AdventHealth Orlando

WORKSHEET: Adults Lacking Capacity

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This worksheet is used to determine and document whether non-exempt <Human Research> involving adults lacking decision making capacity can be approved. (see Footnotes 1 and 2)

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All items in Sections 1-3 must be considered when applicable.
All criteria in Sections 1, 5, 6, 7, or 8 must be met.
All criteria in Section 9 must be met.

1.		**Research involving no more than <Minimal Risk> to subjects**
1.1	☐	The research involves no more than <Minimal Risk> to subjects
1.2	☐	There are adequate provisions for soliciting the permission of an LAR and assent of subjects (see Section 9)
2.		**Considerations for all research**
2.1	●	Does the population targeted for recruitment represent the population with the least degree of impairment compatible with the aims of the study?
2.2	●	Does the research involve risks or discomforts that are greater for subjects who lack capacity than unimpaired subjects?
2.3	●	Have appropriate procedures for assessing capacity to consent to enroll in the study, if necessary, been described in the protocol or other submission materials?
2.4	●	Does the process to assess capacity provide reasonable assurances that the evaluator's judgments will be impartial?
2.5	●	Should the investigator follow a process so that individuals who are not capable under routine procedures might be capable? (see Footnote 3)
3.		**Considerations when subjects might experience fluctuating functional abilities**
3.1	●	Does the consent process include plans to avoid, if feasible, periods during which subjects are likely to experience greater than normal impairment?
3.2	●	Should provisions be included to anticipate fluctuations in capacity? (see Footnote 4)
4.		**Considerations for research involving greater than <Minimal Risk> to subjects**
4.1	●	Has the experimental intervention been tested on animals or humans with unimpaired functional abilities?
4.2	●	Does the protocol or other submission materials include a written description of procedures for minimizing risk?
4.3	●	Is there documentation of the importance of knowledge to be obtained by answering the research question?
4.4	●	Should one or more independent monitors be appointed to assist with various aspects of the study? (see Footnote 5)
4.5	●	Should a list of resources and referrals offered to subjects to assist them in coping with any foreseeable harm?
4.6	●	Should there be a written rationale for the inclusion of subjects with diminished functional abilities?
4.7	●	Should continuing review be conducted more frequently than annually?
4.8	●	Should there be a description of procedures for withdrawing subjects or terminating the study?
4.9	●	Should there be procedures for screening LARs and informing them of their responsibilities?
5.		**Research involving a drug, biologic, or device with no anticipated direct benefit to the subject** *ICH-GCP 4.8.14*
5.1	☐	The objectives cannot be met with research involving subjects who can give consent personally
5.2	☐	Unless an exception is justified, subjects have a disease or condition for which the investigational product is intended
5.3	☐	The foreseeable risks to the subjects are low (no greater than a minor increase over minimal risk)
5.4	☐	The negative impact on the subject's well-being is minimized and low
5.5	☐	The research is not prohibited by law
5.6	☐	Subjects will be closely monitored and withdrawn if they appear to be unduly distressed
5.7	☐	There are adequate provisions for soliciting the permission of an LAR and assent of subjects (see Section 9)
6.		**Research with anticipated direct benefit to the subject**
6.1	☐	The knowledge likely to be gained will improve the understanding of the condition, disease or behavior affecting the subject population
6.2	☐	The research holds out the prospect of direct benefit for the individual subject where the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches
6.3	☐	The research is not prohibited by law
6.4	☐	Subjects will be closely monitored and withdrawn if they appear to be unduly distressed
6.5	☐	There are adequate provisions for soliciting the permission of an LAR and assent of subjects (see Section 9)
7.		**Research with anticipated direct benefit to the subject that is available only in the research**
7.1	☐	There is a direct anticipated clinical benefit to the subjects that is available only in the context of the research
7.2	☐	There are adequate provisions for soliciting the permission of an LAR and assent of subjects (see Section 9)
8.		**Not otherwise approvable research**
8.1	☐	The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of an important problem
8.2	☐	The research will be conducted in accordance with sound ethical principles
8.3	☐	There are adequate provisions for soliciting the permission of an LAR and assent of subjects (see Section 9)
8.4	☐	The IRB has documented the above determinations in the minutes along with protocol-specific findings justifying these determinations

9. Adequate provisions for soliciting assent (see Footnote 6)		
9.1	☐	Assent is required of: ○ All subjects ○ All subjects determined by the investigator to be capable of assent ○ None of the subjects
9.2	☐	Written documentation of assent: ○ Is not required ○ Will be documented by a statement of the research team on the consent document

10. Notes

11. Footnotes	
11.1	Use this Checklist when the research includes individuals who have a condition of a type and severity likely to lead to affect capacity to consent, such as acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders.
11.2	Prospective adult subjects with impairments to functional abilities are presumed to be capable of providing consent unless there is substantial evidence otherwise. The mere presence of a condition that leads to diminished functional abilities should not be considered as indicative of a lack of capacity to consent.
11.3	Such methods might include: 1. designing a stepwise consent process, which involves a waiting period between each phase of the process: capacity assessment, initial presentation of information, and obtaining consent; 2. enhanced presentation of consent information during initial presentation and/or immediately prior to obtaining consent, including: repetition of information (especially misunderstood information), both oral and written presentation of information, multi-media presentation of information, interactive questioning, and written study summaries; 3. continuous dissemination of consent information throughout the course of the study; and 4. conducting the consent process in an environment in which the subject is comfortable.
11.4	Such methods might include: 1. Re-evaluating subjects' capacity over the course of the study 2. Designation of an individual to serve as an LAR 3. Involving potential LARs in the consent process 4. Asking subjects to document their wishes regarding participation 5. Avoiding consent when subjects are likely to experience greater than normal impairment 6. Obtaining consent of subjects who regain capacity
11.5	For example, a subject advocate, such as a member of the target population or family member thereof, or an employee of an organization that advocates for the target population; an individual with expert knowledge of the relevant psychological or physical condition who will monitor the consent of subjects; a health care professional to serve as a consultant to subjects; or a safety and data monitoring committee.
11.6	The content of the assent process should depend on the degree of risk and extent of likely impairments to subjects' functional abilities and should increase in rigor as risk and functional abilities increase.