Building a Central Repository for Research Ethics Consultation Data: A Proposal for a Standard Data Collection Tool

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Abstract

Clinical research ethics consultation services have been established across academic health centers over the past decade. This paper presents the results of collaboration within the CTSA consortium to develop a standard approach to the collection of research ethics consultation information to serve as a foundation for quality improvement, education, and research efforts. This approach includes categorizing and documenting descriptive information about the requestor, research project, the ethical question, the consult process, and describing the basic structure for a consult note. This paper also explores challenges in determining how to share some of this information between collaborating institutions related to concerns about confidentially, data quality, and informatics. While there is much still to be learned to improve the process of clinical research ethics consultation, these tools can advance these efforts, which, in turn, can facilitate the ethical conduct of research. Clin Trans Sci 2015; Volume 8: 376–387

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Introduction

The primary purpose of a clinical research ethics consultation service (RECS) is to provide researchers and other stakeholders with timely advice about the ethical issues raised by either proposed or ongoing research.[1–3] Such services can provide advice across the lifespan of a study, from choice of study design all the way to postpublication translational activities. RECSs may be especially useful when research raises novel issues that may or may not be covered by current regulations, that go beyond practices whose ethical acceptability is well established, or that are matters of debate and uncertainty among regulatory and ethical experts.[4] Research teams may also turn to a RECS for advice on how to anticipate the issues that their institutional review board (IRB) might raise about a research proposal or to respond to the questions raised by an IRB or a National Institutes of Health (NIH) Scientific Review Group.

The number of RECSs at academic institutions has recently increased. Many were established as requisite components of the initial phase of the NIH Clinical and Translational Science Award (CTSA) program. In a 2010 survey, 33 of the then 46 funded CTSAs (72%) had established such a service.[5,6] A few institutions have described their RECS activities,[7–10] but no paper has considered the feasibility and utility of standardizing the collection of data across RECSs.

Aggregate information about consultation activities can be useful for internal, institutional, and broader purposes. Consultation services themselves can use basic information such as which group(s) requests consultations, the questions asked, the ethical analysis applied, and the recommendations made, in order to understand and improve their consultation process and to create materials for researcher education or consultant training. Research institutions can use data about consult volume and requestor satisfaction to assess the demand, responsiveness, and impact of the RECS, to budget funds, and to plan operations. Sharing these data among consult services at different institutions in a controlled and purposeful manner has the potential to improve the quality and value of RECSs nationwide.[11] This could be of particular importance when services advise on issues for which little or no regulation, guidance, or professional consensus exists as well as when a particular service lacks experience on an issue with which peers at other institutions' RECSs have already dealt.

In 2010, the Consultation Working Group of the CTSA Clinical Research Ethics Key Function Committee (referred to as the Working Group) initiated a Consultation Standardization and Data Sharing Project to determine the feasibility of collecting and sharing consult data among institutions. The project participants included research ethics consultants and staff from 11 academic institutions, as well as others with expertise in informatics and research ethics policy issues. The Working Group held multiple conference calls and three face-to-face meetings between 2010 and 2012.

In this paper, the deliberations and progress made toward development of a standardized tool for collecting data about research ethics consultation are reported. The proximate goal of this effort has been to begin a conversation about the utility and feasibility of adopting a standard format for the collection of data on ethics consultations within the CTSA Consortium that could be applied in the wider clinical research community. A consistent approach to the structure and content of data collection can promote data adequacy, comparability, and ease data extraction, thereby facilitating secondary use of data for quality and research purposes both within and across institutions. The ultimate goal of this effort is to encourage the adoption of a refined standard format and the development of a central repository to collect and compare data across institutions. Such a standard approach to data collection and sharing can promote better understanding of variability of both the process and content of research ethics consultation which can allow consultants to learn from each other how best to provide a valuable service to researchers and regulators.

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Standard Data Collection Tool

Early in the deliberations about the development of a standard data collection tool, members of the Working Group shared their personal experience with developing and staffing the RECSs at their home institutions. Institution-specific data collection materials developed to track internal consultations were shared and considered. In general, the RECSs that had developed tracking instruments had done so with the intent of creating internal reports to show the uptake of consultation services and the topics covered. The proposed standard data collection tool presented here reflects the Working Group's consensus regarding which domains be included in a model data collection tool. The proposed tool has two components: (1) five categories of descriptive information about the consult and (2) a consult note which includes six narrative elements.

Descriptive categories

Below, we highlight specific information about a consult that can be organized into five broad categories. Appendix 1 details the proposed data collection tool. Readers will notice that the Appendix 1 highlights (using ***boldfaced** text) a minimum subset of information we recommend could be shared across institutions. Appendix 2 gives specific descriptions of each term included in the data collection tool.

Identifying information

Information such as the date, a consult title, and a specific identification number can allow a specific consult to be distinguished from other consults by the consult team. This information is necessary to permit linking the minimal data in the repository with the additional information maintained locally when sharing information in the repository.

Requestor information

Information about the role (e.g., researcher, student) and/or affiliation (e.g., school, department) can assist in characterizing the individuals who seek consultations. For example, consult services might want to know whether requestors come from a small number of departments; or track how often researchers from nonclinical departments or even outside the institution request consultations. CTSAs might want to know the volume and home departments of investigators to whom services are provided. Consult requestor data additionally covers operational logistics, including how requestors learned about the service and whether they were referred from another institutional office. This information is useful in assessing how aware investigators and others are of the RECS, and the efficacy of various outreach efforts, as well as in measuring the extent of collaboration with other institutional services and administrative entities.

Research project information

Information about research projects' key attributes provides important context for the ethical question or concern under consideration. For example, the "research context" can be used to determine whether the project is one that requires specific ethical or regulatory consideration (e.g., human embryonic stem cells) and allows analysis of which types of studies and research settings generate ethics consultations. Tracking the "stage" within the research process (i.e., design vs. implementation) is important in evaluating whether one goal of research ethics consultation has been met, namely encouraging investigators to consider ethical and social issues as early as possible to avoid having potential problems arise during protocol finalization or subject recruitment. Some consults may relate not to a specific project but to issues that recur in several projects (e.g., appropriate subject remuneration). It can also be useful to consider where along the translational pathway a particular study falls, from discovery science to population impact, to ascertain whether different issues arise at different phases along the pathway. Such pathways have been used by CTSAs to describe the breadth of translational research. *Table 1* illustrates that the four translational phases are inclusive of clinical and public health research and span biomedical and social science methodologies.

Translational research phase	Drug development research (inhaled steroids and asthma)	Genetic testing research (carrier testing and cystic fibrosis)	Public health research (second-hand smoke and lung cancer)
T1 Discovery	Do inhaled steroids reduce lung inflammation? (Laboratory research for molecular mechanisms, biomarkers, and safety; clinical research for safety and efficacy (Phase I and II)	What genes cause CF? (Family genetic studies)	Does secondhand smoke cause lung cancer? (Questionnaires, health system database studies, population database studies)
T2 Development	Do inhaled steroids improve asthma symptoms and lung function? (Clinical research for effectiveness; Phase III)	Are women interested in carrier testing for CF? (Questionnaires, randomized intervention studies, health system database studies)	Are household contacts at increased risk of lung cancer? (Longitudinal studies, cross-sectional studies)
T3 Delivery	Will doctors offer inhaled steroids to patients and will patients use them? (Focus groups, questionnaires, randomized interventions studies, comparative effectiveness studies, health system database studies)	How do physicians offer testing in practice? (Questionnaires, randomized intervention studies, health system database studies)	What educational interventions reduce risk of secondhand smoke? (Questionnaires, intervention studies)
T4 Outcomes	Does the incidence of hospitalizations for asthma decrease? (Health systems database studies)	Does carrier testing decrease the incidence of CF in newborns (population database studies)	Does the incidence of lung cancer in nonsmokers decrease? (Health system database and population database studies)

Table 1. Translational research phases span different research contexts and can involve similar research methods.

Consult request information

Primary ethical questions and concerns, as articulated by consult requestors, are critical to understanding the specific types of ethical, social, legal, regulatory, and other issues that are identified in research, and whether researchers at specific institutions appear to raise certain questions more than others. These data may also reveal new ethical issues arising from novel research, such as what should be done when research using high-resolution imaging techniques or whole genome sequencing produces findings that are incidental to the research objective. This categorization of ethical concerns is also critical to be able to determine how consultants analyze or resolve issues and make recommendations, as well as indicating how consistent they are in doing so.

Consultation process information

Process information is necessary to track the amount of effort required to provide ethics consultations and to identify the specific types of services provided by the RECS. From these data, one can learn about the nature of ethics consultations at different institutions and assess changes over time in the function of the RECS. Given that the range of other programs (e.g., education, training, etc.) on research ethics will differ from institution to institution, some variability in the services provided by the RECS is to be expected.

Supplemental information

Many of the RECS within the CTSA consortium gather additional information beyond what the Working Group decided to include in the standard data collection tool. For example, "Consultation status" could indicate whether the consultation is new, in process, closed, and/or has had follow-up, is urgent or routine, or has a specific deadline. "Type of interaction" could indicate whether the consultation was conducted by phone, Website, email, or in person. "Protocol number" could utilize an existing institutional protocol identification number. "Type of expertise utilized" could indicate the disciplines of, or other expertise provided by, internal consultants and/or external consultants invited on an *ad hoc* basis. Finally, a consultant could collect and retain auxiliary materials such as written protocols, consent forms, and background articles provided by the investigator or relied upon by the consultant.

Consult Note

The primary product of a consultation is a narrative document. Consultants at different institutions use various terms for the document they prepare, i.e., a note, report, or an opinion and while all these terms are reasonable, the Working Group uses the term "note" to emphasize the similarity of this document to those prepared for clinical ethics consultation. Even though there may not be an analog to the medical record where research consult notes are routinely placed, in many cases, the Consult Note is a given to the requestor at the end of the consultation process. The act of providing a written report to requestors can itself be a symbolic gesture that may be valued by the requestor, in addition to the substantive value of the analysis and recommendations themselves. In some institutions, draft consult notes are shared with requestors as part of the consultation process.

The purpose of the Consult Note section of the data collection tool is to provide a detailed account of the substance of the issue posed and advice provided. A Consult Note serves as a synthesis of the deliberative analysis and also documents any recommendations offered. Ideally, a Consult Note is a rich yet concise description of the consultation that can be useful qualitatively. For example, the person using the data collection tool can use the Consult Note section to describe the reason for the consult from the requestor's perspective as well as the reason for the consult identified by the consultant. Differences and similarities between these two perspectives are important for future education of both consultants and researchers.[10] In addition, background information about each case may be highly case-specific; such specificity can be critical in analyzing the case itself even though it not necessary to capture for meta-analysis. Finally, collecting the rich descriptions and analyses of research ethics consultations could prove to be an important initial step in developing a standard method for the analysis of research ethics consultations.

There are six domains in the proposed Consult Note

1. *Reason for the consult*: A brief summary of the reason for the consultation, including the research context and the ethical question(s) can frame the scope of the analysis and provides a concise overview that may be useful for quickly identifying or describing the consultation.
2. *Other issues identified*: Consultants can identify and document ethical issues in addition to those for which the requestor sought assistance. Issues that are sufficiently important can be included in the deliberative ethical analysis. Less pressing issues may simply be noted here and deferred. Whether or not the consultant decides to address them, noting the other issues can be an effective way to document the full scope of ethical issues for the case.
3. *Process*: A short description of the individuals and activities involved in providing the consult should include who was involved in the consult discussions, which documents or other materials were reviewed and/or shared, and how the conversations were conducted (e.g., face-to-face, telephone, email, etc.).
4. *Background*: A description of the relevant background information is provided by the requestor and other stakeholders. The amount and type of background information necessary for an informed analysis will vary based on the research context and ethical issue. Depending on the expertise of the consultant, additional materials may be reviewed and summarized in this section.
5. *Analysis*: The consultant's analysis of the ethical question(s) posed by the requestor is presented in this section. This is the substantive product of the consult and typically comprises the majority of the content in the narrative report and serves as the basis for any recommendations.
6. *Recommendations*: Many, but not all RECS offer specific recommendations to requestors.[5] When provided, recommended actions should be succinctly included in the narrative report.

Demonstration Project

With a data collection tool developed, the Working Group set about testing it across 11 CTSA consult services beginning in 2012. This required each participating institution to agree to a Memorandum of Understanding to govern the collection, scope, and use of the data. In addition to the tool itself, a Web-based data entry system was developed to facilitate data entry into a common repository, with access limited to designated research ethics consultants at participating institutions. The Working Group believes the establishment of a central, controlled-access repository could result in educational initiatives, facilitate empirical research on

consultation, and identify opportunities for quality improvement in the delivery of research ethics consultations and lead to best practices in the field.

The Working Group quickly learned that institution-based users (e.g., consultants, prior requestors, and some institutional officials) had concerns about sharing the detailed information collected in their respective Consultation Notes. These are likely to include detailed information about complex questions. Requestors might be concerned that the nature of the question or the relation between the question and the project itself may be sensitive, either because of institutional public relations concerns or concerns about prematurely disclosing a particular line of research. To avoid concerns about breach of confidentiality related to the institutions at which the consults were provided and/or in reference to the identity of the individuals requesting the consultations, the Working Group decided to designate a subset of the data collection tool to be submitted to the central repository, reporting only the *reason for the consult* and no other information from the *Consultation Note* section. The remainder of the shared information reported to the central repository is sufficient to enable any consultant participating in the data-sharing project who is interested in learning more about a specific case to contact the primary institutional consultant to get more information directly. Using the repository still improves upon the *ad hoc* approach of consultants seeking advice from one another in that it is dependent on existing individual relationships across institutions. The repository provides a broader base of information on relevant issues and identifies consultants with specific experiences.

Second, as with the establishment of any repository with multiple contributors, the Working Group appreciated that data accuracy will be a challenge. One issue with accuracy is that a common data collection tool does not guarantee that each individual completing the tool will answer all the questions in a consistent manner. While the Working Group developed definitions of the data fields in Appendix 2, many of the data options can be open to interpretation. The Working Group has limited the data fields included in the central repository to only those deemed to be essential data, in order to decrease the likelihood of variations in coding, since such variations would diminish the overall value of the aggregate data. A second issue with accuracy is the completeness of the response options. The proposed list of possible responses is not meant to be comprehensive. An "other" category is included under a number of queries to address this concern. If trends among the "other" category are identified over time, new options could be added to the list but would require the recoding of prior responses to keep the data and any output from the repository current.

Third, data sharing requires informatics resources to capture, store, and transmit data. Currently, the demonstration repository we have implemented allows for data entry and structured searching. An additional functionality that is currently in development is the ability to produce reports summarizing data over time and across institutions. Our hope is that the value of sharing basic data among a small number of institutions will be sufficient to justify further consideration of more comprehensive sharing.

Discussion

The long-term goal of collecting data systematically is to make the consultation process more valuable to clinical researchers and other requestors. The proposed collection tool allows RECS to track the types of consults completed. The internal tracking of consults can serve multiple purposes, such as establishing their value, justifying the investment in the service, providing progress reports to those interested, and indicating areas for improvement. Beyond the value of data at the institutional level, a common data collection tool used across sites will facilitate the aggregation and comparison of research ethics consultation across the country. Such data sharing can, for example, enable detection of trends in the ethical questions addressed and raise the collective quality of research ethics. For example, collectively reviewing how consultants approach specific issues may lead to the identification of common approaches and help to advance bioethical scholarship.

Ultimately, the research ethics consultation process and data sharing of consultations should have a positive impact on researchers, other requestors and the ethical quality of research. The Working Group believes the next challenge in enhancing the quality of ethics consultation would be to develop a measure of impact. The impact measure appropriate for each RECS depends on its goals, and is likely to vary from institution to institution. As a result of the ongoing experience with the demonstration project, the working group hopes to identify approach impact measures. Conceptually, four types of impact of consultations are important:

1. *Impacts on the requestors experience and satisfaction,* which are relevant in deciding to allocate resources for the RECS, in light of expected demand.
2. *Impacts on the requestor's actions*, such as modifying a protocol, grant proposal, or manuscript.
3. *Impacts on the project or issue*, which entails describing what happened following the consult, such as whether a study was approved or research results were returned to subjects, and how those events transpired.
4. *Impacts on the consultants/institution*, such as changes to institutional policy, collaborations with investigators, or writing a scholarly article or policy white paper on a research ethics topic.

The current efforts of the Working Group have shed light on research ethics consultation activities across institutions and on the feasibility of information sharing on a broader scale. Moving forward it will be important to evaluate the capability and use of the repository to accomplish two primary goals: (1) helping consultants to address specific questions by facilitating access to extrainstitutional consultants with relevant experience and (2) allowing consultants to solicit and receive feedback from colleagues regarding prior consult processes and recommendations. Expanding the number of data fields and institutions beyond the current CTSA sites and data fields to further achieve these goals will be contingent on both the value of the shared data to the collective institutions and the effort necessary to collect and share the data.

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Appendix 1: CTSA Research Ethics Consultation Data Collection Form

(The information to be included in the shared repository are ***designated**)	**Identifying Information**
***Institution**	
***Title of consult**	
Primary consultant	
***Consult ID**	
***Date of consult** *MM-DD-YYYY*	
	Requestor Information
Lead requestor	
Other requestors	
Name of contact	
How requestor contacted the consultation service *Select all that apply*	❒ Contacted individual consultant ❒ Through CTSA service request ❒ Other
Referrals from other services *Select all that apply*	❒ Hospital ethics committee/Clinical ethics consultant ❒ IRB ❒ Risk management ❒ Biostatistics ❒ Informatics ❒ Ombudsperson ❒ Conflict of interest committee ❒ Legal counsel ❒ DSMB ❒ FDA ❒ NSABB ❒ Other
Contact information	
Role of lead requestor on project *Select one*	❒ PI ❒ Co-investigator ❒ Research staff ❒ Post-doc/fellow ❒ Student ❒ Administrative staff ❒ IRB staff ❒ Research participant ❒ Other
Type of institution *Select one*	❒ CTSA institution ❒ Other academic institution ❒ Government ❒ Industry ❒ Funding agency ❒ Other
Department	

	Research Project information
Title of research project	
Source of research funding *Select all that apply*	❒ NIH (including CTSA pilot funding) ❒ Other government ❒ Non-profit ❒ Industry ❒ Internal ❒ None ❒ Other
***Research activities** *Select one* The purpose of this question is to understand the types of activities that are associated with the research projects that generate consultation requests.	❒ Clinical intervention (drugs, devices, biopsies) ❒ Clinical observation (imaging, EKG, exams) ❒ Behavioral/psychological intervention ❒ Behavioral/psychological observations (surveys, interviews) ❒ Analysis of existing samples/data ❒ Other
***Research stage** *Select one* These are discrete for an individual research project.	❒ Planning ❒ Grant application ❒ Regulatory review ❒ Data collection ❒ Analysis ❒ Publication/dissemination ❒ Post-publication translation
***Translational research phase** *Select one* These phases can be applied to drug development, genetic testing, public health research, and other contexts. (see Translational Phase Table)	❒ Discovery ❒ Development ❒ Delivery ❒ Outcomes ❒ Not Applicable
Research setting *Select all that apply*	❒ Research laboratory ❒ Clinical ❒ Multi-institutional ❒ Community ❒ Other
***Research context** *Select all that apply* These describe the research context in which the regulatory or ethical considerations arise and will be used as "keywords" for searches for relevant, related consultations.	❒ No special context ❒ Indigenous population ❒ Pediatrics ❒ Pregnant women ❒ Prisoners ❒ Innovative treatment ❒ Randomized controlled trial ❒ First-in-human trials ❒ Emergency research ❒ International research ❒ Community-engaged research ❒ Quality improvement research ❒ Human biological samples ❒ Human stem cells ❒ Gene transfer ❒ Vertebrate animals ❒ Select agents ❒ Other

	Consult Request Information
***Primary ethical concern** *Select one* This is the major ethical issue identified by the consultants (not by the requestor). Consider which category is the most important or controversial, and would be the best "keyword" to identify this consult.	❒ Study design (use of placebo, randomization, active controls) ❒ Benefit/risk assessment ❒ Subject selection and recruitment ❒ Research/clinical practice Relationships ❒ Ancillary care ❒ Community considerations ❒ Socially or economically vulnerable subjects ❒ Undue influence/exploitation ❒ Informed consent (assent, competence, proxy) ❒ Privacy/confidentiality ❒ Disclosure of Incidental findings/research results ❒ Study withdrawal/termination ❒ Communication of findings ❒ Broader social impact ❒ Research integrity (misconduct, authorship, data analysis) ❒ Conflict of interest ❒ Legal (liability, ownership, patent issues) ❒ Other
***Secondary ethical concerns** *Select as many as applicable; be inclusive to facilitate keyword searches*	❒ Study design (use of placebo, randomization, active controls) ❒ Benefit/risk assessment ❒ Subject selection and recruitment ❒ Research/clinical practice relationships ❒ Ancillary care ❒ Community considerations ❒ Socially or economically vulnerable subjects ❒ Undue influence/exploitation ❒ Informed consent (assent, competence, proxy) ❒ Privacy/confidentiality ❒ Disclosure of incidental findings/research results ❒ Study withdrawal/termination ❒ Communication of findings ❒ Broader social impact ❒ Research integrity (misconduct, authorship, data analysis) ❒ Conflict of interest ❒ Legal (liability, ownership, patent issues) ❒ Other
Requested level of confidentiality *Select one*	Information shared with: ❒ Local consultation service only ❒ Others if anonymized by individual and institution ❒ Others if anonymized by institution ❒ Others and not anonymized

	Consult Process Information
Consultants participating	
Collaboration with other services *Select all that apply*	❒ Hospital ethics committee/Clinical ethics consultant ❒ IRB ❒ Risk management ❒ Biostatistics ❒ Informatics ❒ Ombudsperson ❒ Conflict of interest committee ❒ Legal counsel ❒ DSMB ❒ FDA ❒ NSABB ❒ Other
Meeting attendees *Select all that apply*	❒ No in-person meeting ❒ Research team members ❒ Research subjects ❒ Representatives of other institutional entities ❒ External consultants ❒ Other
***Amount of interaction (hours)** *Select one* *This should include meeting times and report development*	❒ < 1h ❒ 1-4h ❒ 5-10h ❒ 11-15h ❒ >15 hours
***Additional service(s) provided** *Select as many of these as appropriate for specific services provided*	❒ None ❒ Assessment/capacity of decision maker ❒ Assistance with study design ❒ Clarification of regulations, laws or policies ❒ Assistance with regulatory review ❒ Assistance with consent process ❒ Conflict mediation ❒ Other
	Consult Note
***Reason for consult**	
Other issues identified	
Process	
Background	
Analysis	
Recommendations	

The information to be included in the shared database are ***designated**

Appendix 2: CTSA Research Ethics Consultation Data Collection Form User Guide

Use "Other" when there is no reasonable fit, the current categories are not sufficient, and these fields should be amended.
Individual institutions may create fixed choices for some of the data fields that are suggested as free text.

IDENTIFYING INFORMATION (for repository)	
Institution	The consultant's institution, not the location of the requestors. Institutional information is used to identify a consultation in the shared database.
Title of consult	Use a title that provides enough specific information about the project and/or the consultation question to allow you to recognize the consult.
Primary consultant	Name of who should be contacted if more information about the consultation is needed.
Consult ID	Unique numbers to distinguish each consult.
Date of consult	This can be either the date the consult was initiated or the date the consult was completed, depending on your institutional convention.
REQUESTOR INFORMATION	
Lead requestor	Name of the person requesting the consultation. This should be the person who initiated the consultation or the person most knowledgeable about the research project.
Other requestors	Name of others who participated in the consultation with the lead requestor.
Name of contact	Include if different from the requestor.
How the requestor contacted the service	Whether the requestor contacted the consultation service for this particular consultation or contacted a specific consultant
Referrals from other services	Indicates any institutional entities or external agencies that referred the case but were not involved in the actual consultation. (Participation of other groups in the consultation should be recorded below in *Collaboration with other services.)*
Contact information	Free text field for email addresses, phone numbers or other contact information.
Role of lead requestor on project	Indicates the requestor's role on the project or institutional role if not an investigator.
Type of institution	Indicates the type of institution the lead requestor is affiliated with
Department	Free text field to indicate the lead requestor's affiliation within their institution.
RESEARCH PROJECT INFORMATION	
Title of research project	Free text field to indicate the formal project title.
Source of research funding	Indicates funding of the research project. *Internal* is funding from the requestor's institution, and does not include CTSA funds being redistributed within the institution.
Research Activities *Select one* The purpose of this question is to understand the types of research activities in projects that are associated with consultation requests. When a study involves more than one activity, select the first one on this list that is applicable.	**Clinical interventions-** Includes the use of drugs, devices, invasive biopsies, invasive imaging (bronchoscopy, CT with contrast or sedation). **Clinical observations-** Includes medical history, physical exams, diagnostic tests (blood tests, EKG, pregnancy tests), non-invasive imaging (ultrasounds, MRI, CT). **Behavioral/psychological/interventions-** Includes engagements that are intended to change knowledge, attitudes or behaviors. **Behavioral/psychological/observations-** Includes surveys, focus groups, interviews, and other observations to asses knowledge, attitudes or behaviors. **Analysis of existing samples/data-** Samples or data previously collected, already 'on the shelf' or 'in a database.' **Other-** *Fill in the text box.*
Research stage *Select one* These are discrete for an individual research project.	**Planning-** Includes all study planning and design except for grant-related activities. **Grant application-** Includes writing or revising a grant application. **Regulatory review-** Includes initial applications to IRBs, ESCROs, or federal agencies such as the NIH, FDA or RAC before the study is initiated. **Data collection-** Includes questions that arise once a study has begun. Also includes questions that arise during recruitment. **Analysis-** Includes questions that arise about the interpretation of data or other questions that arise after data collection is completed **Publication/dissemination** - includes presenting research in public, publications, and media communications. **Post-publication translation -** Includes issues specific to commercialization of research (e.g., intellectual property or marketing).

Translational research phase *Select one* These phases can be applied to drug development, genetic testing, public health research, and other contexts. A particular research approach (observational research, randomized controlled trials, survey research, health system database) can be applied across phases	**Discovery (translation to humans)** (Testing science discoveries for clinical effect and/or applicability) **Development (translation to patients)** (Evaluation in human subjects under controlled environments to form the basis for clinical applications and evidence-based guidelines) **Delivery (translation to practice)** (Research on the application of new interventions that yields knowledge on best ways to implement the interventions) **Outcomes (translation to populations)** (Investigations of factors and/or interventions that influences population health; ultimately results in improved health of the public) **Not applicable-** Use this option if the translational phases do not apply to the research project. **USE TABLE 1 TO ASSIST WITH APPROPRIATE CHOICE**
Research setting	Indicate any settings in which the research discussed in the consultation takes place.
Research context *Select all that apply* These describe the research context in which the regulatory or ethical considerations arise and will be used as "keywords" for searches for relevant related consultations.	**No special context** **Indigenous population-** Involves participants who are considered 'first peoples' or natives of the location where the research is conducted (e.g., aboriginal persons, Native Americans). **Pediatric population-** Involves children (ages 0 to 18/21). **Pregnant women** **Prisoners** **Innovative treatment-** Includes activities in the boundary between research and clinical treatment. **Randomized clinical trials-** If participants or other groups are randomized **First-in-human trials-** Not previously studied in humans. **International research-** Location of the research activities will occur outside the United States. **Community-engaged research-** Involves communities in the design, implementation and interpretation of the study. **Quality improvement research-** Involves using established approaches to improve effectiveness. **Emergency research-** Involves an emergency situation and consent to participate may be waived under FDA regulations. **Human biological samples-** Involves using human tissues, serum or DNA. **Human stem cells-** Involves embryonic or adult stem cells but does not include hemopoietic stem cells. **Gene transfer-** Involves inserting new genes into humans, either directly or by modifying cells that are transferred. **Vertebrate animals-** Involves animals ranging from rodents to non-human primates. **Select agents-** Involves microorganisms and toxins specifically identified in DHHS and USDA regulations as having the potential to pose a threat to human, animal or plant health. **Other-** *Fill in the text box.*.
CONSULT REQUEST INFORMATION	
Primary ethical concern *Select one* This is the major ethical issue identified by the consultants (not by the requestor). Consider which category is the most important or controversial, and would be the best "keyword" to identify this consult.	**Study design-** Options to design a study, including use of placebo, randomization and active controls. This category and should selected before benefit/risk assessment. **Benefit/risk assessment-** Balancing or assessing benefits and harms of study activities. Include questions about data and safety monitoring (e.g., whether or not a plan is required, or what type of plan is required). **Subject selection and recruitment-** Which populations to include, how to approach participants and whether to provide research incentives. **Research/Clinical practice relationships**- When research and clinical roles overlap, such as when clinicians enroll patients in clinical trials, or concerns arise about participant understanding of research versus clinical care. **Ancillary care-** Obligations to provide care in the context of research study, such as responding to elevated blood pressure. **Community considerations-** Includes cultural concerns, religious concerns for participants and concerns about community attitudes or impact. **Socially/economically vulnerable subjects-** Should be used when some or all of the participants are socially or economically disadvantaged (homeless people, schizophrenia). **Undue influence/exploitation-** Concern that the participants may be pressured (undue influence) to join or remain in research. Concern that study participation may take unfair advantage (exploitation) of participants.

	Incidental findings/reporting results- Concerns about whether or how to disclose individual research findings about individual participants to themselves or family members. **Communication of findings-** Concerns about how best to communicate the overall, aggregate findings to the research population or the community. **Broader social impact-** Whether potential social impact of the research itself should influence decisions about study design and/or publication. In other words, should this research be done at all, and should the results be published? **Research integrity-** Concerns about misconduct, authorship or integrity of data analysis. **Conflict of interest-** Concerns that researchers, institutions or sponsors may have competing financial commitments that are relevant to the design or conduct of the research **Legal-** Strictly legal issues such as liability, patent or ownership issues that require analysis from legal counsel. **Other-** *Fill in the text box.*
Secondary ethical concerns	Select as many as applicable using the directions above. Be inclusive to facilitate keyword searching.
Requested level of confidentiality	The level of confidentiality specified by the requestor for this consultation related to inclusion the repository.
CONSULTATION PROCESS INFORMATION	
Consultants participating	Free text to list names of consultants participating in the consultation.
Collaboration with other services	Indicates other services that are collaborating with the consultation service to make recommendations to the requestor. Other groups that refer a case to the consultation service but do not participate in making recommendations should be recorded above in *Referrals from other services*.
Meeting attendees	Indicates the types of participants in the consultation.
Amount of interaction	Include time spent in conversation, research and documentation by the primary consult team.
Additional service(s) provided Select as many of the listed services as appropriate for the consult.	**None-** Use this option if the consult did not concern any of the options below (i.e., the consultant engaged in providing general ethical advice only). **Assessment/capacity of decision maker-** Specific assessments of individual participants, either about the appropriateness as a surrogate decision maker or the capacity of a potential participant to decide to join a study. **Assistance with study design-** Specific discussion about alternative design approaches to address ethical concerns. **Clarification of regulations, laws or policies-** Includes specific discussions about these as they apply to the requestor's research. **Assistance with regulatory review-** Includes advice or assistance about regulatory decisions or processes. **Assistance with consent process-** Includes assistance improving disclosure and understanding of information to join a study. **Conflict mediation-** Involves simultaneous discussion with multiple parties in a dispute to improve communication and resolution of conflict. Does not require an agreement to follow recommendations. Do not choose this option if all parties were not engaged with the consultation. **Other-** *Fill in the text box.*
CONSULT NOTE	
Reason for consult	Two or three sentences to describe the reason for the consult from the consultant's perspective. This should provide enough information so others have a general idea about the research question, project, and the ethical concern. *Do not use specific identifiers related to the requestor, investigator, institution, etc.*
Other issues identified	Describe any other issues identified by the consultants in the course of consultation, distinct from the reason for the consult.
Process	Describe process elements, including who was contacted and how, the urgency of and time spent on the consultation, and types of interactions.
Background	Background information about the research project and/or about the requestors.
Analysis	Describe the ethical, regulatory and other issues identified by the consultants, how or why these issues might differ from those identified by the requestor, and how consultants considered or weighed identified issues.
Recommendations	Describe specific recommendations made by the consultants.