WELCOME TO HUMAN SUBJECTS RESEARCH UTS-JTS (our "IRB" – Institutional Review Board)
A FAQ FOR STUDENTS & FACULTY

1. What is an IRB and why do I need to know? From the policy: "Any member of the JTS or UTS faculty, staff, or graduate student bodies who plans to initiate **research involving human subjects** must submit a protocol" [that is, a proposal with your plan of research and your methodology] "for IRB review and approval prior to beginning the project." Everyone (faculty, students, staff) must submit an application online at https://form.jotform.com/jekress/irb-application---utsjts), and everyone must show a certificate of completion after taking the NIH training module (online at https://phrp.nihtraining.com/users/login.php) in order to ensure a baseline of knowledge about what is considered ethical and unethical treatment of human subjects. The full policy is online at: https://www.dropbox.com/s/tdbbavl72k3gib5/2017-03-21UTS-JTS%20%20Institutional%20Review%20Policy.docx?dl=0

2. Why is this policy needed? Because persons who become research "subjects"/participants in studies involving biomedical and behavioral research should be treated ethically and not harmed by our research. And Federal regulations require it – it's called the Federal Policy for the Protection of Human Subjects or "Common Rule" (Code of Federal Regulations - "CFR"). As *theological institutions*, we want to be mindful of the religious and spiritual, as well as ethical mandate to *first do no harm*, and to safeguard the justice, wellbeing, dignity, and freedom of every living being. Protecting confidentiality, the right to privacy, and care around sensitive personal issues (i.e., not traumatizing or *re*-traumatizing people) are the main issues to be considered in a review. The principle of informed consent is integral to the ethical conduct of research with humans. Proper protection of documents and data is another key ingredient to maintaining participants' private information. When doing research on sensitive subjects (such as trauma, abuse, or addiction), we also need to be *especially* careful not to stir up strong feelings in our research participants without a plan for helping them to deal with those feelings in a safe way. We must protect anonymity as appropriate so that participants (&/or their communities) are not exposed to harm to reputation, relationships, education, or livelihood. IRB review and a good informed consent procedure also protects *you* the researcher(s), JTS/UTS, and any host institution(s), from undue exposure to liability.

3. What is human subjects research?
   a. Human subjects: If you are planning to research that involves a living person, and you plan to collect data through "intervention" (for example, an experiential practice, healing circle, ritual, etc.) or "interaction" (for example, a focus group or interview with an individual). Data from public databases or historical information (i.e. dead people) are not included.
   b. Human subjects *Research*: This refers to *empirical* research where you are doing something or talking about something with someone that is meant to be "generalizable," i.e., *add* to the body of general knowledge about a topic (for example, does this practice help people in their healing from abuse, or does a particular test or evaluation reveal important information about personality traits, learning styles, etc.?) If your research merely replicates old research without advancing the body of knowledge in the field, it is generally not considered worth the potential

harm to individuals to conduct it. Normally coursework (which is not research per se) or ministry practices that would be part of the everyday activities of a congregation or organization (if not being used to gather data) are not included.

4. What is Informed Consent? Informed consent is the main way in which research subjects are informed about the potential risks and benefits of their participation in a study, and have enough knowledge to freely consent to participate. The required elements of an informed consent form, to be given to potential research subjects to sign (or refuse) before conducting the research, are spelled out in the full IRB Policy. Minors (persons under age 18), and vulnerable adults (legally defined), require informed consent by a parent or legal guardian. An outside institution may *also* be required to give consent depending on the setting where you will do your research (e.g., a hospital; a congregation; a hospice; a community organization or agency). A sample Informed Consent letter is included as Appendix A in the IRB Policy.

5. What are the procedures for retaining research records? These are spelled out in Appendix B in the IRB Policy. Retain data securely for at least 3 years (to be accessible for audit), and ensure confidential storage on campus both during and after the research. If you destroy your data, you must do so in an accepted secure manner (such as shredding, wiping all drives, etc.).

6. How do I submit a proposal, and what happens next? *Everyone* proposing research with human persons must submit their proposal using the form online (see paragraph 1 above.) There are three levels of review, as determined by the IRB Board after receiving your proposal: exempt, expedited, and full. Your proposal should specify which of those levels you think applies, based on the criteria in the Policy. *Exempt* research is that which is determined *by the IRB Board* not to fall under the category of human subjects research as defined above, based on the criteria set forth in the Common Rule (see the Policy for details), and for which no IRB review is required. *Expedited* review is for research that is considered to entail no more than minimal potential for harm (again, see the Policy for details), and can be reviewed by just one member of the IRB Board. *Full* review will entail a detailed examination of the proposal by the full IRB Board. The Board will notify you of approval, with or without any required changes. Remember that *you may not begin your research before* you have received the green light from the IRB Board, and be prepared to make some changes to your protocol, if required by the IRB Board, before you proceed. *Note:* Major changes to your procedure after you have begun your research requires a new review (normally this would be Expedited).

7. Any questions? Feel free to contact the UTS-JTS IRB Chair, Dr. Jeffrey Kress at jekress@jtsa.edu. You may also consult with the Union reps to the IRB: Dr. Pamela Cooper-White at pcooperwhite@uts.columbia.edu or Dr. Sam Cruz at scruz@uts.columbia.edu.

8. **DON'T WORRY!** Most people find that going through this process helps sharpen their thinking about their research, and clarifying their methodology toward the best possible research results. We welcome your questions, and are happy to help you and your advisor craft a good proposal that will meet the requirements of the IRB.