment purposes, then the investigator can identify the subjects. Even if the investigator can determine the identity of subjects, the study may qualify for an exemption if it meets the federal guidelines.

(603)Data, Documents, Records, Specimens Generated Separately: Does the research involve the collection or study of data, documents, records and/or specimens generated separately from this research?

This question is making the distinction between data, documents, records, and specimens that are **created** (not collected) solely for research purposes and those that are created as part of standard of care or normal practices. It is also making the distinction between specimen samples created as a part of this study and those already in existence collected for reasons other than this particular study. For example if data the being collected is clinical data from patient charts, information about staff from their personnel files, the use of commercial cell lines, etc. then the research involves the collection of study data, documents, records and/or the analysis of specimens generated separately from your research.

(634) Remaining Categories for Exempt Status: Will the research involve educational practices and be conducted in an established or a commonly accepted educational setting (such as a school)? Also **Does the research involve normal educational practices?**

These questions can be confusing because UTHSC is an educational institution in which researchers are faculty, staff, residents, and students and often the research is being performed as part of an academic program. However, this question is specifically asking whether the research will be taking place within a typical instructional setting such as a classroom or clinic and whether such research is evaluating normal educational practices such as teaching methods, classroom management, etc.

(634) Remaining Categories for Exempt Status: Will the research involve educational practices and be conducted in an established or a commonly accepted educational setting (such as a school)?

This question can be confusing because UTHSC is an educational institution in which researchers are faculty, staff, residents, and students. However, just because one is performing research as part of an academic program or within an educational institution, it does not mean that the subject matter of the research itself involves educational practices. Rather, this question is specifically referring to a research study whose subject is 1) a pre-existing or new educational program for health care professional, students or patients, or 2) an actual academic class (usually within a classroom setting) in which teaching methods, classroom management, etc. is evaluated. So answer this question "Yes" only if the study is actually evaluating educational practices.

(638) Not Exempt, Explain and (652) Begin Exempt Application: Purpose of Research

It is important to pay attention to instructions regarding the type of application the system is instructing you to select. If it tells you that the study is exempt, be sure to select this category. If the system tells you that your study is not exempt and that it is either expedited or full board, be sure to select one of those categories before hitting “save and continue” to move forward.

Note: If you administering a survey to children or observing the behavior of children and are interacting with children during the observation, then your research will not qualify for exemption, but may be expedited. **(653) Studies Involving Records, Data, Documents, Specimens**

45CFR46.101(b)(4): Describe the defining features of the records, data, documents or specimens to be examined, such as the presenting problem, diagnosis, or types of treatment being investigated.

If this study involves cell lines, describe the defining features of the population from which the cells were derived. If the study involves records, describe the defining features of the study population, diagnosis, or types of treatment that you are evaluating. This question is trying to understand the study population. You will be asked to describe the types of data you will be collecting/analyzing in the last question in section 653.

(654) or (675) Informed Consent: Can the study practicably be conducted if informed consent is required for the collection/use of records, data, documents, or specimens

It is often the case that studies involving retrospective chart review could not be practicably carried out if consent were required because funds and personnel do not exist to contact all potential subjects to secure their consent; and failure to include all potential subjects might result in skewed analysis of the results of the study. Certainly in the case of use commercial cell lines, in most cases the study could not be practicably carried if consent were required and failure to include all potential subjects might result in skewed analysis of the results of the study. For survey research, observational research, or program evaluation research (that will be published or presented at a professional conference), a full consent form is usually not warranted, but a shortened cover statement can and should be used in situations where informing the subject would not affect the outcome of the research (see elements of survey consent http://www.utmem.edu/research/research_compliance/IRB/consent.php). For such studies, you should indicate that the research can be practicably carried out even if informed consent is required. In a later question, you will ask for alteration of consent since you will be using a short form. If informing subjects about the study would alter the results of the study, you may indicate here that the study could not be practicably carried out if consent is required, and in a later question (685) you can explain why.

(655) or (688) Alteration Requested for Records, Data, Document, Specimen Use: Are you requesting an alteration of informed consent for collection/use of records, data, documents or specimens?

There are several circumstances in which this might apply. If you are conducting a survey and/or observational research (and informing subjects about the observation will not influence the outcome of the study) in most circumstances you may use an informed consent cover statement which is a one page document briefly describing the study (see elements of survey consent http://www.utmem.edu/research/research_compliance/IRB/consent.php). To use this shortened form, however, you must request alteration of consent. The subject's willingness to fill out the survey or to be observed demonstrates their consent.

You would also request an alteration of consent if you cannot gain the subject's permission in person, but can contact them by phone or via the internet.

(657) and (685) Waiver of Informed Consent: Why can the research not be practicably carried out without the waiver of consent?

In most cases, for studies involving retrospective chart review, at least one of first two categories apply: 1) funds and personnel do not exist to re-contact all potential subjects to secure their consent; or 2) failure to include all potential subjects might skew the analysis of the results of the study.

(698) Sub Form Complete

Be sure to follow any instructions regarding the selection of the type of application indicated. If the system determines that your study is not exempt after all, and indicates that your study is expedited or full board, you should select the appropriate category as indicated.

(3327) Number of Alternative Consent Procedures

Regardless of whether you are requesting waiver or alteration of consent, if you receive this question while filling out the application, you will be required to answer this question and fill out the informed consent sub-form, in the next section. In the next section (see below), you will be asked to answer questions regarding the waiver or alteration of informed consent and the HIPAA authorization.

This initial question is not asking if there is more than one consent form. It is asking whether there is more than one consent process. For example if there are two groups of subjects, and for one group you are requesting waiver of consent, and for the other you will be giving a consent cover statement to subjects regarding their participation, then you have two consent processes and you should answer "two" to this question. If you have two groups of subjects, but sets of subjects are receiving a consent cover statement regarding study participation, then you only have one process, and you should answer "one".

(3332) or (3325) Informed Consent: Note this may be a different section number than 3332 or 3325. Regardless it will be entitled “Informed Consent”

Again, regardless of whether you are requesting waiver of consent, you will be required to create an informed consent sub-form, and to answer the corresponding questions regarding informed consent and waiver of HIPAA authorization for each consent process. If you answered “one” to the above question, then you fill out one sub-form. If you have more than one consent process, then you fill out the appropriate number of sub-forms, one for each consent process (see above).

(3365) Conditions: Check all of the following conditions that apply to the request for waiver or alteration of consent:

Retrospective Chart Reviews and Cell Lines: It is often the case that studies involving retrospective chart review could not be practicably carried out if consent were required because funds and personnel do not exist in order to obtain informed consent. Similarly, in the case of use of commercial cell lines, the study could not be practicably carried out if consent were required because the persons from whom the cells were obtained can no longer be identified. (In both cases, the third condition here should be checked.) In addition, the first two conditions must be true in order to qualify for waiver of consent. The research must involve no more than minimal risk to the subjects. The waiver must also not adversely affect the rights or welfare of the subjects. Most of the time, the first two conditions are true for retrospective chart reviews and for studies involving commercial cell lines, so these boxes should be checked as well.

Survey, Observation, and Program Evaluation (that will be published or presented at a professional conference) Research: Forsurvey research, observational research, program evaluation research, a full consent form is usually not necessary, and a shortened consent cover statement can and should be used in situations where informing the subject will not affect the outcome of the research statement (see elements of survey consent http://www.utm.edu/research/research_compliance/IRB/consent.php). For such studies, you should indicate that the research can be practicably carried out even if informed consent is required. However, an alteration of consent must be requested in order to use the shortened form. In order to qualify for an alteration of consent, the first two conditions must be true: The research involves no more than minimal risk to the subjects. The waiver will not adversely affect the rights or welfare of the subjects.

The fourth condition: “The subjects will be provided with additional pertinent information about the study after participation,” only applies to research in which a subject will be debriefed afterwards. One example in which this applies is research in which the subject to research in which subjects are duped as part of an observational study, and then debriefed about the study afterwards.

(3370) Practicality Without Waiver? Why can the research not be practicably carried out without the waiver of consent?

It is often the case that studies involving retrospective chart review could not be practicably carried out if consent were required because funds and personnel do not exist to contact all potential subjects to secure their consent; and failure to include all potential subjects might result in skewed analysis of the results of the study. Certainly in the case of use commercial cell lines, in most cases the study could not be practicably carried out if consent were required because the subjects can no longer be identified. For some chart reviews, the requirement to secure consent might result in leaving out many subjects and this could result in data that is not representative of the whole study population. If informing subjects about the study beforehand would alter the results of the study, you may indicate here that the study could not be practicably carried out if consent is required, check “other,” and then you can explain why such is the case in the text box.

(3375) Without Alteration: Why can the research not be practicably carried out without the alteration of consent?

There are several circumstances in which this might apply. If you are conducting a survey and/or observational research (and informing subjects about the observation will not influence the outcome of the study) in most circumstances you may use an informed consent cover statement which is a one page document briefly describing the study (see elements of survey consent http://www.utmem.edu/research/research_compliance/IRB/consent.php). In this situation, the first three conditions listed may not apply to you. You may select “other” and indicate that this is a minimal risk study involving a survey and/or observation and that you will be using a survey cover statement or consent cover statement following UTHSC guidelines.

(3450) HIPAA: For this research, are you requesting to use the Protected Health Information (PHI) of persons (living or dead) without their authorization (or with limited or altered authorization) to conduct the study, or to identify or recruit potential subjects?

Retrospective Chart Reviews: If you are collecting information from records that contain individually identified health information, then even if you are not recording identifying information, and are not obtaining a signed informed consent form (with the HIPAA disclosure) from subjects, then you should answer “yes” to this question.

Recruitment: If you are reviewing information from the patient’s charts, human resource records, that have identifying health information in order to identify potential subjects, then you should answer “yes” to this question.

(3455) HIPAA Type of Waiver Requested: Please identify the regulatory category under which the request is being made to use Protected Health Information (PHI) without subject authorization.

Only one answer choice should be selected:

For retrospective chart reviews, and for recruitment purposes the first answer choice is the appropriate one “Waiver of subject authorization is being requested.”

The third answer choice, “All Protected Health Information (PHI) to be used is a limited data set” refers to information provided by an institution or individual with whom you have an official

Data Use Agreement and the data provided has a limited number of identifiers such as:: dates of birth; dates of death; dates of service; town or city; state; and zip code.

The fifth answer choice “the health information to be used is de-identified data”. This does NOT APPLY to how the data will be recorded, but to the source documents themselves. Patient charts, for example, are not de-identified data. Some examples of de-identified data include commercial cell lines, census data, or electronic medical records from which all identifiers are removed before they are provided to the researcher.

The last answer choice “the Protected Health Information (PHI) will be used for a review, preparatory to research,” does not apply to recruitment. This should only be selected if the review of the charts is being done before the research study, e.g., to identify a research question.

(3467) HIPAA Alteration Practicality and (3468) HIPAA Waiver Practicality

If you have requested waiver of consent, the information provided here should basically mimic your reasons for requesting waiver of consent. For example, the reason why getting the HIPAA authorization might not be practicable is that funds and personnel do not exist to contact subject to secure their authorization or not including all subjects would skew the data.