**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.

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| **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 trial-** 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. |
| **Support provided**Select as many of the listed services as appropriate for the consult.  | **Ethical Discussion Only-** This is the default option if the consult did not involve 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. |