**CTSA Research Ethics Consultation Data Collection Tool**

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| (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* | 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 |
| **\*Support provided**  *Select as many of these as appropriate for specific support provided* | Ethical discussion only  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 |  |

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