**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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