1.目的 Purpose

提供 IRB 對易受傷害及決定能力欠缺之受試者參加試驗的審查依據，以落實適當保護特殊受試者。

To provide IRB with review foundations regarding vulnerable subjects and subjects lacking decision-making capabilities for trial participation, in order to achieve proper special subject protection.

2. 適用範圍 Scope

適用於審查涉及易受傷害、決定能力欠缺的受試者之試驗計畫案。

This file is applicable to reviewing protocols involving vulnerable subjects and subjects lacking decision making capability.

3.參考文件 References

2.1 醫療法第 79 條 (2017 年 5 月)

Medical Care Act, Article 79 (May 2017)

2.2 藥品優良臨床試驗規範 (2002 年 8 月)

Regulations for Good Clinical Practice (August 2002)

2.3 藥品優良臨床試驗準則 （2014 年 10 月）

Guidelines of Good Clinical Practice (October 2014)

2.4 研究用人體檢體採集與使用注意事項 (2006 年 8 月)

Guidelines for Collection and Use of Human Specimens for Research (August 2006)

2.5 人體試驗管理辦法 (2016 年 4 月)

Regulations on Human Trials (April 2016)

2.6 人體研究法 (2011 年 12 月)

Human Research Act (December 2011)

2.7 民法

Civil Code

2.8 Department of Health and Human Services 45 CFR 46

2.9 FDA: 21 CFR 50

4.名詞定義 Terminology

4.1 易受傷害受試者：係指在自主能力或自願性受到限制時便容易受到傷害之受試者族群。

Vulnerable subjects: refers to subject populations that they are prone to be harmed when their autonomy or restricted voluntariness.

4.2 受刑人：受刑人是指被拘留在拘留所、監獄或懲處機構的人，或已被宣判或等待提訊、審判或判決而被拘留的人。包括法院授命在醫院或勒戒機構治療者。此定義適用於未成年人及成年人。

Prisoners: Refers to those that are detained in detention centers, prisons or penal institutions, or those who have been sentenced or are detained to wait for arraignment, sentencing or conviction, including those who should be treated in the hospitals or rehabilitation institutes authorized by court orders. The definition is applicable to both minors and adults.

4.3 已婚之未成年人：視為有行為能力者。

Married minor: considered as person with capacity.

4.4 成人：達到法定年齡(年滿 20 歲)的人。

Adults: refer to the population has reached to legal adulthood age (20 years old).

4.5 未成年人：未滿法定成年年齡(20 歲)人，當中包括嬰兒、兒童，及少年。

Minors: refers to the population has age that is under the legal adulthood age (20 year old), including infants, children and teenagers.

4.6 無行為能力者：未滿七歲之未成年人或受監護宣告之人。

Incapacitated persons: refers to minors under the age of 7 or the persons under guardianship.

4.7 限制行為能力者：滿七歲以上之未成年人。

Persons with restricted capacities: refer to minors over the age of 7.

4.8 法定代理人：代理行使無行為能力、限制行為能力之權利義務之人。

Legal representatives: refer to persons who can act the rights and obligations on behalf of the incapacitated persons or persons with restrictive capacities.

4.9 法定監護人：父母均不能行使、負擔對於未成年子女之權利義務，或父母死亡而無遺囑指定監護人。

Legal guardian: refers to the guardian of minor offspring that whose parents are unable to exercise or bear the rights and obligations for their minor offspring, or minor offspring whose parents died without appointing a designated guardian in the will.

4.10 決定能力欠缺者：如未成年人、法律宣告受監護及輔助之人、因疾病喪失決定能力之成人或無法完整表達自主意願者。

The person lacking decision making capability: refers to minors, persons under

guardianship and aid by law, adults lost decision making capability due to illnesses, or persons unable to completely express their voluntary willingness.

4.11 受監護宣告之人：對於因精神障礙或其他心智缺陷，致不能為意思表示或受意思表示，或不能辨識其意思表示之效果者，法院得因本人、配偶、四親等內之親屬、最近一年有同居事實之其他親屬、檢察官、主管機關或社會福利機構之聲請，為監護之宣告。

Persons under guardianship: refers to those who have mental disturbance or other intelligent defects, and thus cannot express the meaning, express meaningfully, or recognize the meaning of expression. The court may proclaim that he/she is under guardianship by the application of the person himself/herself, spouse, fourth-degree relatives, other live-in relatives in the past 1 year, the prosecutor, competent authorities or social welfare institutes.

4.12 受輔助宣告之人：對於因精神障礙或其他心智缺陷，致其為意思表示或受意思表示，或辨識其意思表示效果之能力，顯有不足者，法院得因本人、配偶、四親等內之親屬、最近一年有同居事實之其他親屬、檢察官、主管機關或社會福利機構之聲請，為輔助之宣告。

Persons under aid: refers to those who have mental disturbance or other intelligent defects, and obviously do not have sufficient capability to express the meaning, express meaningfully, or recognize the meaning of expression. The court may proclaim that he/she is under aid by the application of the person himself/herself, spouse, fourth-degree relatives, other live-in relatives

in the past 1 year, the prosecutor, competent authorities or social welfare institutes.

5.作業內容 Scope of operation

5.1流程 Process

程序 Procedure	權責 Rights and responsibilities
決定易受傷害及欠缺決定能力之受試者 Determine vulnerable subjects and subjects lacking decision making capability	主持人／試驗委託者 Investigator/Sponsor
審查潛在風險之考量及其保護措施 Review the considerations for potential risks and the protection measures	人委會 IRB
追蹤審查 Follow-up review	主持人／試驗委託者／人委會 Investigator/Sponsor/IRB

5.2 職責Responsibilities

審查涉及易受傷害、決定能力欠缺的受試者之計畫，並要求試驗主持人應提出相關具體的保護措施；且依人、案、時、地等及生理、心理、社會及經驗影響層面審慎進行評估並追蹤。

Review protocols involving vulnerable subjects and subjects lacking decision making capability, and request the Investigator to provide relevant specific protection measures. Additionally, perform evaluation and follow ups carefully for aspects that can be influenced by people, cases, timing, locations, as well as physiological, psychological and social experiences.

5.3 細則

Enforcement Rules

5.3.1 決定易受傷害受試者、欠缺決定能力者

Determine vulnerable subjects and subjects lacking decision-making capability.

5.3.1.1 計畫主持人須於初審案申請表中，確認研究是否包含易受傷害受試者。

The Principal Investigator must confirm that whether the study included vulnerable subjects while submitting the application form for initial review.

5.3.1.2 易受傷害受試者包含：

Vulnerable subjects include:

A. 未成年人、受刑人、原住民、孕婦、身心障礙、精神病患。

Minors, prisoners, indigenous people, pregnant women, physically or mentally disabled persons and patients with mental disturbance.

B. 其他缺乏自主能力或自願性受到限制者 (例如：經濟貧困、教育不足、醫療緊急狀況沒有充分時間思考者、或無法治癒的致命性疾病者等) 。

Those lack autonomy or have restricted voluntariness (e.g. economic disadvantaged or educational disadvantaged population, persons do not have sufficient time to think when encountering medical emergencies, or those with incurable fatal diseases).

C. 身處於階級制度結構中的人員，例如：學生、附屬醫院及實驗室成員、藥廠員工、軍方人士。

Persons within the structure of hierarchy system, e.g. students, staffs of affiliate hospitals and laboratories, employees of pharmaceutical companies and personnel serve in the military.

D. 遊民、難民。

Vagrants, refugees.

E. 居於安養院或護理之家的人。

Residents of long-term care facilities or nursing home.

5.3.1.3 計畫主持人依據研究所涉及受試者對象及風險利益程度，需提供相當具體的保護措施。

The Principal Investigator is required to provide rather specific protection measures based on the subjects involved in the study and the level of risks/benefits.

5.3.1.4 易受傷害受試者參與之研究，不得申請免除審查。

For studies involving vulnerable subjects, the application for review exemption is prohibited.

5.3.1.5 IRB 委員審查此類案件時，一般審查原則：

General review principles for IRB members to review such cases:

A. 計畫書包含了保護受試者權利與福祉的措施，避免或減輕對於受試者權利或福祉之嚴重危害。

The protocol consists of measures to protect subject’s rights and

welfare, and prevent or alleviate subject's rights or welfare from serious crisis.

B. 納入及排除條件，是否過度選擇或排除該族群。非必要不得納入易受傷害族群為受試者；但顯有益於特定人口群或特殊疾病罹患者健康權益或無法以其他研究對象取代之試驗者，不在此限。

Whether the inclusion and exclusion criteria have been over-selective or over-exclusive the population. Vulnerable subjects shall not be included as subjects if not necessary. However, studies that significantly benefit the health rights of the specific population or patients with specific diseases, or no other research subject that cannot be replaced are not subject to such regulations.

C. 預期可能利益與風險之比較。個別受試者可直接因為本研究而受惠，或本研究對於了解或改善受試者的疾患或病況可以提供整體性的知識。

The comparison of expected potential benefits and risks. Individual subject can benefit from this study directly, or this study can provide comprehensive knowledge about understanding or improving the illness or disease status of the subjects.

D. 受試者與其法定代理人或有同意權人之同意的取得方式與告知內容。

The approaches of obtaining the consents from the subject, his/her

legal representative or person who has the right to give consent, and the contents of information.

E. 受試者之自主判斷能力(須考量其年齡、智識度、心理狀況)與研究過程不受脅迫。

The autonomy (depends on the age, intelligent and mental status) of the subject is not coerced during the study process.

F. 以淺顯易懂用語提供受試者研究相關資訊。

Use easy to understand words and phrases to describe study-related information for subjects.

G. 受試者為收容所兒童或其他於學校、醫院、機構等進行之試驗，行使同意權之特殊考量。

Studies involving children from shelter as subjects or the trial sites are located at schools, hospitals, institutes, etc., special considerations are required when exercising the consent rights.

H. 其他特殊考量。

Other special considerations.

5.3.1.6 以未成年人為受試者之研究，須確保：

Studies using minors as subjects must ensure that:

A. 若研究成果與以成人進行效果相同，則應避免以未成年人為研究對象。

If the study results based on minors are the same as the studies based on adults, minors shall not be used for study subjects.

B. 研究目的在於獲取與未成年人健康需求有關的知識。
The study aims to obtain knowledge regarding the requirements for minor's health.

C. 對未成年人的益處，至少與其他普遍可選擇的治療相同。
The benefits toward minors shall at least be equal to other popular optional treatments.

D. 若選擇對未成年人無益之介入性研究，其風險須低，且所得到之知識須有相當之重要性。
If an interventional study not beneficial to minors is selected, the risk level must be low and the acquired knowledge must be rather important.

E. 尊重未成年人的拒絕，除非沒有可替代的醫療方式。
The rejection from minors shall be respected unless no alternative medical treatment is available.

F. 在研究的風險及利益關係較不利時，必須有額外的保護。
When the risks-to-benefits ratio is deviating toward disadvantage outcomes, additional protection measures are required.

G. 未滿七歲之未成年人，應得其法定代理人同意並簽署同意書。
For minors under the age of 7, the consent from their legal representatives and the signed consent forms are required.

H. 滿七歲以上之未成年人，應得其本人及法定代理人共同同意並簽署同意書。

For minors over the age of 7, the joint consent from the subjects and their legal representatives and the signed consent forms are required.

※ 7 歲~12 歲之未成年人，需提供兒童版同意書。(備註：撰寫兒童版同意書時，建議：(1)加註注音符號。(2)使用兒童可理解的詞句，避免使用專業術語。若需使用專業術語，宜附加解釋。(3)可使用圖示或插圖解說。)

For minors aged between 7~12 years old, consent forms for children shall be provided. (Notes: When preparing consent forms for children, it is recommended to: (1) Add Mandarin Phonetic Symbols. (2) Use words and phrases that children can understand, and avoid using professional terms. If the use of professional terms is required, explanations shall be attached. (3) Use photo instructions or picture illustrations.)

I. 微小風險(minimal risk)的研究(45CFR46.404)，必須有父母之中一人許可。

For studies with minimal risks (45CFR46.404), the consent from one of the parents is required.

J. 研究超過微小風險(greater than minimal risk)，但對受試者可能有直接利益(45CFR46.405)應符合下列所有條件者，人體試驗委員會方同意試驗進行：

For studies that have risks greater than minimal risks, but may

benefit the subjects directly (45CFR46.405) and meet all of the following criteria, the IRB will approve the implementation of the study:

(A)利益應超過風險或至少與風險相當

The benefits shall prevail the risk levels or at least be equal to the risk levels.

(B)風險及利益關係，至少與標準或替代性醫療照護相同

The correlation between the risks and benefits shall be at least the same as standard or alternative medical care.

(C)必須有父母之中一人許可

The permission from one of the parents is required.

K. 研究超過微小風險(greater than minimal risk)，對受試者沒有直接利益(45CFR46.406)。應符合下列所有條件者，人體試驗委員會方同意試驗進行：

For studies that have greater than minimal risks, do not benefit the subjects directly (45CFR46.406) and meet all of the following criteria, the IRB will approve the implementation of the study:

(A)風險略高於微小風險(minor increase)。

The risk level has a minor increased.

(B)風險的程度須與受試者真實的醫療狀況相同。

The risk level must be the same as the true medical condition of the subjects.

(C)研究很可能得到極為重要的知識，可協助了解獲緩解個案的疾病狀況。

The study may acquire extremely important knowledge that can help understand how to relieve the disease status of the case.

(D)必須有父母雙方的許可

The permission from both parents is required.

L. 本院不允許 45CFR46.407 所列之研究。(研究超過微小風險，對受試者沒有直接利益且不符合 45CFR46.406 之研究)
Studies listed under 45CFR46.407 are not allowed in this Hospital. (Studies have risk levels over minimal risks, do not benefit the subjects directly and do not meet 45CFR46.406)

M. 採集檢體供研究使用，依行政院衛生福利部 95 年 8 月 18 日公告之衛署醫字第 0950206912 號「研究用人體檢體採集與使用注意事項」法令規定辦理。檢體提供者為未滿七歲之未成年人，由其法定代理人代為同意；滿七歲以上之未成年人，應由法定代理人與檢體提供者共同同意；檢體提供者為無意思能力者，由法定代理人代為同意，無法定代理人 時，由最近親屬代為同意。

With regard to sample collection for research purposes, it shall be performed in accordance with laws and provisions under the Announcement Wei-Shu-Yi-Zi No. 0950206912 dated August 18, 2006: The "Guidelines for Collection and Use of Human Specimens for Research" promulgated by Ministry of Health and Welfare. For sample providers are minors under age of 7, the consents from their legal representatives are required; for minors over the age of 7, the joint consents from their legal representatives and the sample provider are required; for sample providers that are incapacitated persons, the consents from their legal representatives are required; for those without legal representatives, the consent of the next of kin is required.

5.3.1.7 以決定能力欠缺之成年人為受試者之研究，例如：心智或行為失常者...等，須確認：

For studies using subjects lacking decision making capability such as persons with mental or behavioral disturbance, etc., the following shall be confirmed:

A. 如其研究能在心智正常之人身上得到相同的結果，則不能以心智或行為失常者為受試者。

If the study can acquire the same results from persons with normal mentality, persons with mental or behavior disturbance cannot be study subjects.

B. 研究的目的與心智或行為失控者的健康需求有關。
The purpose of the study is correlated with the health requirements of persons with mental or behavioral disturbance.

C. 若選擇對受試者無益之介入性研究，其風險須低，且所得到之知識須有相當之重要性。
If an interventional study not beneficial to subjects is selected, the risk level must be low and the acquired knowledge must be rather important.

D. 對受試者的益處，至少與其他可選擇的治療相同。
The benefits toward subjects shall at least be equal to other optional treatments.

E. 用以評估個別受試者是否有足夠能力來執行知情同意的方法確實且適當。
It is used to evaluate whether individual subject has sufficient capability to execute accurate and proper informed consent approach.

(A)須在其能力範圍內取得其同意，受試者之拒絕應予以尊重。
Consents shall be obtained within their capabilities. Subject's rejection shall be respected.

(B)將定期評估受試者的認知能力，並且會在受試者的決定能力有所改善時，取得受試者參與此研究的意願。

Subject's cognition will be evaluated regularly. And the willingness of the subjects participating in this study will be obtained when the subject's decision-making capability has been improved.

(C)在計畫書中需呈現試驗過程中評估與再評估其知情同意的能力。

The protocol shall be able to present the capability of performing evaluation during the study process and re-evaluating the informed consents.

(D)當需要贊同(assent)時，在計畫書中需呈現取得贊同之程序。

When assent is required, the protocol shall present the procedure of obtaining informed consent.

F. 研究具備適當的程序以取得受試者法定代理人或有同意權人的同意。

The study shall be equipped with proper procedures to obtain the consents from the legal representatives or the person who has the right to give consent of the subject.

(A)受試者為受輔助宣告之人，應得本人及輔助人之同意。

For subjects under aid, consent from himself/herself and the aid are required.

(B)受試者為受監護宣告之人，應得監護人之同意。

For subjects under guardianship, consent from the guardian is required.

(C)受試者雖非無行為能力或限制行為能力者，但於行使同意權時係無意識或精神錯亂，而無法自行為意思表示時，由有同意權之人代為同意。成年人或已結婚未成年之受試者，應依下列順序取得有同意權人之同意：配 偶、成年子女、父母、兄弟姐妹，祖父母。

Although subjects are not incapacitated persons or persons with restricted capacity, if the subject is unconscious or mental disturbed during exercising his/her consent right and thus is unable to express his/her own meaning, the person who has the right to give consent will give consent on behalf of the subject. For adult or married minor subjects, the consent of the person who has the right to give consent is required by following the priority as follows: Spouse, adult offspring, parents, siblings and grandparents.

(D)前項有同意權人所為之書面同意，得以一人代為之；其有同意權人意思表示不一致時，以親等近者為先，親等同者，以同居親屬為先；無同居親屬者，以年長者為 先。

With regard to the written consents given by the aforementioned persons who have the right to give consents,

one person may exercise such right on behalf of another. If the expressions from the persons who have the right to give consents are inconsistent, the decision of the person with closer relative relationship prevails. For relatives with the same level of relevance, the decision of live-in relative prevails. For subjects without any live-in relatives, the decision of the senior prevails.

G. 對於受試者無直接利益之非治療性研究，不可使用代理同意，除非符合下列條件：

For non-therapeutic studies that do not benefit the subjects directly, consents from subject's representatives are not allowed unless the following conditions have been met:

(A)研究僅能納入無法親自執行知情同意的受試者才能達到研究目的

Studies that must include subjects who cannot complete informed consent in person to achieve study purposes.

(B)對於受試者可預期的風險低

Studies that have low expected risk levels toward the subjects.

(C)對於受試者福祉之負面影響很小

Studies that have extremely small negative impacts on the welfare of the subjects.

(D)法律所未禁止之研究

Studies that are not prohibited by law.

(E)針對此類受試者族群之納入，IRB 應充分討論並納入此類受試者之意見，並留下書面記錄

For the inclusion of such subject population, the IRB shall completely discuss about it and include and document the comments of such subjects in written records.

(F)受試者須密切監測，若有發現不當的影響時應退出試驗。

Subjects must be closely monitored, and withdraw from the study if any inappropriate influences occur.

5.3.1.8 以受刑人為受試者之研究，須確認：

For studies involving prisoner subjects, it is required to confirm the following conditions:

A. 需有熟悉受刑人權益之人擔任諮詢專家，詳細閱讀相關資料並出席會議參與討論。

It is required for persons who are familiar with prisoner's rights as consultation experts to read relevant information carefully and attend meetings for participating in discussions.

B. 受刑人亦有同等接受研究用藥及其他治療的機會。

Prisoners also have equal rights to the opportunities of receiving investigational drugs and other treatments.

C. 納入研究時，應不受脅迫而為自願加入。

When including prisoners in the study, their participation shall be voluntary and without coercion.

D. 研究設計及結果是否可能使受試者遭受歧視或其他傷害。

Whether the study design and results may result in prisoner subjects being discriminated against or suffering from other harm.

E. 需考量受刑人是否因參與研究而可能得到或損失任何利益，其程度不足以影響受刑人參與試驗之決定，例如：一般生活狀況、醫療照護、食物品質、生活設施及在獄中賺錢的機會等。

It is required to consider whether prisoners may obtain or lose any benefits through participating in the study without influencing their decisions about study participation, e.g. general living status, medical care, food quality, living facilities, opportunities to make money in the prison, etc.

F. 需確認受刑人是否會因為參加研究而列入假釋之考量條件，每位受刑人均被清楚告知參與研究不會影響其假釋權利。

It is required to confirm that whether the prisoner may be considered eligible for parole by participating in the study, and whether each prisoner has been clearly informed that their

participation in this study will not influence their rights to apply for parole.

G. 研究涉及的風險與非受刑人願意承擔的風險相當。

The risks involved in the study are equivalent to the risks that non-prisoners are willing to bear.

H. 監獄內招募受試者的程序對所有受刑人而言都是平等的， 且不受監獄機關或其他受刑人的任意干涉。

The subject enrollment procedures in prisons are equal to all prisoners without being subject to prison institutes or arbitrarily interfered by other prisoners.

I. 資料係以受試者族群能了解的語言來呈現。

The information shall be presented in the language that the subject population can understand.

J. 追蹤檢查或照護要有充分的準備，須考量個別受刑人刑期之長短而做好相關準備，並告知參與研究者相關事實。

The follow-up examination or care shall be prepared completely. The duration of imprisonment of individual prisoner shall be considered and prepared correspondingly. Prisoners participating in the study shall also be informed about relevant facts.

5.3.1.9 以孕婦、胎兒為受試者之研究，須確認：

For studies based on pregnant women and fetuses, it is required to confirm the following conditions:

A. 一般規定，不應以孕婦、胎兒為研究對象。除非符合下列條件：

Normally pregnant women and fetuses must not be study subjects unless the following criteria have been met:

(A)研究目的為保護或提升孕婦、胎兒的健康，或獲得關於懷孕的知識。

The purpose of the study is to protect or enhance the health of the pregnant women and fetuses, or to obtain the knowledge about pregnancy.

(B)其研究對於胚胎或嬰兒的風險非常低。

The study has extremely low risks to the fetus or the infant.

(C)非懷孕婦女不適合做為此研究之受試者。

Non-pregnant women are not suitable for being the subjects of this study.

B. 只有於動物研究及非孕婦之人體試驗均已完成後，且有相關數據討論孕婦與胎兒之潛在風險，才許可孕婦或胎兒為研究對象。研究須符合下列其中一點：

Only the animal studies and non-pregnant women human studies have been completed, and relevant data discussing potential risks of pregnant women and fetuses are available, pregnant women or fetuses could be study subjects. Such study must meet one of following conditions:

(A)研究雖對胎兒有風險，但對婦女或胎兒的直接益處大於風險。

Although the study has risks to fetuses, the direct benefits toward women or fetuses are greater than the risks.

(B)研究對胎兒的風險極低，而該研究之目的為帶來重要且無法以其他方式獲得的生物醫學知識。

The study has extremely low risks to fetuses, and the purpose of the study is to bring important biomedical knowledge that cannot use other ways to obtain.

C. 達成研究目的的過程中，所有風險發生的可能性已降到最低。

During the process of achieving study purposes, the possibility of the occurrence of all risks has been reduced to the minimum.

D. 儘量減少母親因參與研究而被迫決定終止懷孕的可能性。

Eliminate the possibility of forced pregnancy termination of the Mother as much as possible due to participating in the study.

(A)不會以金錢或其他方式影響受試者終止懷孕之決定。

The decision of terminating a pregnancy of the subject shall not be influenced by money or other ways.

(B)與研究相關的人員不可參與決定受試者是否需終止懷孕以及其進行時機、方法與程序。

Study-related personnel are prohibited to participate in the

decision making that whether the subject shall terminate the pregnancy, its' timing, approach and procedures.

E. 確認知情同意程序：

To confirm the procedures of informed consent:

(A)孕婦及胎兒參與研究必須對孕婦本人或胎兒父母詳盡地告知研究對胎兒可能引起的影響並取得其同意後，方可進行。

For studies involving pregnant women and fetuses, their participation in the study can only be granted after the influences of the study on the pregnant women themselves or the parents of fetuses have been informed in detail and their consent have been obtained.

(B)研究對象為胎兒時，應由其母親同意。

When the study subject is the fetus, the consent shall be given by the mother.

(C)研究的目的僅增進胎兒的利益，但對母親無益，便需要由父母雙方的同意。

If the purpose of the study is only to increase the benefit of the fetus rather than that of the mother, the consents from both parents are required.

(D)若孕婦切結無法得知父親是誰或不知去向、父親未能到場或懷孕是由性侵害或亂倫導致，便不須有父親的同意。

If the pregnant woman declares that the father is unknown, the location of the father is unknown, the presence of the father is unavailable, or the pregnancy is the results of sexual assault or incest, the consent from the father can be exempted.

5.3.1.10 生存力不明的新生兒所參與的研究，須確認：

For studies involving newborns with unclear survival rate, it is required to confirm that:

A. 研究符合下列其中一項：

The study has met one of the following conditions:

(A)必須是對新生兒沒有附加的風險或風險已降到最低及研究的目的是為了要增進某些新生兒的存活機會，或

The study must have no additional risks to the newborn, or the risks have been reduced to the minimum, and the purpose of the study is to increase the survival rate of certain newborns, or

(B)該研究目的為帶來重要且無法使用其他方式獲得的生物醫學知識，且研究對新生兒不會造成額外風險。

The purpose of the study is to bring important biomedical knowledge that cannot use other ways to obtain, and the study does not cause additional risks to newborns.

B. 已進行臨床前期試驗與相關臨床試驗，且有資料可評估此研究對新生兒的潛在風險。

Pre-clinical trials and relevant clinical trials have been conducted, and data are already available to evaluate whether the study may cause potential risks to newborns.

C. 與研究相關的人員不得參與決定是否繼續維持新生兒的生存力。

Study-related personnel are prohibited to participate in the decision making of whether the survival of the newborn shall be maintained.

D. 必須取得具行為能力的母親或父親或其法定代理人的同意。

The consent from the capacitated mother or father or the legal representative must be obtained.

5.3.1.11 新生兒出生後確定不能存活，且參與研究，必須是：

For newborns that are determined unable to survive after birth, it is required to meet the following conditions for them to participate in the study:

A. 已進行臨床前期試驗與相關臨床試驗，且有資料可評估此研究。

Pre-clinical trials and relevant clinical trials have been conducted, and data are already available for evaluating the study.

B. 沒有人工的支持其生命功能。

Studies not involving artificial life support systems.

C. 試驗的程序本身不會終止新生兒的心跳和呼吸，與研究相關的人員不得參與決定是否繼續維持新生兒的生命。

The study itself does not contain procedures terminating the heartbeats and respiration of the newborns. Study-related personnel are prohibited from participating in the decision making of whether the life support of the newborn shall be continued.

D. 對新生兒沒有附加的風險，及研究目的涉及重要生物醫學知識的發展，且無法使用其他方式獲得的生物醫學知識。

There is no additional risk to the newborns, and the purpose of the study involves the development of important biomedical knowledge that cannot use other ways to obtain.

E. 必須取得具行為能力的母親和父親的同意。

The consents from the capacitated mother and father must be obtained.

5.3.1.12 以社區或特定族群為受試者之研究，須考量：

For studies using community-based or special population as subjects, it is required to consider the followings:

A. 視需要，機構需協助支持研究團隊邀請社區代表參與研究過程(包括：設計、執行、及結果之傳播)。

The institute shall help the research team and support the process of inviting community representatives to participate in the study

(including design, implementation and the dissemination of the results) if necessary.

B. 視需要，研究團隊得邀請社區代表參與研究設計、執行及資料分析。

The research team may invite the community representatives to participate in study design, implementation and data analysis if necessary.

C. 視需要，研究團隊須告知社區代表有關研究結果，或由特定社區代表協助傳播研究結果。

The research team must inform the community representatives about study results, or ask the specific community representative to help disseminate study results if necessary.

5.3.1.13 以原住民為受試者之研究，須確認：

For studies using indigenous people as subjects, it is required to confirm the following:

A. 除依法規規定外，應諮詢、取得各該原住民族之同意；其研究結果之發表，亦同。

In addition to the regulations according to the laws and provisions, the consents from individual tribes shall be consulted and obtained; so do the publication of the study results.

B. 前項諮詢、同意與商業利益及其應用之約定等事項，由中央原住民族主管機關會同主管機關定之。

With regard to the previous conventions such as consultation, consents, business benefits as well as the applications, the central indigenous competent authorities along with relevant competent authorities shall be responsible for the conclusions.

5.3.1.14 受試者為學生與員工。需要符合以下條件，才可以納入學生或員工為受試者：

For studies using students and employees as subjects, the following conditions shall be met to include students or employees as subjects:

A. 符合臨床研究的受試者選擇條件。

Meet the inclusion criteria for the subjects of clinical study.

B. 研究者或與研究相關的人員，不負責直接評核參與研究之學生的學業表現。

The researchers or study-related personnel shall not be directly responsible for evaluating the academic performance of the students participating in the study.

C. 研究者或與研究相關的人員，不負責直接評核參與研究之員工的工作表現。

The researchers or study-related personnel shall not be directly responsible for evaluating the working performance of the employees participating in the study.

D. 應使用公開招募方式進行，不得以個別徵詢。

Public enrollment is required, and individual inquiring is prohibited.

5.3.2 追蹤審查

Follow-up review

5.3.2.1 除了固定的期中報告審查與進行實地訪查外，委員會可視情 況，增加期中報告頻率，或使用知情同意問卷調查表進行抽樣問卷調查，以確保受試者之權益。

In addition to fixed interim reports and site inspections, if applicable, the IRB may increase the frequency of interim report or conduct survey sampling using informed consent questionnaires to ensure the rights of the subject.

6.附件 Attachment

6.1 附件一(KMUH/IRB/AF/2.4-01/11.0) 易受傷害受試者、欠缺決定能力者審查檢核表(未成年人)

Attachment 1 (KMUH/IRB/AF/2.4-01/11.0) Review Checklist for Vulnerable Subjects and Subjects Lacking Decisions Making Capability (Minors)

6.2 附件二(KMUH/IRB/AF/2.4-02/11.0) 易受傷害受試者、欠缺決定能力者審查檢核表(決定能力欠缺之成年人)

Attachment 2 (KMUH/IRB/AF/2.4-02/11.0) Review Checklist for

Vulnerable Subjects and Subjects Lacking Decisions Making Capability (Adults lacking decision making capability)

6.3 附件三(KMUH/IRB/AF/2.4-03/11.0)　易受傷害受試者、欠缺決定能力者審查檢核表(受刑人)

Attachment 3 (KMUH/IRB/AF/2.4-03/11.0) Review Checklist for Vulnerable Subjects and Subjects Lacking Decisions Making Capability (Prisoners)

6.4 附件四(KMUH/IRB/AF/2.4-04/11.0)　易受傷害受試者、欠缺決定能力者審查檢核表(孕婦、胎兒)

Attachment 4 (KMUH/IRB/AF/2.4-04/11.0) Review Checklist for Vulnerable Subjects and Subjects Lacking Decisions Making Capability (Pregnant Women, Fetuses)

6.5 附件五(KMUH/IRB/AF/2.4-05/11.0)　易受傷害受試者、欠缺決定能力者審查檢核表(生存力不明的新生兒)

Attachment 5 (KMUH/IRB/AF/2.4-05/11.0) Review Checklist for Vulnerable Subjects and Subjects Lacking Decisions Making Capability (Newborn with unclear survival rate)

6.6 附件六(KMUH/IRB/AF/2.4-06/11.0)　易受傷害受試者、欠缺決定能力者審查檢核表(新生兒出生後確定不能存活)

Attachment 6 (KMUH/IRB/AF/2.4-06/11.0) Review Checklist for Vulnerable Subjects and Subjects Lacking Decisions Making Capability (Newborns that are determined unable to survive after birth)

6.7 附件七(KMUH/IRB/AF/2.4-07/11.0)　易受傷害受試者、欠缺決定能力者審查檢核表(社區或特定族群為受試者)

Attachment 7 (KMUH/IRB/AF/2.4-07/11.0) Review Checklist for Vulnerable Subjects and Subjects Lacking Decisions Making Capability (Community-based or special population)

6.8 附件八(KMUH/IRB/AF/2.4-08/11.0)　易受傷害受試者、欠缺決定能力者審查檢核表(原住民為受試者)

Attachment 8 (KMUH/IRB/AF/2.4-08/11.0) Review Checklist for Vulnerable Subjects and Subjects Lacking Decisions Making Capability (Indigenous people)

6.9 附件九(KMUH/IRB/AF/2.4-09/11.0)　易受傷害受試者、欠缺決定能力者審查檢核表(受試者為學生與員工)

Attachment 9 (KMUH/IRB/AF/2.4-09/11.0) Review Checklist for Vulnerable Subjects and Subjects Lacking Decisions Making Capability (Student and employees)